Briefly

Infringement procedure: The European Medicines Agency (EMA) has launched an investigation into "deficiencies in the safety reporting system" of side effects from 19 drugs produced by pharmaceutical giant Roche Registration Ltd. "The initiation of the infringement procedure follows a pharmacovigilance inspection carried out in 2012 by the UK Medicines and Healthcare products Regulatory Agency (MHRA), which identified serious shortcomings of Roche's pharmacovigilance processes," the European regulator stated in a press release (www.ema.europa.eu/docs/en_GB/document_library/Press_release/2012/10/WC500134176.pdf). The British review had identified 80 000 reports of possible side effects, including more than 15 000 deaths, that had not been analyzed by Roche, as required by European Commission regulations. "Following the inspection, the company was requested to take corrective actions to ensure the correct processing of reports of suspected adverse drug reactions. In addition, the company was requested to report any missing cases of suspected adverse drug reactions to the appropriate EU authorities in accordance with the current legislation. The EMA's Pharmacovigilance Risk Assessment Committee (PRAC) is currently reviewing data provided by Roche, which include previously missing case reports and corrections to previously processed data. As part of the assessment, the PRAC is evaluating whether these deficiencies may have an impact on the overall risk-benefit balance for any of the medicines involved," the EMA stated in a background document (www.ema.europa.eu/docs/en_GB/document_library/Medicine_QA/human/000582/WC500134174.pdf). — Wayne Kondro, *CMAJ*

Psychiatric discharges: The Council of Academic Hospitals of Ontario will provide $6.3 million to implement a new model for handling discharges of patients with mental health problems from nine hospitals in the province. Headed by the Lawson Health Research Institute in London, Ontario, the "Transitional Discharge Model (TDM) is designed to reduce length of stay and rates of readmission for patients, as well as improve overall outcomes," according to a council press release (www.caho-hospitals.com/media-releases/2012/10/24/caho-announces-2012-artic-projects/). "The transition from hospital to community is complex and can be challenging for people who have been diagnosed with a mental illness. Recent research shows the first days and weeks following psychiatric discharge are particularly high-risk periods, with 43% of suicides occurring within the first month post-discharge. The TDM ensures that a seamless safety net exists throughout the discharge and community reintegration processes. Under this approach, hospital staff will continue to provide care until the patient is connected with a community care provider following discharge. Discharged patients will also receive peer support from someone who has successfully integrated into the community after a psychiatric diagnosis." Although intended as the primary method of information exchange between an inpatient and outpatient care team about a patient's diagnostic findings, the hospital's management of the medical problem and arrangements for follow-up care, hospital discharge summaries are all too often delayed, incomplete or inadequate (www.cmaj.ca/lookup/doi/10.1503/cmaj.109-4318). — Wayne Kondro, *CMAJ*

Manipulating science: Medical devices giant Medtronic was "heavily involved in drafting, editing, and shaping the content of medical journal articles authored by its physician consultants who received significant amounts of money through royalties and consulting fees" to the tune of US$210 million between 1996 and 2010, according to the US Senate Finance Committee. Among specific findings of the committee's 16-month investigation into 13 journal articles related to a bone growth stimulating protein called Infuse that is used in spinal fusion surgery, was one that "Medtronic officials inserted language into studies that promoted InFuse as a better technique than taking a bone graft from the pelvic bone (autograft technique) by emphasizing the pain of the autograft technique," according to the *Staff Report on Medtronic's Influence on Infuse Clinical Studies* (www.finance.senate.gov/newsroom/chairman/download/?id=e54db17c-a475-4948-bd81-69c8740c6aaf). In another finding, the committee stated that "Medtronic documents show the company unsuccessfully attempted to adopt weaker safety rules for a clinical trial studying InFuse in the cervical spine that would have allowed the company to continue the trial in the event that patients experienced severe swelling in the neck." Committee chair Max Baucus (Democrat-Montana) called Medtronic's writing of segments of the studies a blatant case of manipulation. "Medtronic's actions violate the trust patients have in their medical care. Medical journal articles should convey an accurate picture of the risks and benefits of drugs and medical devices, but patients are at serious risk when companies distort the facts the way Medtronic has," Baucus stated in a press release (www.finance.senate.gov/newsroom/chairman/release/?id=b1d112cb-230f-4c2e-ae55-13550074fe86). — Wayne Kondro, *CMAJ*

