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 nonprescription 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.

DOI:10.1503/cmaj.071831

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 frenetic 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.

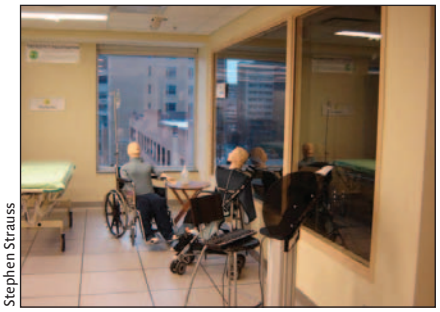
This fumbling could have potentially fatal consequences, points out Anjum Chagpar, manager of the Healthcare Human Factors Group. "With every minute that passes, there is a 10% decrease in the likelihood of a successful resuscitation."

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-

facturers to "demonstrate adherence to good design practices."

This has since been expanded into what is known as the IEC 60601-1-6 design code, which sets a similar standard for the usability of medical devices around the world. To meet the standard, companies need both human factors skill and objectivity about their failures.

Tom Ulseth, Smith's worldwide marketing manager, says "There is a lot of value to an objective perspective like that which Toronto brings. When you bring work inside it becomes too close to you, you become too biased about it working."

To which Cooper adds: "The devices shouldn't be evaluated by engineers, that is by the people who are designing them. They should be evaluated by the people who are using them." — Stephen Strauss, Toronto, Ont.

DOI:10.1503/cmaj.071820

The search for integrity in the cosmetic surgery market

The death of a Toronto woman from complications following liposuction has prompted Ontario to undertake a wholesale review of the regulation of cosmetic and aesthetic surgery, and sparked a national debate over which physicians should be allowed to perform invasive procedures.

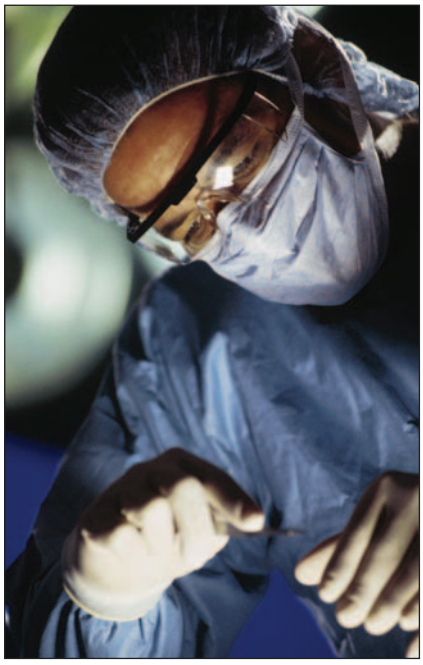
In September, 32-year-old real estate agent Krista Stryland died following liposuction performed by Dr. Behnaz Yazdanfar of the Toronto Cosmetic Clinic. Yazdanfar is a family physician with no formal surgical training who claims on her website to perform a wide range of invasive procedures, including breast surgery, liposuction and tummy tucks.

In the aftermath of Stryland's death, it was revealed that the College of Physicians and Surgeons of Ontario has failed to act after struggling for years with the issue of cosmetic surgery performed by physicians with no formal surgical training.

College President Dr. Preston Zuliani acknowledged that more could have been done to deal with the issue of unqualified physicians performing cosmetic procedures. The college is now fully committed to a plan of action that ensures only qualified plastic surgeons can perform such invasive procedures.

"In retrospect, might we have been more aggressive, earlier?" Zuliani inquires. "Yes, that's a fair statement. But I think we're making up for it now. We consider this to be a very important issue of public safety and public trust."

Following Stryland's death, the college canvassed the more than 2400 members to determine the extent to which doctors may have expanded their practices to include cosmetic and aesthetic procedures without having obtained appropriate training. It is believed several hundred doctors, mostly family physicians, have been advertising themselves as "cosmetic surgeons," but have not been telling patients they are not formally qualified to perform surgery.



Comstock

The lucrative and burgeoning area of cosmetic surgery has enticed some family physicians into the field, while also luring a few charlatans and hacks, including an unlicensed husband and wife team who performed home-based liposuction on a Massachusetts woman. She died, as did Toronto real estate agent Krista Stryland, after being operated on by a family physician with no formal surgical training.

By late December 2007, the college had notified 16 physicians that they are being investigated to determine if they are qualified to offer these medical services. Some 20 others who haven't answered a college questionnaire about their qualifications had until the end of 2007 to respond or their licenses could be suspended.

The college has declined to identify the physicians, or indicate whether they have been asked to cease all invasive cosmetic procedures, until the investigation is completed.

A college committee of experts is also drafting recommended changes to provincial legislation that would expand the association's regulatory authority and ability to shut down facilities that do not meet basic medical standards.

Plastic surgeons, who have long lobbied provincial colleges to impose restrictions on physicians advertising themselves as cosmetic surgeons, applauded the efforts but lamented the fact that cosmetic surgery remains unregulated in most Canadian provinces.

Dr. David Kester, president of the Canadian Society for Aesthetic Plastic Surgery, said only British Columbia and Alberta now regulate cosmetic procedures. The former initiated a rigorous regime in the early 1990s to rein in a growing number of private surgical clinics.

In Ontario, however, Kester says a family physician only needs to notify the provincial college that they are changing the scope of their practice and then meet with a mentor who assesses their ability to perform the new procedures. Most plastic surgeons consider that an inadequate assessment of ability to perform complex, invasive procedures, he adds.

Dr. Gordon Wilkes, president of the Canadian Society of Plastic Surgeons, says most so-called "cosmetic surgery" procedures are actually extensions of complex reconstructive surgery that plastic surgeons train for years to perfect. Despite this, aggressive advertising by cosmetic surgeons attempts to convince prospective patients that procedures are simple and risk free.

"There is no integrity in the marketplace," Wilkes says. "The public confuses cosmetic surgery with plastic sur-