FOR THE RECORD

## Share the rewards, physicians urged

Physician payments models, particularly fee-for-service, must be scrapped or overhauled if Canada is to ensure sustainability of the health care system, a prominent academic think tank says.

Arguing that Canadian taxpayers have not reaped the cost savings projected to accrue from health care investments and productivity gains of the past decade, the Mowat Centre and the School of Public Policy and Governance at the University of Toronto in Ontario contend that physicians and other health professionals, as well as facilities such as hospitals, have been reaping a windfall while compromising the system's fiscal health.

"Attention must now focus on how to recover the cost-savings that new service delivery models and new technologies have seeded within the healthcare system. Technological advancements and more efficient ways to provide care have meant that per unit costs of many procedures have been falling. Unfortunately, these efficiencies have not necessarily reduced government spending. Instead, added volumes have actually led to increased public spending since the fee paid by governments for each procedure has often remained the same or even risen. The healthcare pricing mechanism is fundamentally broken," the think tank states in *Fiscal Sustainability and the Transformation of Canada's Healthcare System: A Shifting Gears Report* (www.mowatcentre.ca/pdfs/mowatResearch/41.pdf).

As a consequence of some services and procedures having become less costly and time-consuming, "unit costs are collapsing in many areas, including surgeries, diagnostics, specific drugs and even hands-on patient care, yet spending continues to rise," the report states.

That's been particularly true for spending on physicians, the report adds. "Canada's doctors have had a very good decade. For example, total clinical billings have risen in Ontario by an average of 8.9 per cent per year in the past five years. A hard cap on total physician payments, like the one imposed in the 1990s, could be justified. Even increases of 3 per cent — still above inflation levels — could curb spending growth by $5 billion over the life of a four year agreement and would result in fee schedule adjustments downward of an average of 3-4 points per year (given current volume trends). This hard cap could be considered if other reform options are not forthcoming from physicians."

Among options that should be considered are fee reductions in certain specialties and a move away from fee-for-service, the report states. "Membership-based group systems could be expanded with payments made to physicians (and allied practice professionals) for the management of care in facilitated networks."

Similar means of reducing clinical purchasing costs should also be applied to "pharmacies, home care, acute care (including post-discharge care), and long-term chronic care (with patient navigation)," the report states, adding that lab services may be a legitimate sixth target.

Along with reform of clinical purchasing, the report urges the adoption of four other "transformative" principles, to wit:

- "Modernize the organization of hospitals by disrupting clinical business models. The current system, where many procedures are done either in general hospitals or in a doctor's office, does not allow efficiency gains to be realized. Much that goes on today in a general hospital could be provided more efficiently elsewhere: academic centres could focus on excellent diagnostic work-ups, specialty clinics could provide routine procedures efficiently and accessibly, and networks of care could monitor patient well-being. As today, these alternative organizational structures would exist as part of the public healthcare system and, oftentimes, within the governance umbrella of existing hospitals.
- Use virtualization to develop new roles for providers and patients. The virtualization of provider-patient and provider-provider interactions is creating new opportunities for healthcare system redesign and sustainability. It comes at a time when the scopes of practice of various health professionals are already changing quickly in many settings. Virtualization can allow health professionals to use the telephone and email for patient interaction — as well as encouraging more breakthrough technologies. Virtualization will also mean that healthcare access will no longer be contingent on geography and region, thereby allowing more savings without adverse effects on care. Export markets and new revenue streams could also open up for Canadian providers of care.
- Widely deploy digitization in the second decade of Infoway. After years of government capital investment in health information technology, operational costs have now begun to fall in areas like diagnostic imaging. Policy makers need to actively recover the cost-savings from these productivity gains and reinvest them. They can support the process of IT modernization by reforming agencies so that they can respond to technological change more quickly, and by providing more of the available IT funding directly to care providers. This may begin by supporting grassroots innovation in healthcare, including the use of smart phones and tablets to enable doctors to communicate more effectively and deliver treatment more quickly.

- Devolve decision-making selectively and where appropriate. Policy makers should consider expanding the accountability functions of regional bodies, strengthening specialty care networks, and supporting organic mergers and acquisitions within the system. Any system transformation primarily focused on significant governance reforms—for example by reinventing regional bodies from scratch — could actually distract attention from the more organic reforms needed that will have a positive impact on fiscal sustainability and produce unnecessary delay in implementing transformative change." — Wayne Kondro, *CMAJ*

## Health Canada in the regulatory slow lane

Health Canada regulators are slow to compel drug makers to make labelling changes needed to inform users about safety concerns related to a drug, and slower still to disclose almost any manner of information to the public about most departmental findings, according to the Auditor General of Canada.