Primary care variability: Canadian efforts at reforming primary care have had variable degrees of success because of such barriers as "a lack of role clarity, appropriate provider remuneration schemes and financial incentives, strong governance structures, and interprofessional education and training," accord-

ing to the Conference Board of Canada. "Most provinces have put much effort into building interprofessional primary care teams, and some have been successful in improving clinical outcomes for patients. But most of the current models are still not working optimally," Thy Dinh, senior research associate, health economics at the Conference Board stated in a press release (www.conferenceboard.ca/press/newsrelease/12-10-31/Primary_Care_Teams_are_not_as_Effective_as_they_Could_be_Because_of_Three_Sets_of_Barriers.aspx). "There is a need for better use of information and communication technology, along with improved monitoring and evaluation, and appropriate funding models. And many barriers could be overcome with improved communication, greater levels of trust and the creation of incentives for individuals to work effectively within teams." A pair of Conference Board briefing documents — *Current Knowledge About Interprofessional Teams in Canada* and *Barriers to Successful Interprofessional Teams* (www.conferenceboard.ca/e-library/abstract.aspx?did=5157) — also contend that "compared with other developed countries, Canada's primary health care sector is inadequately supported and organized." — Wayne Kondro, *CMAJ*

Less forum shopping: European Union regulations must be "tightened" to prevent manufacturers of medical devices from getting new products on the market by seeking approval in a member state in which the rules are loosest, the United Kingdom's Parliamentary Science and Technology committee says. The strengthening of clinical, evidentiary requirements regarding the safety and performance of a device must also be strengthened, the committee stated in a report, *Regulation of medical implants in the EU and UK* (www.publications.parliament.uk/pa/cm201213/cmselect/cmsctech/163/163.pdf). "Transparency was a significant concern as we found that the evidence on safety and performance of implants was not fully published by manufacturers and the operation of notified bodies (who are responsible for approving manufacturers' implants for use) was not transparent. Perceptions of secrecy can be, and have been, very damaging to public trust in the regulatory system." The committee's investigation was prompted by a spate of medical device recalls in Europe, including ones for faulty metal-on-metal hip replacements and breast implants. "We were shocked to hear about the practice of so-called 'forum shopping', where manufacturers shop around for the least stringent regulatory regimes in which to get their medical implants approved," Andrew Miller, chair of the Science and Technology Committee, stated in a press release (www.parliament.uk/business/committees/committees-a-z/commons-select/science-and-technology-committee/news/121101-medical-implants-report-published/). — Wayne Kondro, *CMAJ*

Football follies: Arguing that the National Football League essentially committed fraud by concealing the risks of concussions and that the league breached a common law duty to protect players, lawyers for thousands of former professional football players have asked a United States district court to reject a league bid to have concussion cases tossed on the grounds that they're a matter falling under the purview of collective bargaining. "On the NFL's watch, football has become the site of perhaps the gravest health crisis in the history of sports. Professional football, for all its aesthetic appeal and financial success, can be devastatingly violent," states the *Memorandum of Plaintiffs in Opposition to Defendants National Football League's and NFL Properties LLC's Motion to Dismiss the Amended Master Administrative Long-Form Complaint* (http://nflconcussionlitigation.com/wp-content/uploads/2012/01/MTDReplyBriefFINAL.pdf). "The NFL knew that players were exposed to risks of severe neurological injuries, yet did nothing to prevent them. It failed to warn players about the dangers of concussive and sub-concussive impacts; to advocate prophylactic rule changes; or to implement equipment standards adapted for head trauma. To the contrary, the NFL glorified the hyper-violent collisions most likely to lead to head trauma and orchestrated a disinformation campaign to conceal the resulting brain injuries." The flood of concussion litigation over the past year has prompted considerable debate about the legal obligations of sports leagues, associations and administrators, as well as educational institutions, sports equipment manufacturers and others involved in the vast industry of sport, to protect the health and safety of players of any sport at any level of play (www.cmaj.ca/lookup/doi/10.1503/cmaj.109-4243). — Wayne Kondro, *CMAJ*

