Comments

Regarding

Differences in Patient Access to Innovative Medicines Between Canada and the United States

To

The Interim Industry, Business and Labor Committee
North Dakota Legislative Assembly
Bismarck, North Dakota

From

Dr. D. Wayne Taylor, Ph.D., F.CIM
Executive Director
The Cameron Institute
And
Founding Director
Health Services Management Programme
McMaster University

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D. Wayne Taylor, Ph.D., F.CIM
Executive Director

263 John St. South, Suite 203,
Hamilton ON L8N 2C2 Canada
905-577-6200
www.cameroninstitute.org

Mr. Chairman, Ladies and Gentlemen,

Thank you for the opportunity to appear before you today to comment upon the differences in patient access to innovative medicines between Canada and the United States.

Let me begin by providing a bit of background to healthcare in Canada. According to the Canadian Constitution, healthcare is the responsibility of the 10 provinces, but given the federal government's unlimited constitutional power to raise revenues through taxation and other means, a significant proportion of provincially funded healthcare is financed by the federal government conditional upon criteria established by the federal government namely universality, comprehensiveness, accessibility, portability and public administration. Government funded healthcare in Canada is called Medicare.

I doubt anyone here today would disagree with me that universality is a good thing for a developed country in 2010. Both Canada and the United States (U.S.) have universality: Canada by virtue of the federal *Canada Health Act* which stipulated the five criteria for federal funding cited above, and the United States *de facto* through universal access to emergency department services as provided originally by the *Hill-Burton Act* and then Title XVI of the *Public Health Service Act.*

The debate about the future of healthcare in the United States, in my opinion, should not be about universality, but about the specter of a single-payer system. Canada's is largely a single-payer, pay-as-you-go, first dollar system. All "medically necessary" (as defined by government) physician and hospital services are paid for by the provincial government. This represents about 70% of healthcare spending in Canada. Canadians cannot purchase private insurance to cover these services. **The rest of our healthcare, the remaining 30% including drugs, is paid for by private insurance (usually provided by an employer but not always) or cash. Prescription drugs account for 85% of all drug purchases. Most prescription drugs are virtually free to seniors and low income individuals and families through point-of-sale, provincial government reimbursement with the patient paying only a low co-payment on the prescription fee in most cases.** Almost two-thirds of seniors age 65 or older had 5 or more

prescriptions in 2008. Overall, government drug programs cover about 48% of the population. Private drug purchases account for 52% of all prescription drugs and 48% are public sector purchased. About two-thirds of Canadians have private drug insurance (about the same proportion as in the U.S.).

Wherever one lives, healthcare costs money. Excellent healthcare costs a lot of money. So healthcare is rationed almost everywhere in the world to some degree or another. Governments ration it through budget limitations, and free markets place limits upon healthcare largely through the insurance price mechanism. In Canada we talk about government healthcare spending as being public health insurance but in reality it is not. There is no demographically-based, actuarial function involved; there is no risk pooling or sharing as there is in the provision of insurance. Government funding of healthcare in Canada has become simply the single, largest, provincial government, budgetary expenditure item financed through a very redistributive tax system.

Contrary to news reports, drugs are not the single most important driver of rising healthcare costs in Canada. Hospital labor costs are (as they are in the United Kingdom). Collectively, health sector labor costs are the single largest slice of the healthcare budget pie. Ironically, labor costs are the one single market price that is "sticky", i.e. does not respond to the downward pressures of negative economic forces. Current inflation in Canada is about 1%, overall healthcare spending will probably go up 3% this year, while nurses wages will be increasing 6%. So what has to give? Generally, any growth in the capacity of the government funded health sector – no more doctors, no more hospital beds, and no new drugs. Why? The nurses' unions represent the second largest voting bloc in Canadian politics second only to the teachers' unions. It is much easier for both policy-makers and the media in Canada to attack private sector, big business rather than public sector, big labor.

