The financial state of Canadian hospitals

On average, Canadian hospitals operated in the black during fiscal 2010/11, but just barely and largely because of the funding of facilities in three Western provinces, according to the Canadian Institute for Health Information (CIHI).

Hospital revenues exceeded expenses by a weighted average of 0.12% in Canada, CIHI states in the latest findings generated by its Canadian Hospital Reporting Project, an interactive benchmarking tool that was designed to allow for comparisons of hospital financial performance (www.cihi.ca/CIHI -ext-portal/internet/en/documentfull /health+system+performance/indicators /performance/indicator_ent). The tool makes comparisons across 21 clinical indicators and nine financial indicators of hospital effectiveness, governance, patient safety, and appropriateness and accessibility (www.cmaj.ca/lookup/doi /10.1503/cmaj.109-4178).

It is accessible only to hospital administrators and others in the health care system, unless specific requests are made for information from CIHI. The results are not made available automatically on the CIHI website because “the indicators are high-level and have been designed to help health care managers identify areas for potential improvement,” Crystal Mohr, media relations coordinator for CIHI, writes in an email. “The CIHI has a lot of other information on hospital and health system performance that is more geared to a public audience and available on our web site.”

The findings indicate that hospitals in Saskatchewan (1.23%), British Columbia (0.4%), Manitoba (0.27%) and Prince Edward Island (0.07%) had revenues exceeding incomes in fiscal 2011. But deficits were reported for hospitals in Nova Scotia (–0.06%), New Brunswick (–0.33%), Ontario (–0.40%), Quebec (–0.42%), Newfoundland and Labrador (–1.17%), and the Northwest Territories (–1.86%). Tallies for Alberta and the Yukon Territory were “outside the reportable range.”

The data indicate that Canadian hospitals spent a weighted average of 4.82% of their revenues on administration (including “general administration, finance, human resources and communication expenses”) in fiscal 2011, with the Yukon (10.44%), spending the most, followed by the NWT (8.1%), Ontario (6.15%), Newfoundland and Labrador (5.51%), Nova Scotia (4.87%), Quebec (4.84%), New Brunswick (4.79%), Manitoba (4.55%), Saskatchewan (4.54%), BC (3.53%) and Alberta (3.3%). Data for PEI was not included because of quality problems.

The cost per weighted case — which is defined as a “hospital’s average full cost of treating the average acute inpatient,” excluding physician compensation — was highest in Alberta ($6341), followed by Newfoundland and Labrador ($6265), Saskatchewan ($5868), BC ($5475), Manitoba ($5457), New Brunswick ($5392), Nova Scotia ($5385) and Ontario ($5143). Data for Quebec was unavailable, while that for the NWT was outside the reportable range, and that for PEI and Yukon were unreliable for quality reasons. The national average was $5485. Adjusting for labour rate variations across the country, the cost per weighted case was highest in the NWT ($10 198), followed by Yukon ($7694), Newfoundland and Labrador ($6700), New Brunswick ($6493), Alberta ($6179), Nova Scotia ($6062), Manitoba ($6094), Saskatchewan ($5690), BC ($5388) and Ontario ($5690). Data for Quebec was unavailable, while that for PEI was disqualified. The national average was $5463.

Other findings included:

• “The average amount spent to operate information systems, as a percentage of total expense, was 2.7%.

The Northwest Territories and Newfoundland and Labrador reported the lowest percentages at 0.8% and 1.2% respectively, while Alberta and Ontario reported the highest percentages at 3.6% and 3.0% respectively.

• On average, total personnel in nursing inpatient services worked 47.9 hours per weighted case in 2009-2010. Prince Edward Island and the Yukon Territory reported the highest values at 62.3 hours and 57.8 hours respectively. Ontario and British Columbia reported the lowest values at 42.6 and 45.3 respectively.

• On average, all staff in patient care functional centres worked 68.6% of all hospital worked hours in 2010-2011. Northwest Territories and British Columbia reported the highest values of all jurisdictions at 76.3% and 75.3% respectively. The Yukon and Newfoundland and Labrador reported the lowest values at 62.9% and 64.7% respectively.