An examination of "key Health Canada responsibilities involving timeliness, consistency, transparency, conflict of interest, and risk-based postmarket activities" found that the department "has not adequately fulfilled most of these key responsibilities related to clinical trials, submission reviews, and post-market activities for pharmaceutical drugs," interim Auditor General John Wiersema concludes in chapter four, "Regulating Pharmaceutical Drugs –Health Canada," of the *2011 Fall Report of the Auditor General of Canada* (www.oag-bvg.gc.ca/internet/docs/parl_oag_201111_04_e.pdf).

Wiersema found Health Canada's monitoring of postmarket drug safety to be particularly deficient. "Overall, we found that the Department did not assess potential safety issues, detected through its monitoring activities, in a timely manner. Therefore, changes to drug labels and risk communications were also not timely."

The department conducted no "high priority" postmarket drug safety assessments in 2009 and 2010, relying on industry to make voluntary withdrawals of drugs in cases where postmarket studies had indicated a danger to the public. It undertook 99 "medium" or "low-priority" safety assessments and in 54 cases, a safety risk was identified, either because of the actions of a foreign regulator (25), a new study (15), adverse drug reaction reports (9) or manufacturer information (5). But in 20 of the 54 cases in which it moved to require changes to drug labels, or to inform health professionals or Canadians, it did not do so in anything like a timely fashion. "Health Canada took at least one year to complete 34 of its 54 assessments. In some cases, it took significantly longer. For example, 5 medium-priority assessments required more than two years to complete, and 1 of the 5 required more than three years to complete."

Once a safety review is completed, the process for notifying and compelling manufacturers to make labelling changes is at best haphazard, the audit states. In 12 of 38 cases in which there was some manner of recommendation for a labelling change, "it took Health Canada between 3 and almost 20 months to issue notifications to manufacturers. We also found that the Department had not yet notified the manufacturer of another 6 recommended label updates, even though between 6 and 28 months had passed since the recommendations were first made."

As a consequence of that industry-friendly approach, "a significant amount of time can pass before recommended risk communications are issued to Canadians."

As for the more than 800 complaints that Health Canada received about drugs from consumers, health care professionals or others, the department has not followed its own guidelines for prioritizing and examining those complaints.

Similarly, Wiersema's report says that Health Canada's system for determining which adverse drug reaction reports to monitor isn't risk-based or expeditious, while in making a determination as to which clinical trial sites to inspect, using such criteria as the number of adverse drug reactions occurring at the site, Health Canada "does not regularly collect all of the information necessary to assess these factors and to make comparative risk-based decisions. Because clinical trial sponsors are not required to submit up-to-date information on clinical trial sites, inspectors must call each site directly to find out the current status of the clinical trial site and the number of participants enrolled."

Health Canada's stated goal is to inspect 2% (80 of 4000) of Canadian clinical trial sites in a single year but the department completed just 52 inspections in 2009 and just 50 in 2010. "Officials indicated that the target (of 80 per year) could not be met because of a lack of resources and the reallocation of existing resources to other programs."

In the six cases where clinical trial sites were found to have been noncompliant in 2009 and 2010, Health Canada's follow-up has been haphazard and slow. When noncompliance occurs, there are no established timelines for issuing notifications and two cases which the Auditor General examined, follow-up to determine whether corrective action was taken took nearly four months. "Health Canada should strengthen its risk-based approach for monitoring and assessing clinical trial adverse drug reaction reports and for inspecting clinical trial sites, so potential safety issues are mitigated," the report states.

Wiersema also indicated that commitments to disclose information about clinical trials to Canadians have all but amounted to naught, including promises made as early as 1999 to report annually on clinical trial inspections. "There remains no definitive, publicly accessible source of information on clinical trials authorized by the Department."

The audit also found that while the department meets specified deadlines for reviewing new drugs, it falls well short of doing so when reviewing generic drugs, over-the-counter drugs requiring clinical review or "post-market change submissions" such as safety-related labelling modifications.