In the United States, according to the National Health Expenditure Accounts for 2007, prescription drugs represented a declining share of health care cost growth from 1998-2006. Beyond political expediency, to turn on the innovative pharmaceutical industry makes no sense. The value of medicines is self-evident. When I was a child my father had an ulcer. The only treatment was surgery. Today hardly any ulcers are operated upon – they are all managed with drugs. There has also been significant reduction in the mortality due to and morbidity associated with HIV/AIDS, cancer, hypertension and heart disease due to the greater availability and utilization of newer and better drugs over the past few decades. It has been estimated that up to 60% of the increase in cancer survival rates has been due to drugs and 50% of the reduction of death by heart disease. As a result there has been a reduction in costly hospital and nursing home admissions.

Despite the economic downturn of 2008 and onwards, the pharmaceutical industry maintained its scale of commitment to the discovery and development of new medicines by investing $65 billion in research and development in 2008 – twice the total budget of the National Institutes of Health, five times more than the average U.S. industry relative to sales, and ten times more than the average industry per employee.

In 2007, the U.S. Bureau of Labor Statistics projected that the biopharmaceutical industry would add 69,000 U.S. manufacturing jobs while manufacturing jobs would be lost in computer electronics (-158,000), motor vehicles (-153,000), machinery (-147,000) and most other industries. According to a study conducted by Archstone Consulting in 2009 the research-based, biopharmaceutical industry provides nearly 700,000 jobs directly, and over 3 million jobs indirectly and induced – a multiplier of 4.3 (as compared to a multiplier of ~1.0 for government spending.) Employment growth in the biopharmaceutical industry has been twice that of other industries.

Over 700,000 substances will be studied over a 12 year period to yield one marketable, innovative, human drug. Nearly 3,000 compounds are currently under development in the U.S. – a 50% increase over a decade ago, and twice that of the rest of the world. On average, today, it takes $1.3 billion to bring a prescription drug to market, 90% of which never break-even to recoup all research and development costs thus requiring successful firms to rely upon a "portfolio" of products to realize its revenue needs.

As someone who cut his teeth in regulatory economics I know that **the single payer system in Canada, coupled with its globally unique split between public and private financing responsibilities, is more costly and provides less care than it would under a market-based insurance framework. That is why report after report identifies Canada as having amongst the longest wait times, the oldest technology, the lowest per capita distribution of health professionals, and the poorest access to newer, better drugs within the developed world even though we are the fifth highest spender on healthcare.**

If you read *Time* magazine, or the *New York Times*, or watch *MSNBC* one would think that Canada's healthcare system is a medical nirvana. It is not; and compared to the United States, our single-payer system has hurt us.

In the 1960's most measures of healthcare were roughly equal between Canada and the United States regarding spending, number of doctors, outcomes and so on. Over the decades American spending has outpaced Canadian spending. As a result you get more healthcare. Some efficiency is lost in the United States because of the lack of tort reform, the lack of competitive insurance markets, and the non-taxation of health benefits but, comparatively speaking, that is offset by the inefficiency of monopolistic, single-payer dominance in Canada. The specter I mentioned earlier is an America without tort reform, without competitive insurance markets, but also with huge public sector health spending as well – the worst of both countries combined.

So let me focus on the impact that government involvement has had on drug access in Canada.

Canada's approach to prescription drug policy and reimbursement produces no overall cost advantages compared to those of the United States but there is a real difference in access to new medicines between the two countries. Yes, our prescription drugs are less expensive but our generics are much more expensive thus balancing the equation. In 2007, per capita spending on prescription drugs was 1.5% of per capita GDP in Canada compared to 1.7% in the United States. Canadians spent 2.5% of their personal income after taxes on prescription drugs whereas Americans spent 2.3%.

First of all, in 2007 it took Health Canada 487 days, on average, to approve a new drug as being safe and effective – 75% longer than the 277 days it took the Federal Drug Administration (FDA) even though both bodies usually end up approving the same drugs.