Liverpool review: In the wake of accusations that an evidence-based framework for delivering end-of-life care to the terminally ill is serving as a "euthanasia pathway," the United Kingdom's Association for Palliative Medicine, the National End of Life Care Programme and a range of other national organizations will conduct a review of integrated care pathways. Under the gun is the controversial Liverpool Care Pathway, which offers guidance in such areas as symptom control, comfort measures, the discontinuation of inappropriate measures and anticipatory prescribing of medication, along with psychological and spiritual care of the patient and family (www.cmaj.ca/lookup/doi/10.1503/cmaj.109-3104). The review will solicit "the views of people with personal experience of end of life care, including the Liverpool Care Pathway," the association stated in a press release (www.apmonline.org/documents/135168935061647.pdf). As well, "the National End of Life Care Programme will work with a number of hospital Trusts to undertake a snapshot review of complaints received about end of life care. This will include complaints relating to the use of the Liverpool Care Pathway and any communication or perceived communication issues." The view of clinicians will also be sought. "We know that there are some concerns amongst the public and some professionals about integrated care pathways. We want to take time to identify and explore any concerns properly, look at the evidence and find ways to improve practice," Dr. Bee Wee, president of the association, stated in the release. "In the meantime, we must remember that there are people today approaching the

end of their lives, and that they and their families are going through a tremendously vulnerable time. Our members are already seeing heightened anxieties in daily practice due to the misrepresentation of tools which are designed to improve end of life care. I would urge all to take a balanced and considered approach when debating these issues." — Wayne Kondro, *CMAJ*

Gastrointestinal burden: One in 150 Canadians have Crohn disease (CD) or ulcerative colitis (UC), at a cost of $2.8 million to the Canadian economy, including $1.2 billion in direct treatment costs and $1.6 billion in lost productivity, according to the Crohn's and Colitis Foundation of Canada. Roughly 233 000 Canadians are now living with inflammatory bowel disease (IBD), including 129 000 with CD and 104 000 with UC, the foundation states in a report, *The Impact of Inflammatory Bowel Disease in Canada* (www.isupportibd.ca/pdf/ccfc-ibd-impact-report-2012.pdf). "Canada has among the highest reported prevalence (number of people with CD or UC) and incidence rates (number of new cases per year) of IBD in the world" as roughly 5700 new cases of CD, and 4500 new cases of UC, are diagnosed annually, the report states, while noting that "the causes of CD and UC have not been determined. There is growing evidence suggesting that there is a combination of genetic and environmental factors that inappropriately activate the gastrointestinal immune system. Research looking into internal and external factors contributing to IBD includes the search for specific bacterial triggers, as well as other environmental triggers such as diet, antibiotic use and lifestyle. The possibility of more than one environmental or infectious trigger that leads to a similar set of symptoms confounds the research agenda to find both a cause and a cure for IBD." Among recommendations is a call for "recognition of IBD as a national health priority and increased resource allocation for chronic care models that reflect the episodic nature of IBD and optimize healthcare delivery." — Wayne Kondro, *CMAJ*

Constitutional revisions: Far greater transparency about medical errors and greater patient input regarding end-of-life care are among 10 areas in which the United Kingdom's Department of Health is proposing to include in an overhaul of the National Health Service (NHS) constitution. As a corollary to government plans to legislate a "duty of candour" within NHS, the agency's constitution will be revised to create a higher onus to report patient safety incidents and disclose errors to patients, the Department of Health states in *A consultation on strengthening the NHS constitution* (https://www.wp.dh.gov.uk/publications/files/2012/11/Consultation-on-strengthening-the-NHS-Constitution.pdf). A "contractual requirement" will be created and "greater force" will be given to an existing constitutional pledge "to acknowledge mistakes, apologise, explain what went wrong and put things right quickly and effectively." The department also proposes that the patient involvement provisions of the constitution need to be strengthened "to make clear that patients make decisions rather than decisions being made for them. We also propose to make clear that this right also applies to involvement in discussions and decisions about a patient's end of life care, and that their families and carers should be involved too, where appropriate." — Wayne Kondro, *CMAJ*