Moreover, public disclosure of findings and decisions are neither timely nor thorough. Monographs for the 34

new active substances that were approved in 2009 and 2010 were posted on the department website in a timely fashion but the department didn't meet its own guidelines for publishing "decision documents" for those products.

And forget about information about the status of conditionally approved drugs, Wiersema added. Health Canada doesn't provide consumers with that kind of information, as does the United States Food and Drug Administration. Nor does it disclose information about rejected or withdrawn drugs, as does the European Medicines Agency (on the grounds that health professionals are thus better informed when contemplating off-label use of a drug).

In response to all of the concerns raised by Wiersema, Health Canada vowed to make changes to its processes, typically within a year or two. — Wayne Kondro, *CMAJ*

## And the loser is ...

The United States spends 2.5 times the average of other Organisation for Economic Co-operation and Development nations on health but while it does a good job in providing cancer care and treating acute conditions in hospitals, it "does not perform well in primary care and in preventing costly hospital admissions for chronic conditions," the OECD states in its annual review of health care.

Canada similarly spends more than the OECD average, although not as much as the US, the OECD states in the Canadian section of *Health at a Glance 2011: OECD Indicators* (www.oecd.org/dataoecd/13/0/49084244.pdf). With regard to outcomes, "Canada's survival rates for breast and colorectal cancer are among the highest in the OECD. Canada also does well in primary care, preventing costly hospital admissions from chronic conditions such as asthma and uncontrolled diabetes. High in-hospital adverse events and long waiting times are a concern."

"Certain in-hospital adverse events are higher in Canada. Obstetric trauma (vaginal delivery with instruments) occurred in 13.7% of deliveries (OECD average 5.5%). Rates of foreign body left in during procedure, and accidental puncture or laceration were also high, although Canada's standing may be adversely affected by its more complete data recording," the report adds.

Health spending in Canada gobbled up 11.4% of gross domestic product in Canada in 2009, above the 9.6% rate across OCED countries, and trailing only the US (17.4%), the Netherlands (12%), France (11.8%), Germany (11.6%) and Denmark (11.5%).

Canada spent US$4363 per capita (adjusted for purchasing power) on health, again above the OECD average of US$3233. The unadjusted per capita rate was US$4139, of which US$1643 was spent on hospitals/nursing homes, US$1171 on physicians, specialists and dentists, US$860 on pharmaceuticals and US$271 on public health and administration.

In a bid to determine whether the US was getting more bang for its buck, the OECD compared American spending to that of Switzerland, Canada, Germany, France and Japan and found that spending on physicians and specialists was 2.5 times higher, spending on hospitals was 60% higher, spending on administration was 2.5% higher, while spending on drugs was also higher "but overall accounts for a smaller share of total health spending than in other countries" (www.oecd.org/dataoecd/12/16/49084355.pdf).

"Leaving aside spending on administration, the high level of spending in the United States may be due to: The cost (or price) of health care being higher in the United States than elsewhere; The United States providing more health care — more doctors' appointments, more surgery, more drugs, more diagnostic tests, longer stays in hospital — than in other countries; [or] Some combination of the two. Evidence suggests that prices are high (see next section) and some (but not all) quantities of services provided are high."

Prices for health services and goods are "substantially higher" in the US, the OECD adds, noting that the cost of a coronary artery bypass graft, for example, is US$34 358 in America and US$22 694 in Canada.

Nor can the higher cost be attributable to the provision of a greater number of services. The data indicate that the US falls well below OECD averages in the terms of the number of practising physicians per 1000 population, the number of doctor consultations, the number of hospital beds, the number of hospital discharges and the average length of stay in hospitals. But it ranks well above OECD averages in term of the use of expensive diagnostic equipment such as MRIs and CT scanners and substantially higher in terms of elective surgeries.

Is the quality of care higher?

Using select indicators, the OECD concludes that the US "performs well in some subsystems such as cancer care and treating acute conditions in hospitals, but does not perform well in primary care and in preventing costly hospital admissions for chronic conditions." — Wayne Kondro, *CMAJ*

## Canadian contribution to global health unfocused

Canada should develop and adopt a national multisectoral global health strategy, in conjunction with revisions to its foreign aid policy, so as to get a bigger bang for its buck and "maximize Canada's impact in global health," the Canadian Academy of Health Sciences says.