• The average value for the Average Age of Equipment is 10.4 years. Only eight jurisdictions reported data sufficient for the calculation of provincial averages for this indicator, underscoring persistent data quality issues pertaining to Average Age of Equipment.” — Wayne Kondro, CMAJ

National medical devices strategy urged

Plans appear to be afoot to develop a national medical devices strategy. But organizers are loath to put a price tag on the initiative, though they argue that governments should be prepared to invest heavily, and quickly.

“Most advanced countries have identified medical devices as a high priority and Canada has not done that. We have no national strategy on medical devices and we are trying to establish

For the record

The findings indicate that hospitals in Saskatchewan (1.23%), British Columbia (0.4%), Manitoba (0.27%) and Prince Edward Island (0.07%) had revenues exceeding incomes in fiscal 2011. But deficits were reported for hospitals in Nova Scotia (–0.06%), New Brunswick (–0.33%), Ontario (–0.40%), Quebec (–0.42%), Newfoundland and Labrador (–1.17%), and the Northwest Territories (–1.86%). Tallies for Alberta and the Yukon Territory were “outside the reportable range.”

The data indicate that Canadian hospitals spent a weighted average of 4.82% of their revenues on administration (including “general administration, finance, human resources and communication expenses”) in fiscal 2011, with the Yukon (10.44%), spending the most, followed by the NWT (8.1%), Ontario (6.15%), Newfoundland and Labrador (5.51%), Nova Scotia (4.87%), Quebec (4.84%), New Brunswick (4.79%), Manitoba (4.55%), Saskatchewan (4.54%), BC (3.53%) and Alberta (3.3%). Data for PEI was not included because of quality problems.

The cost per weighted case — which is defined as a “hospital’s average full cost of treating the average acute inpatient,” excluding physician compensation — was highest in Alberta ($6341), followed by Newfoundland and Labrador ($6265), Saskatchewan ($5868), BC ($5475), Manitoba ($5457), New Brunswick ($5392), Nova Scotia ($5385) and Ontario ($5143). Data for Quebec was unavailable, while that for the NWT was outside the reportable range, and that for PEI and Yukon were unreliable for quality reasons. The national average was $5485. Adjusting for labour rate variations across the country, the cost per weighted case was highest in the NWT ($10 198), followed by Yukon ($7694), Newfoundland and Labrador ($6700), New Brunswick ($6493), Alberta ($6179), Nova Scotia ($6062), Manitoba ($6094), Saskatchewan ($5690), BC ($5388) and Ontario ($5690). Data for Quebec was unavailable, while that for PEI was disqualified. The national average was $5463.

Other findings included:

• “The average amount spent to operate information systems, as a percentage of total expense, was 2.7%.

The Northwest Territories and Newfoundland and Labrador reported the lowest percentages at 0.8% and 1.2% respectively, while Alberta and Ontario reported the highest percentages at 3.6% and 3.0% respectively.

• On average, total personnel in nursing inpatient services worked 47.9 hours per weighted case in 2009-2010. Prince Edward Island and the Yukon Territory reported the highest values at 62.3 hours and 57.8 hours respectively. Ontario and British Columbia reported the lowest values at 42.6 and 45.3 respectively.

• On average, all staff in patient care functional centres worked 68.6% of all hospital worked hours in 2010-2011. Northwest Territories and British Columbia reported the highest values of all jurisdictions at 76.3% and 75.3% respectively. The Yukon and Newfoundland and Labrador reported the lowest values at 62.9% and 64.7% respectively.

• The average value for the Average Age of Equipment is 10.4 years. Only eight jurisdictions reported data sufficient for the calculation of provincial averages for this indicator, underscoring persistent data quality issues pertaining to Average Age of Equipment.” — Wayne Kondro, CMAJ

National medical devices strategy urged

Plans appear to be afoot to develop a national medical devices strategy. But organizers are loath to put a price tag on the initiative, though they argue that governments should be prepared to invest heavily, and quickly.

