FOR THE RECORD

Federal health minister urges provincial crackdown on physicians who overprescribe opioids

While flatly rejecting provincial calls for a ban on generic oxycodone, Federal Health Minister Leona Aglukkaq argued that it's up to the provinces and territories to control opioid abuse by cracking down on doctors who've been footloose in prescribing the painkillers.

And if the provinces and territories aren't up to the task, they should be willing to cede some of their jurisdiction over health and allow the federal government to step in with legislation to constrain the authority of some physicians to prescribe such drugs, Aglukkaq stated in a sharply worded missive to health ministers (www.hc-sc.gc.ca/ahc-asc/media/ftr-ati/_2012/2012_173-eng.php). "If there is consensus that provincial and territorial action is insufficient, then I am open to discussing what level of federal intervention would be appropriate. This could include possible new and/or amended regulatory requirements under the Controlled Drugs and Substances Act — for example, regulations that place restrictions on prescribing and/or dispensing practices for potentially addictive drugs in Canada."

Aglukkaq also invited the provinces and territories to forward any information they may have about physicians who are being overly generous in the prescription of opioids so that the federal government can act to curb their abuses. "OxyContin was approved by Health Canada in 1996 for a limited number of uses. Part of the reason it was abused so much was in part because it was prescribed for conditions it was never intended to deal with, and given out in amounts far greater than was needed," she wrote. "Under the Controlled Drugs and Substances Act, Health Canada can, under certain conditions, remove the ability of doctors, pharmacists and other health care practitioners to provide certain drugs. If you have evidence showing that abuse is happening, **bring it forward**, [emphasis in original] and I will take appropriate action."

Arguing that the federal government should not be in the "political" business of preventing beneficial generic drugs from coming on to the market, Aglukkaq also issued several broadsides at Ontario Health Minister Deb Matthews, who contended that it would be a "complete abdication of responsibility" for the federal government to allow generic oxycodone to be sold once the patent on the brand-name version expires Nov. 25 (www.cmaj.ca/lookup/doi/10.1503/cmaj.109-4326).

"There is no basis in the Food and Drugs Act for the Minister of Health to withhold approval of a drug where the drug is otherwise considered safe and effective for its recommended use. The law does not permit approval to be withheld on the basis of misuse," Aglukkaq wrote.

Moreover, "banning a generic version of one drug would do little to solve the actual problem. There are almost 100 authorized drugs in Canada that are in the very same class of drugs as OxyContin. Banning all these drugs because they have the potential to be addictive would help dry up the drug supply for addicts, but would lead to pain and suffering for patients who desperately need them."

It would also set a dangerous precedent, she argued. "I want to be crystal clear: I do not believe that politicians should pick and choose which drugs get approved. While intentions may be noble in this circumstance, what stops future politicians from caving into public pressure and allowing unproven, unsafe drugs on the market once political pressure starts to mount? A drug approval process based on politics is a recipe for disaster. Health Canada will continue its scientific review process of generic versions of OxyContin based on whether the benefits outweigh the risks when used as prescribed and, as always, this will be completed without political interference. It's important to remember that OxyNeo is, to date, not authorized to make claims that it is 'tamper-proof', 'tamper-resistant' or 'harder to abuse'. Health Canada had a panel of experts evaluate the evidence of describing drugs in this fashion, and found that there was insufficient proof to back up these claims."

Matthews' contention that the "streets would be flooded" with generic oxycodone "could only occur if the provinces and territories, and the medical professions they regulate, let it happen," Aglukkaq wrote. "Generic forms of OxyContin would still be available by prescription only. It is not an over-the-counter drug that can be accessed by the general public. If the country is 'flooded' with prescription drugs, it can only be in part because some medical professionals are making it possible."

Aglukkaq and Health Canada also announced that federal authority under the Controlled Drugs and Substances Act would be used to "impose tough new conditions in the licences of dealers allowed to provide products containing the controlled release formulation of oxycodone," (www.hc-sc.gc.ca/ahc-asc/media/nr-cp/_2012/2012-174-eng.php). "Companies will be required to report suspicious and unusual activities, in addition to Health Canada's current requirements to report loss and theft. Health Canada inspectors can and will be dispatched to investigate anything that seems suspicious, and appropriate action will be taken, up to stripping companies of their licence to distribute or sell narcotics. If illegal activity is suspected, Health Canada inspectors will also refer the case to law enforcement."

