

## FOR THE RECORD

**More isotope woes forecast**

The fragility of the world's medical isotope production chain is again expected to disrupt supply this summer. Europe's Association of Imaging Producers and Equipment Suppliers issued an "urgent update" indicating that 2 of Europe's 3 isotope-producing nuclear reactors will undergo extended maintenance shutdowns over the course of the year, which will likely limit the availability of isotopes ([http://interactive.snm.org/docs/Update\\_04FEB\\_Production\\_TC99.pdf](http://interactive.snm.org/docs/Update_04FEB_Production_TC99.pdf)).

Noting that a global workshop organized by the International Atomic Energy Agency in February indicated that Canadian suppliers are now operating beyond sustainable levels, Association President Marc Gheeraert stated in the update that Europe can expect supply shortfalls on the order of 40%–75%.

The global workshop, attended by 16 countries, forecast supply chain problems for several years, as only 5 countries — Canada, Belgium, France, the Netherlands and South Africa — produce the key isotope technetium 99m, and some 95% of world supply is created by 5 reactors, all over 40 years of age. "Participants noted that, due to the age and increasing maintenance requirements of the major production reactors, the vulnerability of the isotope supply chain is likely to persist, if not to increase, for several years," stated Nuclear Energy Agency Director General Luis Echavarri in a summary of the workshop.

**Pharma bears responsibility for labelling**

The United States Supreme Court has ruled that compliance with Food and Drug Administration label warnings does not imbue pharmaceutical companies with immunity from lawsuits seeking redress for injuries caused by adverse drug reactions.

Rejecting drug giant Wyeth's argu-

ments (which were supported by the former George W. Bush administration) that federal oversight and regulation of drugs provides a legal shield against damages awarded by juries in any of the 50 states, the Supreme Court ruled 6–3 to uphold a state of Vermont verdict that awarded US\$6.7 million to a musician whose arm was amputated after promethazine (Phenergan) was errantly injected into an artery instead of a vein (*Wyeth v. Levine*, No. 06-1249).

Guitarist Diana Levine was injected using the "IV push" method and when the anti-nausea drug entered her artery, she developed gangrene. She successfully argued in a Vermont court that Wyeth had failed to properly inform doctors about the risk of administering promethazine via IV push.

Just because a drug is approved by the FDA doesn't mean that a state no longer has the right to regulate the conduct of businesses that harm citizens, wrote Justice John Paul Stevens, on behalf of the majority. "Failure-to-warn actions, in particular, lend force to the FDCA's [Food, Drug, and Cosmetic Act] premise that manufacturers, not the FDA, bear primary responsibility for their drug labelling at all times."

The ruling emboldened Democrats in Congress to introduce legislation that would allow similar lawsuits to proceed against companies that make heart devices, hip replacements, catheters and other medical devices. — Wayne Kondro, *CMAJ*

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**Global burden of food-borne disease**

Interim data about threats from food-borne disease should be more rapidly and broadly disseminated via the Internet, while clear and simple messages about those threats must become the norm, according to a World Health Organization gathering.

Precise information on the burden of food-borne disease will help policy-makers to allocate resources effectively to the design and implementation of prevention and control measures, says the meeting report of the WHO Initiative to Estimate the Global Burden of Foodborne Diseases. More than 30 stakeholders representing international and nongovernmental organizations, consumer groups and industry attended the Foodborne Disease Stakeholder Meeting in Geneva, Switzerland, on Nov. 20, 2008.

Poor countries stand to benefit most from the initiative, as their high levels of food-borne-related illness and death serve as "a major obstacle" to development efforts, adds the report, *Increasing Impact Through Collaboration*.

Stakeholders also declared that the generation of data is not enough and asked the WHO to "not just perform analysis of the data but also make policy recommendations as this will ensure a nonbiased and balanced view."

The WHO's Department of Food Safety, Zoonoses and Foodborne Diseases launched the initiative in September 2006 to estimate death and disability due to food-borne diseases, focusing on microbial, parasitic and chemical causes. Meeting participants also deemed the 5-year term of the initiative to be overly "short." — Christine Navarro, Hamilton, Ont.



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The WHO has launched an exercise to estimate the global burden of food-borne diseases using a measure that accounts for acute illness and premature deaths.