“Most advanced countries have identified medical devices as a high priority and Canada has not done that. We have no national strategy on medical devices and we are trying to establish
that,” says Dr. Tofy Mussivand, director and CEO of the Medical Devices Innovation Institute and professor of surgery and engineering at the University of Ottawa and Carleton University in Ontario.

“Governments, not only federal but provincial governments, should have some priority for that kind of risk taking because if one medical device becomes successful we’re talking about billions of dollars per year in revenue,” adds Mussivand, who organized the Oct. 4–5 2012 Medical Devices Summit, the second to have been convened to advance the creation of a national strategy.

“The return on investment is so huge that the risk becomes insignificant,” adds Mussivand, who invented an artificial cardiac pump. He argues that while artificial heart valves, pacemakers, defibrillators and artificial hip joints took several hundred millions of dollars in investment to make it to market, the return on investment has been in the billions.

Delegates to the summit urged the creation of a national leadership council to oversee the creation and development of a national strategy, Mussivand says. “Medical devices are needed for improving health care, reducing the cost of health care, increasing productivity and competitiveness in global markets, creating jobs, enhancing prosperity and increase export — because we have really poor export in medical devices.”

He adds that a strategy would help to reduce Canada’s $4 billion per year trade deficit in medical devices. “The global market for medical devices is $1 trillion. If Canada only captured five or 10% of this, it’s more than any export we have in any other sector. We have potential. We have to capitalize on it and use it.”

The 2011 iteration of the summit identified obstacles to a strategy as including: inadequacies in medical devices expertise and skill; inadequate identification of needed innovations; lack of investment in both the public and private sectors, especially in early high-risk stages; lack of incentives to attract and retain industry; and lack of harmonization in technical standards both within Canada and with other nations. — Adam Miller, CMAJ

Apply sex and gender lens to health initiatives, Butler-Jones urges

Though there isn’t a “one size fits all” solution, Canada must better address sex (biological characteristics) and gender (sociocultural factors) in its health policies and programs, according to the chief public health officer of Canada.

To reduce health inequities, “Canada needs to: recognize and understand the importance of sex and gender in health; foster a shared vision and collective action to ensure sex and gender are key considerations in public health research, programs, policy and practices; and build on (and share) sex and gender evidence from research and practice.” Dr. David Butler-Jones states in The Chief Public Health Officer’s Report on the State of Public Health in Canada, 2012 (www.phac-aspc.gc.ca/cphorsphc-respcacsp/2012/chap-5-eng.php#a1).

“Governments, the private sector, not-for-profit organizations, educational institutions, communities and individuals must all broaden their perspectives and check their preconceptions to ensure that Canada is taking advantage of opportunities to plan, deliver and develop effective interventions that take sex and gender into account. Sex- and gender-based analysis (SGBA) can be used to tailor programs, policies and interventions in a careful and respectful manner to help reduce health inequalities,” Butler-Jones added.

“Given the importance of sex and gender in shaping health and well-being, it is essential that they be considered in the development, implementation and evaluation of research, programs and policies. Too often, they are either not factored into these areas or else generic characteristics and scenarios about men and women are used that assume a ‘one size fits all’ approach. This overly simplistic tactic risks producing evidence that is incomplete or misleading. Targeted programs for women and/or men should be reconsidered to encompass the diversity of the population and avoid division,” the report states. “In addition, more data on sex and gender and the effectiveness of programs are required. It is important to consider sex and gender in all research activities, and not just health research. This requires improved capacity to capture the information needed to identify trends, future concerns and the effectiveness of initiatives, interventions and strategies that incorporate sex and gender. Though broad consideration of sex and gender across sectors supports an understanding of the complexities and interactions of health determinants, behaviours and outcomes, it requires the development of analytical tools in research and surveillance to properly investigate these complexities.”