"Federal action is only one compo-

nent of tackling prescription drug abuse," the release added. "Medical practitioners who prescribe drugs fall under provincial and territorial jurisdiction. Accordingly, Minister Aglukkaq strongly encouraged provinces and territories to speak with their local medical associations about the topic, and to strengthen provincial and territorial practices to fight prescription drug abuse, which include establishing training requirements, setting scopes of practice for physicians and other practitioners, and monitoring prescription practices." — Wayne Kondro, *CMAJ*

Global Fund overhauls grant procedures

A new grant process to focus aid more directly on needy countries and a new executive director have been introduced at the embattled Global Fund to Fight AIDS, Tuberculosis and Malaria.

The new funding model will theoretically provide more resources to countries with the highest disease burdens, while the new executive director, Dr. Mark R. Dybul, former United States global AIDS coordinator, replaces Dr. Michel D. Kazatchine, who resigned earlier this year in a gesture of protest against the governing board's decision to appoint a general manager to oversee implementation of a consolidated transformation plan that was unveiled in November 2011 in the wake of allegations of fraud and mismanagement (www.cmaj.ca/lookup/doi/10.1503/cmaj.109-4108).

The new funding model will group each nation into one of four "country bands … based on a composite score generated based on a combination of a country's (i) Gross National Income (GNI) per capita and (ii) disease burden," according to the decision points of the Global's Fund's 28th board meeting (www.theglobalfund.org/en/board/meetings/twentyeighth/).

Lump sums will be allocated to each of the four bands and then be subsequently apportioned among them. "The principles for these criteria are as follows: i. Transparency: The factors for 'ability to pay' and disease burden should be objective and use widely accepted and available data; ii. Proportionality: To adjust funding to population size, the disease burden measure should take into account the scale of affected persons (in terms of absolute numbers, not percentages) by the three diseases in each country; and iii. Comprehensiveness: To avoid putting a country in more than one Country Band, the burden metrics for each of the three diseases in a country should be aggregated into a composite disease-burden measure."

Board chair Simon Bland lauded the change as a means of making "our grants even more effective and capable of achieving real impact" (www.theglobalfund.org/en/mediacenter/newsreleases/2012-11-15_Global_Fund_Board_Decides_on_Transition_to_New_Approach_for_Funding_Grants/). The release adds that the new model "will change the way implementers apply for financing, get approval of their proposals and then manage their grants. Once fully developed, it will encourage the development of robust national strategic plans in each country, and strive for more simplicity and efficiency. The new system will rely on country dialogue to inform a process that leads to submitting a concept note, as well as early feedback from the Global Fund, other donors and technical experts on how the proposal may need adjusting before moving forward. That is expected to reduce waiting times, and to improve the overall success rate of applications. Another important change will be more flexible timing for grant applications: instead of having to apply at one set time, implementers will be able to better align the submission of grant proposals with their own national planning cycles."

Bland also lauded Dybul's appointment, calling him a "true leader, who can take the Global Fund to the next level" (www.theglobalfund.org/en/mediacenter/newsreleases/2012-11-15_Global_Fund_Appoints_Mark_Dybul_as_Executive_Director/).

Dybul, who helped create the US President's Emergency Plan for AIDS Relief, is codirector of the Global Health Law Program at the O'Neill Institute for National and Global Health Law at Georgetown University in Washington, DC.

The Global Fund's board also voted to absorb the Affordable Medicines Family — malaria (AMFm) into its core operations. Created as a pilot project in 2009 to improve access to artemisinin-based combination therapies (ACTs), the AMFm "drove down the price of ACTs through a factory-gate subsidy on behalf of buyers in pilot countries, combined with measures to support the safe and effective scale-up of access to ACTs" (www.theglobalfund.org/en/mediacenter/newsreleases/2012-11-15_Board_Approves_Integration_of_AMFm_into_Core_Global_Fund_Grant_Processes/).