Five points: The Conference Board of Canada has identified five priorities, including primary care reform, as essential to ensuring the sustainability of the health care system. Primary care reform should primarily be achieved by making interdisciplinary family care teams the standard across the country, Glen Hodgson, senior vice-president and chief economist at the Conference Board states in a summary of the findings of the first Summit on Sustainable Health and Health Care (www.conferenceboard.ca/economics/hot_eco_topics/default/12-11-06/five_priorities_for_fixing_the_canadian_health_care_system.aspx?utm_source=twitter&utm_medium=social&utm_campaign=share). The remaining four priorities? More "intensive and standardized" use of information technology; linking of health professional compensation to "more patient outcomes, not to activities like treatment or consultation, within a clear accountability structure;" greater care of the elderly in their homes and communities; and greater investment in wellness and preventive health measures. — Adam Miller, *CMAJ*

Perkin awards: The College of Family Physicians of Canada has named the 2012 recipients of the Reg L. Perkin award for "outstanding patient care, significant contributions to the health and well-being of their local community, and commitment to family medicine teaching and research." The 10 recipients, one from each of the college's 10 provincial chapters (from left to right on the Canadian map) are: Dr. Stanley Lubin, Vancouver, British Columbia; Dr. Michel Donoff, Edmonton, Alberta; Dr. Daniel Johnson, Kindersley, Saskatchewan; Dr. Frances Berard, Notre-Dame-de-Lourdes, Manitoba; Dr. Peter Wells, Collingwood, Ontario; Dr. Andrée Gagnon, Blainville, Québec; Dr. Greg Donald, Ammon, New Brunswick; Dr. Jane Brooks, Middleton, Nova Scotia; Dr. Paul Kelly, Summerside, Prince Edward Island; and Dr. Edgar Mayo, Burin Bay Arm, Newfoundland and Labrador. Their bios are available at http://fpoy.cfpc.ca/?page_id=30. "Our 2012 award recipients are dedicated to providing comprehensive care for their patients, and supporting their students and colleagues," Dr. Sandy Buchman, the college's president, stated in a press release. "They each have unique areas of interest including palliative care, emergency medicine, advanced trauma life support, obstetrics, and support for enhanced use of electronic medical record systems. Many also channel their passions into family medicine research and teaching the next generation of family physicians. They are stellar examples of the outstanding family physicians we are so lucky to have to provide Canadians with high-quality health care." — Wayne Kondro, *CMAJ*

Activity-based boondoggle: The United Kingdom's "payment by results" system of funding the National Health Service and other forms of activity-based funding "is not fit" for the country's current and future health needs, according to a report from the independent health charity The King's

Fund. Activity-based funding, which is increasingly being adopted in Canada, has long been lauded as a means of promoting efficiency, though critics say it shifts the focus toward increasing patient volume at the expense of quality of care (www.cmaj.ca/lookup/doi/10.1503/cmaj.080594). The King's Fund study, *Payment by Results: How can payment systems help to deliver better care?*, argues that the payment by results model of funding hospitals "is most appropriate to elective care and is less suited to other services where less rather than more activity is desirable, and where the nature of the service means that competition and choice is limited and the main requirement is to ensure there is the capacity to meet variable levels of demand" (www.kingsfund.org.uk/sites/files/kf/field/field_publication_file/payment-by-results-the-kings-fund-nov-2012.pdf). The model offers little incentive to shift care from hospitals to other settings and is "not well suited to promoting continuity and co-ordination of care." As well, trade-offs are inevitable as different funding models promote, and achieve, different objectives, the report adds. "The starkest potential conflicts are between cost and quality and cost and maintenance of supply. There is a risk of widespread failure if tariffs are pushed down to a level where even an efficient provider cannot maintain high-quality services. As more and more objectives are loaded on to payment systems, the risk increases that they will conflict and that their impact will be unpredictable and difficult to evaluate."