The report contends there are sex and gender differences in the areas of physical, mental and sexual health. “Biological and socially constructed differences between men and women interact to affect individual susceptibility to particular health risks, health-seeking behaviours, outcomes and treatments. By examining health outcomes in the areas of physical health (e.g. hypertension), mental health (e.g. depression) and sexual health (e.g. STIs [sexually transmitted infections]), it can be seen how and why these differences occur in terms of the influence of sex and gender.”

In the area of physical health, for example, the report notes that “approaches to preventing and managing the onset of chronic disease must reflect differences among men, women, boys and girls so as to most effectively address and/or avoid adverse health outcomes. Being overweight and/or obese can influence the development of many chronic diseases. As such, it is important to address unhealthy weights as early as possible, and school-based, gender-focused health promotion interventions are ideally positioned to address the gender differences that occur in the physical activity and food and beverage consumption behaviours of boys and girls. Gendered experiences, stereotypes and societal expectations can influence approaches to physical
activity. Perceptions of girls’ and boys’ sports and activities can influence participation across the life-course. Communities across Canada offer programs that educate and encourage women and girls in sports and challenge gender stereotypes and homophobia.”

“The perception of cardiovascular disease (CVD) as a ‘man’s disease’ has affected the cardiac health of women, who have been under-represented in cardiovascular research, treatment and health prevention practices,” the report adds. “CVD has only recently been recognized as one of the leading causes of death and ill health among Canadian women. Whereas factors such as sex affect symptom presentation and disease identification, gender can influence health care seeking behaviours as well as health practitioners’ reactions to symptoms. Heart health organizations in Canada are targeting women in social marketing, public awareness and health promotion campaigns to encourage them to learn about cardiac health.”

Meanwhile, “addressing mental health with a sex and gender lens requires increasing understanding, providing sex and gender sensitive services, reducing women’s risk factors and improving capacity of LGBTQ [lesbian, gay, bisexual, transgender and queer] organizations to address stigma and offer support. Gender roles, life experiences and event-specific risk factors are often cited as contributors to common mental disorders that disproportionately affect women. The reproductive health of women, particularly postpartum depression (PPD), may have long-term health outcomes for mothers and their children. Addressing the outcomes of maternal depression involves a greater understanding of the complex interactions between mental health and other factors.”

Among measures urged to promote sexual health are marketing and educational campaigns to “proactively address negative perceptions of sexual health, gender and age and the changing social trends and sexual practices of older adults.” As well, Butler-Jones urged improvements in sexual health education programming for youths.

“Healthy relationships rely on having positive perceptions of self-image and sexual health. Repeated exposure to sexualized images can have negative effects on the cognitive and emotional development of girls and boys leading to poor body image, low self-esteem, eating disorders and depression. School-based interventions can reach a large number of children and youth; they have been shown to reduce risks of HIV and AIDS, other STIs and unplanned pregnancies over the long term. However, barriers to effective school-based sexual health education programs include allotted time or teaching materials as well as the comfort level of students, teachers, families and the community at large. Practices that show promise include those that address sexual risk and protective factors as well as non-sexual factors, programs that increase the knowledge and skills of parents and community members who interact with youth, and programs that provide access to health services for all youth and include diversity,” Butler-Jones stated in the report.

— Wayne Kondro, CMAJ

Medication reconciliation lagging

Although Canada has made strides in the use of medication reconciliation to reduce adverse drug effects, hospital readmissions and hospitalizations for ambulatory care sensitive conditions, the complexity of the task, lack of strong leadership and inadequate resources to implement the patient safety measure remain obstacles in accelerating implementation, according to a new report.

To redress the deficiency, Accreditation Canada, the Canadian Institute for Health Information, the Canadian Patient Safety Institute and the Institute for Safe Medication Practices Canada, will develop a “comprehensive strategy to engage and involve senior leaders (including board members) in understanding their roles and responsibilities in advancing medication reconciliation across their organizations,” the quartet state in a report, Medication Reconciliation in Canada: Raising the Bar (www.accreditation.ca/uploadedFiles/Medication%20Reconciliation%202010%2031%202012.pdf).