The move will allow for the facility to be made available to all eligible countries, and should allow for an evolution of its operations to include the development of malaria rapid diagnostic tests, the press release added. "By introducing modifications and integrating it into the Global Fund grant processes, the Board has improved this valuable mechanism and made it available to all eligible countries that wish to implement it," stated Gabriel Jaramillo, general manager of the Global Fund. — Wayne Kondro, *CMAJ*

Great Britain's public health challenges

The rising incidence of liver disease, inexplicable and unjustifiable variations in access to health care, incoherent national surveillance systems for noncommunicable diseases, and "congenital anomalies and important medical, environmental and lifestyle risk factors" are the major challenges facing the British public health system, according to England's chief medical officer.

The rate of liver disease is particularly troubling as international data indicate that "this is the only major cause of mortality and morbidity which is on the increase in England whilst decreasing among our European neighbours," Chief Medical Officer Professor Dame Sally Davies states in the *Annual Report of the Chief Medical Officer:*

Volume One, 2011: On the State of the Public's Health (www.dh.gov.uk/health/2012/11/cmo-annual-report/).

Attributing the increase in liver disease to obesity, undiagnosed hepatitis infection and "harmful alcohol use," Dr. Davies added in the first public health report that she has produced since assuming the post in June 2010 that there is a need for clinicians to "improve their efforts to detect early signs of liver disease. This will entail appropriate risk assessment strategies in their populations, and use of appropriate tests to identify liver disease that can be reversed or treated. These measures need to be integrated across all aspects of service provision for optimum efficacy but in particular, a proactive approach needs to be adopted so that we reduce presentations at a late stage of disease."

The existing inequities in access to health care are a function of such factors as "delayed presentation, delayed diagnosis, and delayed entry into care," the report states. "Improvement in access to health care services and early detection and diagnosis improve outcomes, reduce unwarranted variations, and reduce costs. For example, the percentage of women who access maternity services late could be reduced through targeting vulnerable and socially excluded groups, and breastfeeding rates could be improved through peer support and education supported by health professionals. Good glucose control can be achieved in people with diabetes if everyone with diabetes is identified early and receives care to the expected standards. Monitoring and evaluation provides an assessment of the quality and performance of preventive services and healthcare and is essential to understanding the benefits and harms resulting from different rates of access and provision. Much unwarranted variation can be addressed by establishing population based systems of care, and applying evidence based patient pathways."

Among the areas in which the British system is most deficient is the provision of care to patients with cancer, the report notes. "Survival for many cancers remains poor in comparison with other developed countries, with delay in diagnosis being a key reason for poor survival rates. Lung cancer in particular has one of the poorest five year survival rates with even the best English survival rates well below the European average. Since 2000, a number of new preventive and screening programmes have been introduced such as NHS smoking cessation services, bowel cancer screening, newborn bloodspot screening, diabetic retinopathy screening, and routine human papilloma virus (HPV) immunisation for females aged 12-13 years. The past few years have seen an improvement in coverage of routine childhood (preschool) immunisations, particularly in London, where coverage has been lower historically. Coverage of breast and cervical screening programmes has also improved. Other successes include more than 380,000 people in England successfully quitting smoking with NHS Stop Smoking Services in 2010/11, and early access to maternity services, with over 80% of pregnant women accessing timely services in all English regions except London. … There are marked geographic variations in immunisation uptake of measles, mumps and rubella (MMR) in young children, HPV in females aged 12-13 years, and influenza in older people. Access to specialist services such as alcohol treatment, drug use services, and obesity operations vary across England. For patients with long term conditions such as coronary heart disease, chronic obstructive pulmonary disease (COPD), diabetes, renal disease, and dementia, registrations in general practice, when compared with expected prevalence, show marked under diagnosis. There is considerable geographic variation in renal replacement therapy for chronic kidney disease."

Davies also argued that there is a need for a "set of coherent national surveillance systems" to serve as an early warning of disease trends and emerging threats. "The cost of late detection of a threat can be very high indeed, for example when the impact of thalidomide went undetected for much too long. The history of public health suggests that it is not enough to prepare for the health problems we already know about."

Earlier this year, Chief Public Health Officer of Canada Dr. David Butler-Jones argued in his report on the state of public health that the primary challenge facing Canada's system is its failure to address sex (biological characteristics) and gender (sociocultural factors) in health policies and programs (www.cmaj.ca/lookup/doi/10.1503/cmaj.109-4344). — Wayne Kondro, *CMAJ*

Underperforming Outback

Invited to "tell it like it is," Australia's National Mental Health Commission pulled no punches, grading mental services Down Under as deserving no more than an "F," for outright and abject failure.