But playing a "more strategic role in global health" would necessitate a focusing of Canadian efforts in five areas, the Academy's Expert Panel on Canada's Strategic Role in Global Health states in its report, *Canadians Making a Difference* (www.cahs-acss.ca/wp-content/uploads/2011/11/Canadians-Making-a-Difference-Report.pdf).

The five areas?

"Indigenous and circumpolar health research; population and public health; community-oriented primary health care; smart partnerships in health education and research; and global health innovation."

An "all-of-Canada" approach — involving governments, academia, civil society and the private sector — toward crafting such a multisectoral strategy or framework would "have the greatest

chance of realizing the potential of the five strategic opportunities," the report states.

To that end, it proposes the establishment of a global health commission to "develop a national multi-sectoral global health strategy, with specific recommendations, metrics, and measurements of success over time, building upon the insights gained from the earlier listening phase. The final step would be to create a mechanism to monitor the outcomes and impacts of the strategy to enable continuous feedback and improvement." It should be composed of high-level national leaders from inside and outside of global health representing a range of sectors including government, media, religious/spiritual organizations, civil society organizations, and private sector companies, the report states.

Canada currently invests $559 million per year in global health through programs with five primary objectives: "development assistance; funding research and innovation; supporting multilateral organizations and initiatives; providing disaster relief; and ensuring health security."

But the impact of that investment is "less than it could be as a result of the lack of a national global health framework or strategy," the academy states, arguing that Canadian efforts should be focused on activities which redress health inequities, promote cost-effectiveness of health systems and create an "opportunity for shared or mutual learning and the development of common solutions."

A focusing of Canadian resources would also yield domestic benefits, the report adds. A focus on indigenous and circumpolar health, for example, would "help facilitate the delivery of health services in communities through integrated health centres." Focusing more resources on population and public health, including the social determinants of health, would provide the federal government with a foundation from which "to assess the health impacts of all new major social and economic policies."

Canada could also become a major global player in primary health care reform, health education and health research, the academy argues.

In the case of primary care, "Canada's strong capacity in health worker training could, in the spirit of mutual learning, help develop initial and refresher training programs for LMIC [low- and middle-income countries] health workers at all levels, which could strengthen primary health systems. … Through reflecting on the lessons learned from our own primary health-care experiences and building on the expertise of others, especially local partners, Canada would be well positioned to partner with LMIC communities, institutions, and governments to support planning, implementation, and evaluation of sustainable, community-based, primary health-care systems. There is also a growing need for comprehensive, accurate, and implementable frameworks for the evaluation of primary health care." — Wayne Kondro, *CMAJ*

## Trade-offs between health coverage and costs

Adopting a lowest common denominator approach to determining what minimum health services should be included in American health insurance plans is a surefire ticket to suffering and the sacrifice of lives, a United States physician advocacy group says.

In a harshly worded *An Open Letter to Secretary [of Health and Human Services Kathleen] Sebelius and President [Barack] Obama regarding the Institute of Medicine's recommendations on the Essential Benefits under the 2010 Health Reform Law*, the 18 000-member Physicians for a National Health Program, a nonprofit organization which advocates for the creation of a universal, comprehensive single-payer national health program, calls for the rejection of industry-friendly minimalist standards for health services included in insurance plans.

A recent Institute of Medicine (IOM) "proposal would base the required coverage on the benefits typical of plans currently offered by small businesses — enshrining these skimpy plans as the new standard. These bare-bones policies come with a long list of uncovered services and saddle enrollees with unaffordable co-payments and deductibles," the physicians state (www.pnhp.org/iom-letter/letter.php).

"Already, millions of underinsured Americans forgo essential care: adults with heart attacks delay seeking emergency care; children forgo needed primary and specialty care; patients fail to fill prescriptions for lifesaving medications; and serious illness often leads to financial catastrophe," the letter adds. "The inadequate coverage the IOM recommends would shift costs from corporate and government payers onto families already burdened by illness. Yet this strategy will not lower costs. Delaying care often creates even higher costs."

"The IOM committee was riddled with conflicts of interest, many members having amassed personal wealth through their involvement with health insurers and other for-profit health care firms," the physicians assert, concluding that "sadly, the committee's damaging recommendations suggest that this corporate bug has also infected the IOM."

The Patient Protection and Affordable Care Act of 2010 specified that insurance plans had to include 10 general categories of essential health benefits: "ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance abuse disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; (and) pediatric services, including oral and vision care."