Bonus air miles for mental fitness: The Canadian Mental Health Association (CMHA), the charitable foundation Healthy Minds Canada and the AIR MILES Reward Program have jointly created an interactive website that hopes to "improve the mental fitness" of Canadians. Entitled "My New Head," the website provides 20 bonus air miles to users who "sign-up and answer a few brief survey questions that are centered on four key subject areas: Mind, Body, Self and Life," the association states in a press release (www.cmha.ca/news/how%e2%80%99s-your-mental-fitness/). "Based on one's individual answers, customized content is generated that participants can complete at their own pace including: reading, watching and listening to various mental health–focused pieces. Participants are then asked to make their way through various fun self-monitoring challenges. Additionally, and as a reward for successfully completing and working through the initial challenges, participants will have an opportunity to unlock bonus content and challenges." Or as the website (http://mynewhead.com/) states: "We know what you're thinking: 'Umm, I already own my head.' But do you really? When life gets busy and stressful it can feel like we're not fully in control of our mental wellbeing - like we don't actually own our head. This is your opportunity to take back control and make that head spectacular." — Wayne Kondro, *CMAJ*

Nursing numbers: A record number of registered nurses graduated from Canadian institutions in 2010/11 but admissions declined for the first time in a decade and there's a looming shortfall in teachers at nursing schools, according to a report from the Canadian Nurses Association and the Canadian Association of Schools of Nursing. There were 10 827 registered nursing graduates in 2011, a 6.9% increase over 2010, according to the report, *Registered Nurses Education in Canada Statistics, 2010-2011 — Registered Nurse Workforce, Canadian Production: Potential New Supply* (http://www2.cna-aiic.ca/cna/documents/pdf/publications/NSFS_Report_2010-2011_e.pdf). But the system isn't training enough people to replace the 38.7% of faculty members in nursing schools in the 55+ age cohort and the 17.9% in the 60+ age cohort (309 of 1729), the report adds. "While there has been some increase in Masters and Doctoral admissions and graduate rates, the replacement pool (master's and doctoral graduates) for retiring faculty is inadequate if enrolments in undergraduate programs remains at current levels." There's a need for better human resource planning, Barb Mildon, president of the Canadian Nurses Association argued in a press release (www.cna-aiic.ca/en/new-report-from-national-nursing-organizations-shows-record-high-number-of-rn-grads/). "The responsiveness and sustainability of our health-care system is dependent upon careful collaborative management of our health human resources. To ensure investments in education translate into full-time employment and appropriate staffing of the health-care system, provincial and territorial governments, employers, and educational institutions must share information and evidence consistently and work on pan-Canadian strategies." — Wayne Kondro, *CMAJ*

Public health accreditation: Canada's first stand-alone faculty dedicated to public health has become Canada's first School of Public Health to be granted accreditation by the United States Council on Education for Public Health. The University of Alberta's public health faculty has completed the rigorous accreditation process after six years of effort, the Edmonton-based institution announced in a press release (www.publichealth.ualberta.ca/en/School%20of%20Public%20Health%20News/2012/November/UAlbertasSchoolofPublicHealthfirstaccreditedinCanada.aspx). "The Council recognizes the efforts of the University of Alberta to make ongoing improvements to ensure that students receive a high-quality education that advances them toward their career goals," stated Laura Rasar King, executive director of the council. Martin Ferguson-Pell, acting provost and vice-president (academic) at the University of Alberta, added that "this is an example of visionary leadership shown by the University of Alberta to effect positive change in our world. The School of Public Health receiving accreditation reflects excellence in teaching and learning, and the innovative research done at the University of Alberta." The school was created in 2006 through the merger of the Alberta Centre for Injury Control and Research, the Centre for Health Promotion Studies and the Department of Public Health Services. It currently has about 300 enrolled graduate students. — Wayne Kondro, *CMAJ*

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