"People with a severe mental illness have their life expectancy reduced by 25 years on average due to the increased likelihood of heart-related conditions, diabetes and obesity," Allan Fels, chairman of the National Mental Health Commission in Australia, stated in the preface to the first report card on the nation's performance in the provision in mental health services.

"The statistics related to physical illness and early death among people with mental health difficulty are appalling," Fels, foundation dean of the Australia and New Zealand School of Government in Carlton, state of Victoria, added in *A Contributing Life: the 2012 National Report Card on Mental Health and Suicide Prevention* (www.mentalhealthcommission.gov.au/media/39270/NMHC_ReportCard_Enhanced.pdf).

Asserting that the report card provides a unique focus on the needs of the families, supporters, and individuals affected by mental illness, the commission called it "a world first of its kind" (www.mentalhealthcommission.gov.au/media/39529/Media%20Release%20-%20Launch%20of%20National%20Report%20Card%20into%20Mental%20Health%20and%20Suicide%20Prevention%20.pdf). "Built on the personal stories of people who aren't often heard — people with a lived experience of mental health difficulty, their families and supporters — the report card

views mental health as an issue affecting every aspect of the life of a person; a 'whole-of-life approach'. Its theme, 'A Contributing Life', recognises that people with mental health difficulties need the same things as everyone else — a stable home, a decent education, a job, family, friends and healthy relationships, good treatment and access to services and rights," the commission added in the press release.

But Australia has a long way to go, Mark Butler, federal Minister for Mental Health, stated in a press release (www.health.gov.au/internet/ministers/publishing.nsf/Content/8B36FD85B9BCF765CA257AC3000104A9/$File/MB130.pdf). "There is more road ahead of us than behind us."

Following Canada's lead, the report urges the creation of a national mental health care strategy. Among recommendations are reducing the early death of Australians with severe mental illness by improving their physical health; increasing access to home-based visits to support families and children; providing local interventions to prevent suicide; and minimizing the use of seclusion and restraint.

The recommendations parallel ones urged by the Mental Health Commission of Canada in its national mental health care strategy (www.mentalhealthcommission.ca/SiteCollectionDocuments/strategy/MHCC_Summary_EN.pdf).

As is always the case with proposed mental health strategies, the question invariably becomes the extent to which they are actually implemented, Fels noted. "Every five years or so something is done about mental health and then it gets forgotten, but the government now needs to actually implement their policies." — Paul Kudlow, *CMAJ*

Mandatory influenza immunization

Given that flu kills as many as 8000 Canadians annually, and hospitalizes 20 000 others, health care workers shouldn't object to influenza vaccination being made a "condition of service," the Canadian Nurses Association (CNA) argues.

Mandatory vaccination policies "should be introduced if health-care worker influenza immunization coverage levels are not protective of patients, and reasonable efforts have been undertaken with education and enhancing accessibility to immunization. CNA considers mandatory immunization policies by employers to be congruent with the Code of Ethics for Registered Nurses in Canada and the obligation to act in the public interest," the association asserts in a *Position Statement on Influenza Immunization of Registered Nurses* (http://www2.cna-aiic.ca/cna/documents/pdf/publications/PS_Influenza_Immunization_for_RNs_e.pdf).

"CNA believes this statement demonstrates the value of immunization for public health and recognizes influenza as a serious illness that disproportionately affects vulnerable populations, putting them at higher risk of complications," Barb Mildon, president of the association, added in an open letter to nursing colleagues (http://www2.cna-aiic.ca/cna/documents/pdf/publications/Open_Letter_Influenza_Immunization_for_RNs_e.pdf).

But while the CNA and others, including *CMAJ* (www.cmaj.ca/lookup/doi/10.1503/cmaj.121679) are urging mandatory influenza immunization, nurses in British Columbia were elated over their success in lobbying the provincial government to retreat from new regulations that would have required health care workers to be immunized or wear masks while dealing with patients. "Given the clearly conflicting evidence about the effectiveness of the shot, we were very much opposed to policies aimed at forcing workers to get it," Debra McPherson, president of the BC Nurses' Union, stated in a press release (https://www.bcnu.org/News/News.aspx?page=News Releases_November 30_2, 2012).