Asked by Sebelius to provide guidance on what constitutes essential health benefits, an IOM panel argued in its report, *Essential Health Benefits: Balancing Coverage and Costs*, that as Obama's legislation focused on providing access to health insurance for workers in small firms and "individuals in the first years of the health insurance exchanges," the definition of essential health benefits should initially be "what is typical in the small employer market. The committee noted that the insurance plans offered by small versus large employers differ primarily in their benefit design and administration rather than in what benefits are covered"

(www.nap.edu/catalog.php?record_id=13234).

"A benefit package that is more expensive also places greater demand on the federal budget to provide subsidies for low-income purchasers and on state budgets to cover some newly eligible Medicaid enrollees," the panel added, recommending that governments adopt an approach to essential health benefits in which they first "set a cost target" and thereafter "determine what could be purchased within that constraint." Subsequent national standards for essential health benefits should be "guided by a national average premium target," while state governments should be given the latitude to "adopt a variant" of the federal standard.

If there is no trade-off between coverage and cost, there will be a number of consequences, the panel concluded. "If the benefits are not affordable, fewer people will buy insurance. If the benefit design makes access too difficult, people will not get the care they need. If health care spending continues to rise faster than GDP [gross domestic product], the value of the EHB is [essential health benefit] likely to be eroded." — Wayne Kondro, *CMAJ*

## Seniors often taking 10 or more medications

Canada's seniors are vastly overmedicated, according to the Canadian Institute for Health Information (CIHI).

About two-thirds of seniors on public drug programs use five or more drugs and one-quarter have claimed 10 or more under their policies, states a CIHI report, *Health Care in Canada, 2011: A Focus on Seniors and Aging* (http://secure.cihi.ca/cihiweb/products/HCIC_2011_seniors_report_en.pdf).

More than half of seniors use prescription drugs to treat two or more chronic conditions, with heart failure and blood pressure topping the list. The report also indicates that physicians are increasingly prescribing more and more drugs per senior across a variety of drug classes, placing them at increased risk of drug interactions and adverse effects.

"In 2009, about two-thirds (63%) of seniors on public drug programs in six provinces were claiming five or more drugs from different drug classes; nearly one-quarter (23%) had claims for 10 or more. In 2002, by comparison, 59% had claims for 5 or more drug classes and 20% had claims for 10 or more," the report states.

Seniors taking five or more medications for one or more chronic illnesses were twice as likely to report adverse effects as those taking one or two prescriptions, the report states. Seniors are also at greater risk of experiencing adverse effects because they have reduced renal and liver function.

The report adds that physicians may not always be aware of over-the-counter medications or supplements their patients are taking in conjunction with prescriptions, as a 2008 survey revealed that only 48% of seniors "who had at least one chronic condition and who were taking regular prescription medications reported having had their medications reviewed by a medical doctor in the previous 12 months."

CIHI also said that at least 10% of Canadian seniors on public drug programs were taking medications from the Beers list of drugs that are ineffective for, or harmful to, elderly people (*Arch Intern Med* 2003;163:2716–24).

The report also asserts that chronic illness plays a greater role than age in driving health care costs. "The increasing number of seniors itself will not threaten Canada's health care system, but it will require the system to adapt to meet changing health care needs. Among those challenges: to what extent the Canadian health care system has met seniors' needs to date, how it will likely need to adapt to continue to meet these needs into the future and how Canadians' health care needs may change as the population shifts over the next 20 to 30 years."

With seniors expected to comprise 25% of the population by the year 2036, the report recommends that the health care system handle the influx by focusing attention on four key areas: "improving integration of care across the continuum, focusing more on primary and secondary prevention measures, adopting and making efficient use of new technologies, and collecting better information to inform decision-making. Many of these approaches have at least, in part, already been built into existing provincial and territorial plans."

The system faces several other challenges, including home care, the report adds. "Among the almost 1 million seniors receiving formal home care, more than a third (34%) reported daily pain and 14% reported signs or symptoms of depression. And while 97% of home care clients also have informal support to help maintain their independence, these informal caregivers—typically seniors' spouses and children—are feeling the stress. Almost one in five informal caregivers (17%) reported distress in their role. Often, the care they provided is required around the clock; social services may be needed to help support these caregivers in their roles. In contrast to home care clients, almost a third (31%) of seniors in long-term care showed signs of depression, almost one in six (16%) reported daily pain and 5% had an advanced pressure ulcer."