Medication reconciliation is the formal process by which “medication information is communicated consistently across transitions of care,” the report states. It is a “systematic and comprehensive review of all the medications a patient is taking to ensure that medications being added, changed or discontinued are carefully assessed and documented.”

There are currently two Required Organizational Practices (ROPs) related to medication reconciliation that facilities must comply with if they are to receive Accreditation Canada approval. One applies to reconciliation at admission and the other to reconciliation at transfer or discharge.

Because of concerns over the cost of implementing the standards, stiffer standards were “scaled back” in 2008 to require that reconciliation “is implemented in one client service area at admission and one client service area at transfer or discharge; [and that] there is a documented plan to implement medication reconciliation throughout the organization, which includes locations and timelines.” To that end, in 2011, the ROPs “were customized with specific guidelines and tests for compliance. In 2010-2011, the Medication Reconciliation at Admission ROP was adjusted to incorporate the unique requirements of ambulatory/outpatient services, home/community services, and emergency departments. In 2011-2012, the Medication Reconciliation at Transfer or Discharge ROP was enhanced to clarify the important process steps for acute care, long-term care, ambulatory/outpatient services, and home/community services.”

As a consequence, the report states, “there has been a gradual improvement in organizational performance” with respect to medical reconciliation but the two ROPs remain among the three least complied with of the 37 ROPs now being used as a part of the accreditation procedure.

“At an organizational level, national compliance with the medication reconciliation requirement (medication rec-
Unregulated care providers in the community setting.

- Including medication reconciliation as part of the curriculum of health care practitioners in Canadian faculties of medicine, nursing and pharmacy, prior to entering practice.
- Continuing collaboration with professional associations and national partners to create a comprehensive communication strategy to support medication reconciliation efforts in Canada. This strategy will target health care providers; provincial, territorial, and federal health ministries; and the public.”

According to the report, the cost of preventable, drug-related hospitalizations in Canada is roughly $2.6 billion per year, while 20% of patients discharged from hospitals experience an adverse event, with about 66% of those being drug-related. An Accreditation Canada survey of 288 health organizations in 2011 indicated that only 60% had a process for medical reconciliation at admission, and only 50% at transfer or discharge. — Wayne Kondro, CMAJ

Wide mix of health care measures featured on US election ballots

It’s often said there’s a world of difference between America’s states and no more concrete proof of that proposition exists than the outcomes of a host of health-related ballot measures in the Nov. 6 United States general election.

Voters in various states were asked for their opinion on issues ranging from euthanasia to abortion, legalizing marijuana (for medical or recreational use), mandatory health insurance, home care, smoking and the labelling of genetically modified foods.

Although the final outcome of several measures is still undecided and won’t be for days or weeks to come until the ballot counting procedures are complete, the fate of many health-related initiatives has already been sealed. In Louisiana, for instance, 70% of voters supported an amendment to protect Medicaid funding from budget cuts. In Montana, 71% of voters checked “yes” on a referendum requiring parental notification for minors receiving abortions. Other measures receiving strong support in some jurisdictions include prohibiting mandatory health insurance (Wyoming), introducing a smoking ban in public places and workplaces (North Dakota) and legalizing medical marijuana (Massachusetts).

Marijuana measures were popular, appearing on ballots in Colorado, Arkansas, Massachusetts, Montana and Oregon. Both Colorado and Washington voted to legalize the recreational use of the drug, with each state about 55% in favour. Massachusetts approved an initiative to legalize medical marijuana, while Montana voted to enact a new medical marijuana program. But the results were negative in Arkansas (for legalizing medical marijuana) and in Oregon (for regulating growth and sale of cannabis).

Another popular measure — appearing on ballots in Florida, Montana, Wyoming and Alabama — was to prohibit mandatory health insurance, as set out in US President Barack Obama’s Affordable Care Act. Only Florida voted down the measure (barely, at 51%), while the other three states overwhelmingly supported it.