The CNA position statement argues that mandatory influenza immunization of health care workers (HCWs) is needed to substantially bolster immunization rates. "Studies have shown that there are different reasons why HCWs are not immunized, which relate to the vaccine, the disease and barriers to immunization. There can be a perception of vaccine inefficacy, fear of side-effects, overestimation of the risks of the vaccine or a belief that the vaccine should be used for people at higher risk. There can also be a misperception of the risk of contracting influenza, lack of knowledge about the possible severity of the disease or even misperceptions about the transmission of influenza to patients. There are also barriers to immunization, including lack of time or lack of convenience of accessibility. Active multi-faceted staff-influenza programs have achieved, at best, immunization rates of 55 to 70 per cent. An increasing number of health-care organizations and professional associations have been supporting the institutional requirement of immunization as a condition of service. Such programs allow exceptions due to medical, religious and/or philosophical reasons and have been effective in increasing HCW-immunization coverage to over 90 per cent."

Immunization of health care workers decreases infection rates and improves patient outcomes, while low immunization rates have been "associated with higher rates of laboratory-confirmed hospital-acquired influenza among patients," CNA stated, adding that masks and hand-hygiene measures "do not offer the same level of protection that immunization does." — Wayne Kondro, *CMAJ*

Neglected disease outlays

Canadian research outlays for the world's 31 neglected diseases declined for the fifth consecutive year in 2011 and have become almost exclusively focused on HIV/AIDS, according to the annual G-Finder report.

Canadian outlays fell to $9.27 million (all figures in US$) in 2011, from $9.54 million in 2010 and considerably lower than the $19.98 million spent in 2007, according to the report, *Neglected Disease Research and Development: A Five Year Review*, produced by the non-profit organization Policy Cures (http://www.policycures.org/downloads/GF2012_Report.pdf).

All but roughly $75 000 (primarily a $68 000 grant for research on single-cell flagellate protozoa called kinetoplastids) of Canada's 2011 outlays were in the area of HIV/AIDS, the report states. By comparison, in 2007, Canada spent roughly $15.3 million on research in HIV/AIDS and about $4.6 million on research on other neglected diseases.

The report indicates that while Canada is slicing its outlays for research on neglected diseases, most nations were not, though they were shifting their investments toward basic research, "even as product development funding from industry and philanthropy is also either dropping or becoming focused in only a few diseases and products."

"Some governments now appear to be in it for the long haul, which is great," report author Dr. Mary Moran, executive director of Policy Cures, stated in a press release (www.policycures.org/downloads/G-FINDER_Y5_Press_Release.pdf). "But we're worried that their investment model seems to be shifting back to the 'bad old days' where the public sector funded basic research leaving product development to industry or philanthropy — and consequently almost no medicines, vaccines or diagnostics for neglected diseases were developed. This model doesn't and can't work for truly neglected non-commercial diseases. It's a bit like putting a man on the moon — yes, you need the scientists but you've also got to build the rocket or you'll never get there."

The report indicates that total global funding for neglected diseases research and development (R&D) in 2011 was $3.04 billion. "Despite initial fears, the global financial crisis has not had a dramatic impact on overall neglected disease R&D funding, with public funding essentially stable and decreases from the philanthropic sector largely offset by increased industry funding."

"As in previous years, the three 'top tier' diseases — HIV/AIDS, malaria and tuberculosis (TB) — again received approximately one-third to one-fifth of total global neglected disease R&D funding each, with HIV/AIDS receiving 33.8%, malaria 18.4% and TB 17.3%. However, the share of global funding for these three diseases ($2,113m, 69.4%) continued to decline with cuts for TB (down $45.7m, -8.3%) and HIV/AIDS (down $41.1m, -4.0%) and only a modest increase for malaria (up $14.4m, 2.8%). The 'second tier' diseases — dengue, diarrhoeal diseases, kinetoplastids, bacterial pneumonia & meningitis, helminth infections and salmonella infections — increased their collective share to almost a quarter of global funding (24.1%) in 2011, receiving between 1% and 8% of total funding each. YOY [year over year] funding for dengue increased significantly in 2011 (up $54.0m, 31.8%), mainly driven by industry investment in dengue vaccine development. Changes for the remaining 'second tier' diseases were mixed — funding decreased moderately for kinetoplastids (down $18.9m, -14.1%) and diarrhoeal diseases (down $11.9m, -7.8%) but increased for bacterial pneumonia & meningitis (up $10.7m, 13.1%) and helminth infections (up $2.2m, 3.3%). The 'third tier' diseases — trachoma, leprosy, Buruli ulcer and rheumatic fever — each received less than 0.5% of global R&D funding."