The federal and provincial reimbursement approval processes, disguised as "health technology assessment", then took another 319 days, on average, to decide whether respective provinces would fund or not fund a particular drug (while most private drug insurance plans would cover a new drug as soon as it was approved for sale by Health Canada). Over the past decade there has been a steadily declining trend in the funding of Health Canada approved drugs by government plans. By 2007 only 10% of the new drugs approved by Health Canada had actually been reimbursed by government health plans. Increasingly, if you do not have private drug insurance you are relegated to the lower tier of Canada's two-tier pharmacare system.

Health technology assessment as a rationing tool creates and sustains a risk-adverse, one-size-fits-all, lowest common denominator healthcare culture as we have in Canada, the United Kingdom, Australia and New Zealand. For drugs this means only one drug treatment is needed to treat everyone for each disease or disorder. It is just an arbitrary means by which to say no while delaying care and distorting the incentive for innovation through patent expiration. There is no evidence that health technology assessment improves outcomes – in fact, the contrary. Health technology assessment assumes that drugs affect all people the same way while in fact that is only about 50% true. It also ignores patient-doctor preferences in favor of societal – read political and cost containment – preferences. Single therapeutic choice does not reduce hospital and medical utilization, as in a free market, but increases it due to the delay of care.

Health technology assessment, or as it is referred to in the United States today, "comparative effectiveness", rationalizes this government rationing process. Regardless of the promises made around comparative effectiveness, health technology assessment by any name is simply a non-transparent, closed, politically driven, cost containment-oriented exercise that rations care based upon the "precautionary principle".

The precautionary principle was invoked in banning DDT years ago supposedly to save countless human and animal lives from its killing effects – even though the science 40 years later concludes that DDT has not killed one person. Yet millions have died in Africa, and hundreds of millions have become seriously ill each year, because Africans

lost their number one weapon against the malaria-carrying mosquito. Similarly, **there is no evidence whatsoever that shows Canadians insured privately and having access to almost all drugs approved by Health Canada are any worse off than those who receive their drugs from government. In fact, many patient groups can demonstrate that privately insured Canadians are much better off than those without private drug coverage because of their access to newer, innovative products.**

The precautionary principle also undermines innovation. As leading British research scientist Professor Sir Colin Berry pointed out, all of the great scientific advances of the past 200 years came about by us "learning as we went along". The precautionary principle helps us to ask questions. It does not provide answers unless capricious, inhumane rationing is your goal, and rationing should not be America's goal when it comes to healthcare.

Between 1990 and 2002, 65% of all the biopharmaceutical discovery, research, innovation, development, and commercialization occurred in the United States of America. The U.S. has always been the leader in healthcare innovation that benefits the entire world. Do not abandon this legacy, especially now, as we enter the era of extremely effective, safe, targeted, personalized therapies thanks to our growing understanding of genetics.

As in the United States, a small of number of Canadians pay most of the taxes that fund government funded healthcare. Only a small number of Canadians at any one time are in dire medical circumstances requiring life-saving measures. Thus only a small number of people suffer, whether through confiscatory taxation or lack of adequate care, while the majority neither pay for, nor require, the services of government healthcare. **One proprietary study that I authored several years ago concluded that we allow to die about 2,000 Canadians per year, unnecessarily, due to pulmonary embolisms, as a result of using older vintage blood thinners in total hip and knee replacement surgeries all in the name of hospital drug budget cost containment.**

The one exception to this rule is cancer care. Cancer, it seems, affects almost everyone whether directly or indirectly sometime during their lives. **The Cancer Advocacy Coalition of Canada recently published a report card of cancer care in Canada and found that many Canadians are unable to access the newest and most effective cancer drugs that are available in other countries, such as the United States, due to government cost containment.**

Private sector, prescribed drug expenditure experienced a 7.0% growth rate last year in Canada whereas public-sector, prescribed drug expenditure only grew by 4% - rates consistent with similar rates over the past decade or so. **In Canada, the drugs excluded from public funding are usually first-in-class small molecule drugs, large molecule biologics, more effective (albeit more expensive) reformulations that can recoup their incremental costs through reduced hospitalizations, drugs for the 7,000 or so known "rare" diseases (in which there are only 200,000 or fewer patients) and their**

related "orphan" drugs. Canada does not have an orphan drug policy; the U.S. has had one for 25 years.