Other binding health-related measures included:

- **Massachusetts**: Voted for (63%) Initiative Question 3 to allow the medicinal use of marijuana (www.compassionforpatients.com/an-initiative-petition-for-a-law-for-the-humanitarian-medical-use-of-marijuana/) but against (51%) Initiative Question 2 to allow terminally ill adults with six or fewer months to live to receive life-ending medication from their doctors (www.yesondignity.com/default.asp?c=525&p=1753) according to state election results (www.masslive.com/politics/results/#ballot2).

- **California**: Voted against (53%) Proposition 34 to repeal the death penalty (http://voterguide.sos.ca.gov/propositions/34/) and against (53%) Proposition 37 to mandate special labels for genetically modified foods (http://voterguide.sos.ca.gov/propositions/37/), according to state results (http://vote.sos.ca.gov/returns/ballot-measures/).

- **Arkansas**: Voted against (51%) Issue 5 to legalize medical marijuana (www.sos.arkansas.gov/elections/Documents...
Legislative Referendum No. 2012/Proposed%20Initiatives%20and%20Referenda/Marijuana%20Proposal%20Text%20for%20web.pdf), according to state results (http://results.enr.clarityelections.com/AR/42843/110963/en/summary.html).

Florida: Voted against (51%) Amendment 1 to prohibit the government from requiring individuals to purchase health insurance (http://collins.center.org/2012/flamendments/files/2012/09/Collins-Center-Amendment-1.pdf) and against (55%) Amendment 6 to prohibit the use of public funds for abortions except to save mother’s life (http://collins.center.org/2012/flamendments/files/2012/09/Collins-Center-Amendment-6.pdf), according to state results (http://enight.elections.myflorida.com/Constitutional/Amendment.aspx).

Louisiana: Voted for (71%) Amendment 1 to protect state Medicaid trust fund from budget cuts (http://legis.la.gov/billdata/streamdocument.asp?did =812574), according to state results (http://staticresults.sos.la.gov/11062012/11062012_Statewide.html).

Michigan: Voted against (56%) Proposal 4 to allow home care workers to bargain collectively, create a registry of workers with passed background checks, provide training for home care workers and “provide financial services to patients to manage the cost of in-home care” (http://mibenefits.nicuta.com/election/results/12GEN/900000/04.html).

Montana: Voted for (57%) Initiative Referendum No. 124 to enact a new medical marijuana program, including “establishing specific standards for demonstrating chronic pain; and reviewing the practices of doctors who certify marijuana use for 25 or more patients in a 12-month period” (http://sos.mt.gov/Elections/Archives/2010s/2012/Initiatives/IR-124.asp), for (71%) Legislative Referendum No. 120 requiring parental notification prior to the provision of abortion for a minor (http://sos.mt.gov/Elections/2012/BallotIssues/LR-120.pdf), and for (67%) Legislative Referendum No. 122 to prohibit state or federal government from mandating purchase of health insurance (http://sos.mt.gov/Elections/2012/BallotIssues/LR-122.pdf), according to state results (http://electionsresults.sos.mt.gov/resultsSW.aspx?type=BQ&map=CTY).

North Dakota: Voted for (67%) Measure 4 to ban smoking in public places and most workplaces, including some outdoor spaces (https://vip.sos.nd.gov/pdfs/Portals/BallotLanguageMeasure4-Smoking-Nov6,2012.pdf), according to state results (http://results.sos.nd.gov/resultsSW.aspx?text=BQ&type=SW&map=CTY).

Oregon: Voted for (58%) Measure 77 to allow the governor to declare states of emergency and thereafter, to use lottery monies and other revenues to provide aid to victims (www.leg.state.or.us/11reg/measpdf/hjr1.dir/hjr0007.en.pdf), but against (55%) Measure 80 to create a commission to regulate the growing and sale of cannabis, according to state results (http://oregonvotes.org/results/2012G/1415319963.html).

Wyoming: Voted in favour (77%) of Constitutional Amendment A to prohibit government from forcing people to buy health insurance (http://soswy.state.wy.us/Elections/Docs/2012/2012BallotIssues.pdf), according to state results (http://soswy.state.wy.us/Elections/Docs/2012/Results/General/2012_Statewide_Constitutional_Amendments.pdf).