"Between 2007 and 2011, funding shifted away from the top tier diseases (HIV/AIDS, malaria and TB), which saw their share of global funding fall from 76.6% in 2007 to 69.4% in 2011, to the second tier diseases which increased their share from 16.2% to 24.1%. The third tier diseases remained poorly-funded, collectively receiving less than 1% of global funding each year. Some diseases — including malaria, TB, dengue, bacterial pneumonia & meningitis and helminth infections — have seen a strong upward trend in funding despite the global financial crisis, in some cases (e.g. dengue) driven by increased industry investment as products reach late stage development. Other diseases — including HIV/AIDS, diarrhoeal diseases, kinetoplastids and rheumatic fever — have been in steady decline since the global financial crisis due to government budget cuts (HIV/AIDS), declining philanthropic funding (diarrhoeal diseases and kinetoplastids) or the withdrawal of industry funding (rheumatic fever)." — Wayne Kondro, *CMAJ*

US Health insurance rebates unevenly distributed

Americans received roughly US$1.1 billion in rebates in 2011 as a result of new law that compels health insurers to spend at least 80% of premium income on the actual provision of medical services, but even stronger regulations are needed to ensure that people who are part of large group insurance plans get a greater share of the benefits, according to a Commonwealth Fund report.

The "medical loss ratio" (MLR) regulations, which were introduced as part of US President Barack Obama's health reforms, compel health insurers to use 80% of premiums in the individual and small group (generally a maximum of 50 employees), and 85% in the large group market, on medical services and quality improvement. Employers who don't spend that much must either rebate subscribers or reduce their administrative costs, profits or premiums.

The private foundation's analysis of 2011 data (essentially, the first year in which the new regulations were in effect) indicate that insurers opted to pay out US$1 billion in rebates, while reducing overhead costs by US$350 million. But the industry did not distribute the consumer benefits equally across the market segments, states the report *Insurers' Responses to Regulation of Medical Loss Ratios* (www.commonwealthfund.org/~/media/Files/Publications/Issue%20Brief/2012/Dec/1634_McCue_insurers_responses_MLR_regulation_ib.pdf). "Changes in administrative costs, profits, and medical loss ratios varied considerably across different market segments."

People who purchased insurance in individual, rather than group, plans received US$394 million in rebates. In their segment of the market, the insurers also collectively reduced profits by US$350 million, which indicates that individuals were bearing the brunt of excessively high premiums prior to the health reforms.

The health insurers indicated that they operated the individual segment of the market at a US$313.9 million loss

in 2011, as compared with a profit of roughly US$37 million in 2010.

The industry earned US$2.26 billion in profits in the small group sector in 2011, an increase of roughly $225 million over 2011, while in the large group market, profits soared by roughly US$1 billion to $3.51 billion. People obtaining their health coverage through large groups received a collective $386 million in rebates.

"Although the MLR rule, along with other market and regulatory factors, prompted reductions in administrative expenses in all three market segments, in the group markets it appears that insurers were able to retain those cost reductions in the form of increased profits, rather than passing them on to consumers in the form of reduced premiums," the report notes. "By contrast, both administrative costs and profits dropped in the individual market, indicating that consumers benefitted in the form of restrained premium increases. Premiums did increase somewhat, because of the growth in medical costs, but the increases were less than medical cost increases."

"The primary aim of the MLR regulation was to restrain the proportion of premium dollars that insurers apply to profits and administrative expenses, with the hope that lower overhead will produce lower overall premiums (after taking any rebates into account). Initially, the new minimum loss ratios appear to be producing important consumer benefits in the individual market, but much less so in the group markets. Although insurers have reduced their administrative costs and paid substantial rebates in all three market segments, the rule has not reduced total overhead market-wide in the small- and large-group segments. For that to occur, stronger measures may be needed, either in the form of rate regulation, tighter loss ratio rules, or enhanced competitive pressures," the report adds. — Wayne Kondro, *CMAJ*

***CMAJ* 2013. DOI:10.1503/cmaj.109-4373**