As well, the report notes that "data on wait times in emergency departments and acute care settings shows that seniors wait longer for care than their younger counterparts. For example, 85% of alternate level of care patients (those who have completed the acute care phase of their treatment but remain in an acute care bed) were older than age 65; 47% of these patients were waiting for placement in long-term care." — Kayla Redstone, Ottawa, Ont.

## Quebec unveils medical error registry

Older patients are the most vulnerable to medical mishaps in Quebec, with falls and medication mistakes accounting for roughly two-thirds of all adverse events, according to data from the province's landmark medical error registry.

Hospitals, nursing homes and community health clinics reported some 179 000 mishaps between April and September this year, including both "accidents" or events resulting in harm

to patients, and "incidents" or near misses, reveals the *Rapport Semestriel: des incidents et accidents survenus lors de la prestation des soins et services de santé au québec* (http://publications.msss.gouv.qc.ca/acrobat/f/documentation/2011/11-735-01W.pdf).

But the interim report also indicates that there is widespread underreporting of the total number of adverse events and close calls. As a consequence, it urges that the results be read with caution.

"Quebec is a pioneer in this field, since there is no equivalent register in other provinces," Health Minister Yves Bolduc said in a press release, calling the public database a "complementary tool to the different methods of risk management already in place" (http://communiques.gouv.qc.ca/gouvqc/communiques/GPQF/Decembre2011/06/c4353.html).

Patients over 75 experienced the most accidents and incidents of any age group in the province, accounting for 51% of the cases reported to the registry, including 24 fatal accidents.

The report attributes the trend primarily to the higher consumption of health care services among older patients, particularly as more accidents occurred in nursing homes than in hospitals.

Falls were the most common mishaps, regardless of age, representing some 35% of errors reported by facilities. Medication mistakes, including prescription, dosage and delivery mix-ups, accounted for a further 30% of all accidents and incidents.

However, the fact that incidents (i.e., errors which don't cause direct harm to patients) represented only 10% of the total errors reported to the registry indicates "significant" underreporting, as near misses should vastly outweigh events that cause harm, the report states.

The report also noted that up to 35% of hospitals and nursing homes failed to inform patients or their families of medical mistakes, even though revisions to the province's Health and Social Services Act adopted in 2002 made disclosure legally binding. But the report notes that only two-thirds of the institutions surveyed provided complete statistics to the registry, as some facilities had yet to establish local registries or were unable to finish compiling their data in the six-month period covered by the report.

As a result, "for more than 80 facilities, the data reported for the period is incomplete," the report states.

Even among those facilities that submitted complete datasets, "certain disparities were observed in the manner of collecting the information," the report adds.

Disparities were expected because the registry is a work-in-process that was implemented gradually, the report states. The registry has been in the works since 2002, when Quebec revised its health and social services legislation to mandate the creation of the centralized database along with local registries to compile, analyze and develop measures to reduce rates of medical errors.

As facility participation rates increase and reporting methods are streamlined, "a growth in the number of reported events is therefore expected," the report concludes. — Lauren Vogel, *CMAJ*

Editor's note: Translation by author.

## Class action lawsuit filed on behalf of college athletes who suffered concussions

In the face of growing concern about the long-term impact of concussions suffered while playing sports, a former University of Eastern Illinois football player has launched a class-action lawsuit against the National Collegiate Athletic Association (NCAA) for negligently failing to protect athletes from head injury.

The putative class-action lawsuit, *Arrington* v. *National Collegiate Athletic Association et al*, which was filed in the United States District Court for the Northern District of Illinois, also alleges that the NCAA fails to provide adequate medical support to athletes who suffer concussions during football games.

Adrian Arrington, a strong safety who toiled for the University of Eastern Illinois Panthers between 2006 and 2009, asserts that he experienced memory loss, depression and migraines as a result of concussions suffered on the field.

"For over 30 years, the NCAA has failed its student-athletes — choosing instead to sacrifice them on an altar of money and profits. The NCAA has engaged in a long-established pattern of negligence and inaction with respect to concussions and concussion-related maladies sustained by its student-athletes, all the while profiting immensely from those same student-athletes," the lawsuit states (http://docs.justia.com/cases/federal/district-courts/illinois/ilndce/1:2011cv06356/259901/1/0.pdf?1316122962).

