US considers establishing behind-the-counter drugs

In November, Health Canada received a last-minute invitation to a hearing on whether the United States should approve a new class of drugs for behind-the-counter sales.

United States Food and Drug Administration (FDA) spokesperson Chris Kelly says his agency wanted to know the perspective of the Canadian government, which made sense on the surface: behind-the-counter drugs, provided after discussion with a pharmacist but requiring no prescription, have been part of Canada's national drug schedules since 1995.

But it's not clear how much the United States can learn from this country's experience. Health Canada decides whether a drug is prescription-only and the National Association of Pharmacy Regulatory Authorities and its provincial and territorial counterparts classify non-prescription drugs as over- or behind-the-counter, but Brigitte Zirger of Health Canada's Therapeutic Products Directorate says the Canadian model can't be easily replicated south of the border. The pharmacy regulator's executive director, Karen Wolfe, says "it's very difficult to draw parallels" between the 2 countries' drug regulatory systems.

Drugs kept behind the counter in Canadian pharmacies include EpiPens, Polysporin eye or ear drops, the strongest lice shampoos and Tylenol No. 1 with codeine. Pharmacists counsel patients about the use of the drugs and are reimbursed for their time through dispensing fees that are established by the provinces, a mechanism that serves the public "very well," says Canadian pharmacist Sana Sukkari, of the Lake Erie College of Osteopathic Medicine in Pennsylvania.

Wolfe agrees. "It's a greater barrier for me in Canada to try and get a prescription from a physician than to walk into a pharmacy and have a dialogue with a pharmacist," she says. But in speaking to the FDA at the November hearing, Health Canada's Zirger underscored the differences between the 2 countries. Projecting a brightly coloured map of Canada, she said her aim wasn't to promote tourism, but to show that Canada's system operates in a country with only 13 provinces and territories and could be unwieldy in 1 with 50 states.

American pharmacists support the idea of behind-the-counter drugs, according to recent polls by pharmacists' professional associations, but they want a new scheme for payment. The dispensing fees paid by health care insurers don't cover the costs of counselling by

pharmacists and as a result, some doctors claim, shoppers interact mostly with pharmacy technicians.

Despite this, Kelly says the FDA believes "many consumers are supportive" of a behind-the-counter class of drugs. Not surprisingly, the American Medical Association and other medical groups are strongly opposed and have argued against the need for a new class of drugs, just as the Canadian Medical Association argued against Canada's behind-the-counter classification scheme when it was first proposed here in 1995.

Dr. Joseph Cranston, the American Medical Association's director of science research and technology, testified in November that the association believes that "when a drug is not safe for use by consumers without supervision ... then a physician who is adequately trained to evaluate and diagnose disease and is licensed to prescribe drugs should be responsible for supervising the use of that drug." Cranston added the FDA lacks statutory authority to approve behind-the-counter drugs since the classification isn't established by federal law.

However, a consumer advocacy group claims the debate in the United States is more than a turf battle between doctors and pharmacists. Dr. Sid Wolfe, head of the health wing of the consumer group, Public Citizen, told the FDA in November that "the current push for a behind-the-counter class was precipitated recently by drug companies who make statins and want to switch them to 'over the counter.'"

That switch has been the subject of several FDA meetings, including 1 on Dec. 13, 2007, when Merck requested over-the-counter status for a 20 mg dose of lovastatin (Mevacor). Merck's request was rejected by a vote of 10 to 2, marking the third time that an FDA advisory committee has rejected this proposal for lovastatin. In 2005, committee members heard that statins are sold from behind-the-counter in England. Wolfe says companies that manufacture statins want the option of behind-the-counter sales in the United States, since the FDA and its advisors might be more willing to approve behind-the-counter status than over-the-counter. The stakes are high: the

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The American Medical Association is opposing the creation of a Canada-like category of behind-the-counter drugs, which pharmacists could dispense without a doctor's prescription.

prescription-only statin market in the United States was valued at more than US\$21 billion in 2006.