Canada's drug access for seniors pales in comparison to America's Medicare Part D. A 2008 Canadian study showed that of the 82 most common new drugs, about 55% were publicly reimbursed in Canada while 95% were publicly reimbursed in the U.S. With respect to biologics as well as first-in-class drugs, 35% were publicly reimbursed in Canada; 95% in the U.S.

In addition to this disparity between public and private access within Canada, drugs which must be administered in hospital cannot be paid for by private insurance. Hospitals in Canada receive global budgets from their respective provincial governments and have drug formularies that help contain costs in their fixed drug budgets and private insurance is forbidden for hospital-based services. Many of the drugs excluded from public plans need to be administered in hospital. A number of Canadians, some well-to-do, many working class, now come to the United States and pay cash to receive the pharmaceutical treatment they need.

What of the future? That is anyone's guess. As we meet here today the Government of Ontario is finally acting upon a report I wrote in 2003. Canada's largest province by population is attacking the prices of generics and mandating that they lower their prices by half from being 50% of the innovator product's price to 25% of the brand name price. Supposedly these cost savings will be reinvested in funding new innovator drugs on the government formulary. I say "supposedly" because previously the Ontario government reduced generic prices from being 75% of the brand name price to 50% and very few new innovator drugs were funded. Private insurance companies will also reap the benefit from lower generic prices and, in return for this bonanza, are being cajoled by the government to begin restricting their formularies more along the lines of the less comprehensive government formularies so that the government plans do not look so bad. If this occurs, industry will suffer as it has been shown that utilizing the newest, albeit more expensive, drugs available reduces lost work time in excess of the incremental drug cost. Time will tell what will become of these policy initiatives in Ontario.

Canada's single-payer system does not deliver what insurance-based systems do: guaranteed timely access to and protection from the unexpected burden of expensive but necessary medical services. Where Canadian healthcare policies were initially developed to rid Canadians of any and all financial barriers to care it has in fact institutionalized a very real, albeit artificial, economic limit to what Canadians can receive and not receive in terms of healthcare, especially if they are reliant upon government funding.

What good is a government health or drug plan that respectively covers affordable healthcare and drugs for everyone but will not reimburse expensive, life-saving or life-improving treatments for the desperately ill? What good are these plans that require patients to wait so long that the effective outcome is no better than not being

insured in the first place?

Canadian politicians and media and often warn Canadians against changing anything for fear of becoming like the United States. In fact, if the truth be known by most Canadians,

I sincerely believe that they would embrace the choice and freedom you have in terms of access to drugs even if it meant turning our backs on our version of "medicare" and the predominant democratic-socialist ideology in my home land. Smug Canadians need to open their eyes and see that healthcare for middle-class Americans is the best in the world. So, as a Canadian, I must ask: why should you break it?

Health is an individual responsibility. Healthcare policy should not prescribe government intervention, except in the case of externalities such as epidemics of contagious diseases. Where government intervention is prescribed to the extent that is has been in Canada not only do fiscal deficits occur from time to time but also a permanent democratic deficit.

No other country in the world has walked down the healthcare path we did. The United States would do well to avoid it too.

Thank you.

I will be glad to try to answer any questions you may have.

The Cameron Institute is an alternative, not-for-profit, public policy think tank specializing in the independent study of health, social, and economic issues current in Canada and internationally. The Institute recognizes policy concerns in the health world related to the need for balance between patient safety and access to new, innovative, affordable therapies. It is an objective of the Cameron Institute to provide government decision makers with analyses that will help inform choices. The Institute is also dedicated to educating and better preparing patients, providers, and payers to make appropriate clinical choices.

Dr. D. Wayne Taylor has worked as an executive in the private sector, as a senior public servant, as a political chief of staff, and is the Founding Director of the Graduate Programme in Health Services Management at McMaster University. He remains a tenured faculty member while serving as the Executive Director of The Cameron Institute and as president of his own private international consultancy.