"Specifically, the NCAA has failed to address and/or correct the coaching of tackling methodologies that cause head injuries; the NCAA has failed to implement system-wide "return to play" guidelines for student-athletes who have sustained concussions; the NCAA has failed to implement system-wide guidelines for the screening and detection of head injuries; the NCAA has failed to implement legislation addressing the treatment and eligibility of student-athletes who have sustained multiple concussions in the course of play; and the NCAA has failed to implement a support system for student-athletes who, after sustaining concussions, are left unable to either play football or even lead a normal life," adds the lawsuit, which seeks redress in the form of "medical monitoring and financial recovery for the long-term and chronic injuries, financial losses, expenses and intangible losses."

The class seeking redress is defined as "all former NCAA football players who sustained a concussion(s) or suffered concussion-like symptoms while playing football at an NCAA school, and who have, since ending their NCAA careers, developed chronic headaches, chronic dizziness or dementia or Alzheimer's disease and/or other physical and mental problems as a result of the concussion(s) suffered while a player."

The lawsuit alleges cause for negligence, "fraudulent" concealment of risk to athletes, and failure to enforce concussion policy or provide adequate medical monitoring of concussed athletes.

It notes that although the NCAA makes an average annual profit of US$740 million, it provides "no medical

or financial support to post-collegiate student-athletes who sustained concussions while playing an NCAA sport and who then cope with the costs and care needed resulting from their injuries."

An existing rule that prohibits initial contact of the head during blocking and tackling is not enforced in any meaningful way, the suit alleges. "What is more, the stated rationale behind these penalties has consistently been to protect the player being tackled without regard for the player using the helmet to make the tackle — as he was coached to do. Despite its awareness of these dangerous practices and the increased risk of head injury to the players, during the 1970s, 1980s, 1990s and 2000s, the NCAA turned a blind eye to the players being coached and trained to use all portions of their helmet to block, tackle, butt, spear, ram and/or injure opposing players by hitting with their helmeted heads, and instead elevated its financial self-interest above the physical safety of its student-athletes."

Over the course of the past decade, as awareness of the correlation between concussion and post-traumatic brain injuries increased, the "NCAA failed to act reasonably by developing appropriate means to identify at-risk players and guidelines or rules regarding return to play criteria. The NCAA's inaction increased the risk of long-term injury and illness in student-athletes."

Although NCAA-funded studies concluded that football players shouldn't be allowed back on the field until five to seven days after a concussion and that repeat concussions increase the risk of dementia, depression and other cognitive disorders, "the NCAA continues to allow student-athletes to return to play the very next calendar day after sustaining a concussion" and has "failed to implement any guidelines or rules pertaining to repeat concussions and failed to implement an educational program for athletes with a history of concussions who profess a desire to continue playing football."

In August 2010, the NCAA adopted a regulation requiring universities to have a concussion management plan in place but that approach, the lawsuit argues, leaves athletes subject to the whims of local institutions. Athletes are required to sign a statement that they will report concussion symptoms. "Boiled down to its essence, the plan rejects any measure of responsibility for the NCAA, its member schools, and the coaching staff of individual teams; and instead, puts the burden squarely on the shoulders of student-athletes — the same student-athletes who have just sustained fresh head trauma — to seek out medical attention, or decide whether to seek it in the first place."

Moreover, the suit alleges the NCAA has "actively concealed any correlation between on-field concussions, its return-to-play policies and the chronic mental illnesses and maladies suffered by former student-athletes."

The NCAA has also failed "to establish a proper and adequate methodology to monitor and detect when players suffer concussive or sub-concussive injury in practice or game play. This has increased the risk of injury that will materialize in the future," the suit adds.

The governing body for university sport in America has thus breached the duty of due care by "failing to warn of the risk of unreasonable harm resulting from repeated concussions; failing to disclose the special risks of long-term complications from repeated concussions and return to play; failing to disclose the role of repeated concussions in causing chronic life-long cognitive decline; [and] failing to promulgate rules and regulations to adequately address the dangers of repeated concussions and a return-to-play policy to minimize long-term chronic cognitive problems," the suit argues.

Along with individual redress for injured players, the suit calls on the NCAA to establish a "medical monitoring program" that would include a trust fund to pay for medical costs for concussed players long after their careers have ended. It is also seeks such injunctive relief as system-wide screening, detection and "return to play" guidelines. — Wayne Kondro, *CMAJ*

***CMAJ* 2012. DOI:10.1503/cmaj.109-4070**