Merck spokesperson Ron Rogers says his company is only interested in over-the-counter status for its drug and hasn't been part of the debate for a new, behind-the-counter classification. But executives at GlaxoSmithKline had seemed optimistic that statins would be sold without a prescription. Two weeks after the November hearing on behind-the-counter drugs, Glaxo, Europe's largest drug maker, announced it had purchased the rights from Merck to market lovastatin in the United States if the drug is approved for non-prescription sales. That seems unlikely now, given the advisory committee's vote in December.

But the FDA may still act to establish a behind-the-counter category. Spokesperson Chris Kelley says that after public comments on the issue are reviewed, the next step could be a recommendation or an administrative action. — Miriam Shuchman MD, Toronto, Ont.

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Testing the functionality of new medical devices

It's a scenario likely repeated daily across the country. A hospital needs new pieces of equipment that will cost millions of dollars and have to remain in use for a decade or more.

Competing vendors each proclaim their products is not only the best technically, but also the easiest and safest to operate. To sort out such claims in the past, a hospital might have asked a staff expert to try out the new machinery or sent someone to observe it in use.

But for the last 3 years, institutions have increasingly been turning to the Healthcare Human Factors Group of Toronto's University Health Network for an objective evaluation of the "usability" of competing devices.

Their success at identifying which of several similar machines is most likely going to lead to medical error — particularly when used in an often fre-

netic hospital setting — has allowed the group to become the world's largest hospital-based usability/ergonomics/human factors (these terms are used interchangeably) laboratory.

Housed in a \$6-million facility, the lab now employs 10 full-time staff and 5 graduate students. The not-for-profit Healthcare Human Factors Group claims that one of its great strengths is its access to 3000 University Health Network nurses and 1000 doctors as test subjects.

One classic example of the group's work involved a deliberation by several Toronto-area hospitals over which of 4 competing automatic external defibrillators to buy. All the machines were theoretically so simple to operate that manufacturers had been promoting them as an ideal technology for ordinary people responding to heart attacks in airports and schools.

But the reality was starkly different. In a simulated emergency, simply getting a machine out of its case proved an embarrassing complication. During the test, nurses who were unfamiliar with the device couldn't find the latch that unhooked its carrying case. Others couldn't figure out which of 2 zippers to unzip to take a different machine out its case.

This fumbling could have potentially fatal consequences, points out Anjum Chagpar, manager of the Healthcare Human Factors Group. "With every minute that passes, there is a 10% decrease in the likelihood of a successful resuscitation."

Not only did the tests convince the hospitals which device to buy, it made them aware of how subjective and flawed their initial impressions had been.

Dr. Rick Cooper, who was a participant in testing 3 devices by Chagpar's team, says they went into the evaluation with a "bias based on the specifications of a device and our impressions when we or when experts handled the devices. After the tests were conducted, this was completely turned around," says Cooper, a professor of anesthesia at the University of Toronto. "Our first choice had previously been ranked as fourth."

This sort of ranking is not something that all companies necessarily want. "Some have said we don't want

our product evaluated, and we don't care if you purchase it," says Chagpar.

Other vendors have had to be removed from viewing the test procedures behind 1-way glass because they became agitated watching nurses and doctors make potentially dangerous errors, says Joseph Cafazzo, the University Health Network's director of medical device informatics and health-care human factors team.

Stephen Strauss

The props take a break at the Toronto-based University Health Network's device usability testing laboratory.

Despite the corporate concerns, the lab has become a usability test bed for hospitals and health ministries across the country, as well as for governments and manufacturers elsewhere.

A shining example of the latter is the new "smart" pump-infusion system that the facility helped develop with the American arm of Smiths Group PLC, a London-based company. The process started with pencil and paper drawings; 10 iterations and 2 years of work resulted in a full-fledged machine that is currently awaiting U.S. Food and Drug Administration (FDA) approval.

The cost for the group's services ranges from \$10 000 to \$50 000, depending on the number of devices and their sophistication. The test results are shared with clients, and Chagpar says they hope to start publishing results in peer-reviewed journals in the future.

In a larger sense, the team's efforts represent a realization that human error in operating a device can be a major cause of patient death and injury in an age of sophisticated machinery.

A driving regulatory force has been the FDA's 1997 adaptation of a general principle that required medical manu-