Alabama: Voted in favour (59%) of Amendment 6, which would prohibit individuals and business from being compelled to participate in the health care system (http://alisondb.legislature.state.al.us/acs/ACtionsViewFrameMac.asp?TYPE=Instrument&INST=HB60&DOC_PATH=searchableinstruments/2011RS/PrintFiles/&PHYDOCPATH=/alisondb/acs/searchableinstruments/2011RS/PrintFiles/&DOCNAMES=HB60-int.pdf), according to state results (www.alabamaelectionsresults.com/).

Washington: Voted in favour (55%) of Initiative Measure No. 502 to legalize recreational use of marijuana (http://sos.wa.gov/assets/elections/initiatives/i502.pdf), according to state results (http://vote.wa.gov/results/current/Initiative-Measure-No-502-Concerns-marijuana.html).

Colorado: Voted in favour (55%) of Amendment 64 to legalize recreation use of marijuana (www.sos.state.co.us/pubs/elections/Initiatives/titleBoard/filings/2011-2012/30Final.pdf), according to state results (http://results.enr.clarityelections.com/CO/43032/110939/en/summary.html).

Among other ballot measures that failed was one in North Dakota that would have compelled felony charges against “any individual who maliciously and intentionally burns, poisons, crushes, suffocates, impales, drowns, blinds, skins, beats to death, drags to death, exsanguinates, disembowels, or dismembers any living dog, cat, or horse” (https://vip.sos.nd.gov/pdfs/Portals/FullTextofMeasure5-AnimalCruelty-Nov6,2012.pdf). — Roger Collier, CMAJ

Supreme Court voids Pfizer patent for inadequate disclosure in cascading claims

The Supreme Court of Canada has voided Pfizer Canada Inc.’s patent for the impotence drug Viagra because of the company’s failure to reveal in its patent applications that sildenafil was the active compound that effectively treated erectile dysfunction.

Pfizer’s patent applications for Viagra in 1994 used the technique of “cascading claims” to narrow down their invention from “260 quintillion possible compounds” to essentially two, one which was sildenafil, without actually disclosing that it was the active ingredient that treated impotence, Mr. Justice Louis LeBel noted in the judgment, Teva Canada Ltd. v. Pfizer Canada Inc. (http://scc.lexum.org/decisia-scc-csc/scc-csc/26791/1/document.do).

The claims, LeBel wrote, “ended with two individually claimed compounds, thereby obscuring the true invention. The disclosure failed to state in clear terms what the invention was. Pfizer gained a benefit from the [Patent] Act — exclusive monopoly rights — while withholding disclosure in spite of its disclosure obligations under the Act. As a matter of policy and sound statutory interpretation, patentees cannot be allowed to ‘game’ the system in this way.”

LeBel declared the patent invalid because of the failure to make adequate
Disclosure, as required by the Patent Act. It had been scheduled to expire in 2014 but the Supreme Court ruling will essentially allow generic drug manufacturers to move quickly to create inexpensive versions of the impotence drug.

“The patent system is based on a ‘bargain’: the inventor is granted exclusive rights in a new and useful invention for a limited period in exchange for disclosure of the invention so that society can benefit from this knowledge. Sufficiency of disclosure lies at the very heart of the patent system, so adequate disclosure in the specification is a precondition for the granting of a patent,” Lebel wrote.

It’s only logical to deem the patent invalid because of its failure to disclose what the actual invention was and how it worked, Lebel noted. “This flows from the quid pro quo principle underpinning the Act. If there is no quid — proper disclosure — then there can be no quo — exclusive monopoly rights.”

LeBel also dismissed Pfizer’s argument that voiding the patent would violate international treaty obligations. “Pfizer and the intervener Canada’s Research-Based Pharmaceutical Companies argue that Teva’s submissions are incompatible with Canada’s international obligations, and more specifically with the Patent Cooperation Treaty, Can. T.S. 1990 No. 22, incorporated into Canadian law by the Intellectual Property Improvement Act, S.C. 1993, c. 15, s. 29(1). The essence of this argument is that Teva is advocating for an enhanced disclosure requirement which, Pfizer and the intervener says, is contrary to Canada’s obligations under the Treaty,” he wrote.

“There is no need to address this argument at length. Since, as I have already explained, this is not a case about sound prediction, the Court does not need to consider whether a claim of utility that is based on sound prediction would impose an “enhanced” disclosure obligation on the patentee or whether such an “enhanced” disclosure obligation — if one existed — would be contrary to the Treaty. Neither the parties nor the interveners argue that the disclosure requirements of s. 27(3) violate any international obligations. The only issue in this case is whether the disclosure requirements set out in s. 27 of the Act were met. This argument must therefore fail.”

In response to the decision, Pfizer said in a statement that it “is disappointed with the Court’s ruling and will continue to vigorously defend against challenges to its intellectual property. Patents provide a vital incentive for biopharmaceutical companies to invest in new and life-saving medicines that benefit millions of patients worldwide.”

— Wayne Kondro, CMAJ

Global monitoring framework proposed for noncommunicable diseases

The World Health Organization (WHO) has unveiled a proposed global monitoring framework to help reduce death and disability from noncommunicable diseases (NCDs).

The draft framework, the consensus position of 119 WHO member states, the African Union, the European Union and 17 nongovernmental associations at a Nov. 5–7 gathering in Geneva, Switzerland, will be submitted to the WHO’s executive board for approval in January 2013 and then to the World Health Assembly in May 2013 for adoption. WHO had been charged with developing the framework, complete with targets, as part of the United Nations’ political declaration on noncommunicable diseases, which critics had assailed as entirely lacking in hard targets for improved health outcomes, action to curb controversial trade practices and financial commitments from international aid donors (www.cmaj.ca/lookup/doi/10.1503/cmaj.109-4011).

The framework proposes to create nine voluntary global targets, with 25 specific indicators to be used to measure progress in the reduction and control of heart disease, diabetes, cancer, chronic lung disease and other NCDs. The nine proposed targets are:

• 25% relative reduction in overall mortality from cardiovascular diseases, cancer, diabetes, or chronic respiratory diseases
• At least 10 per cent relative reduction in the harmful use of alcohol, as appropriate, within the national context
• 10% relative reduction in prevalence of insufficient physical activity
• Halt the rise in diabetes and obesity
• 25% relative reduction in the prevalence of raised blood pressure or contain the prevalence of raised blood pressure according to national circumstances
• 30% relative reduction in mean population intake of salt/sodium intake
• 30% relative reduction in prevalence of current tobacco use in persons aged 15+ years
• At least 50% of eligible people receive drug therapy and counselling (including glycemic control) to prevent heart attacks and strokes
• 80% availability of affordable basic technologies and essential medicines, including generics, required to treat major NCDs in both public and private facilities.”

The first of the targets, a 25% reduction in mortality, has already been formally adopted by the World Health Assembly.

WHO officials argued that the targets should help to substantially reduce the global burden of NCDs, which account for 63% of global deaths annually.

“The new global monitoring framework will enable us to assess progress across regional and country settings and to monitor trends,” Dr. Bjørn-Inge Larsen, chairman of the global gathering which crafted the framework, stated in a press release (www.who.int/mediacentre/news/notes/2012/nccd_20121109/en/index.html). “The agreed voluntary targets are aspirational but achievable and they will drive progress in prevention and control at national, regional and global levels.”

“The indicators and voluntary global targets are key building blocks of our fight against NCDs,” added Dr. Oleg Chestnov, WHO’s assistant director-general for NCDs and mental health. “They will provide the foundation for advocacy, raising awareness, reinforcing political commitment and promoting global action to tackle these deadly diseases.”

— Wayne Kondro, CMAJ

CMAJ 2012. DOI:10.1503/cmaj.109-4344