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## Patchwork regulations likely outcome of reproductive technologies ruling

A Supreme Court of Canada decision that struck down key provisions of the Assisted Human Reproduction Act could increase medical tourism and risk to patients, experts in health policy fear.

“There is an absolute lack of protection for patients, and most especially women,” says Vanessa Gruben, an assistant professor of law at the University of Ottawa in Ontario.

The Dec. 22, 2010, split decision (4-4-1) upheld Quebec’s challenge to the federal government’s authority to regulate assisted human reproductive technologies, such as in vitro fertilization. Such regulation, as well as the licensing of fertility clinics, will now be left to provinces and territories. Each will have to draft legislation if it wishes to set standards in this area, Gruben says. Thus far, only Quebec has indicated a keen desire to do so.

A patchwork of provincial laws and regulations is likely to ensue, leading more women to seek treatment in provinces with regulations most favourable to their particular situation, Gruben says.

Dr. Patricia Baird, distinguished professor emerita at the University of British Columbia in Vancouver and chair of the 1989 Royal Commission on New Reproductive Technologies that spawned the federal legislation, concurs on the likely outcome. “I am disappointed about the legislation and concerned that it will lead to a patchwork of clinical standards, and reproductive tourism — if some provinces have little oversight,” she writes in an email.

For example, some provinces may decide to stipulate that fertility clinics can only implant one embryo at a time; others may leave the choice of single or multiple implantation — which increases the risk of multiple births — to the individual clinic and physician. Depending upon a woman’s age or the number of cycles of in vitro fertilization she can afford, she may opt to travel to a province that permits multiple implantations.

The Supreme Court also struck down the information provisions of the legislation that would have enabled the federal Assisted Human Reproduction Agency to create donor registries and compile information for people born from donated eggs or sperm. It did, however, leave in place prohibitions against human cloning, the creation of human embryos for research purposes, the mixing of human and animal genetic materials to form chimeras or hybrids, and the buying and selling of sperm, ova and embryos. Commercial surrogacy contracts also remain illegal.

But the agency will no longer have the authority to regulate such areas as pre-implantation diagnosis, including screening gametes for diseases such as Tay-Sachs or familial Alzheimer disease.

“That’s clearly something the provinces have to do,” says Timothy Caulfield, chair of health law and policy at the University of Alberta in Edmonton.

The ruling has left the agency in limbo and scrambling to determine how to carry out its adjusted mandate. A spokesperson refused comment, referring all inquiries to Health Canada, which said it is “studying the decision.”

Caulfield believes there’s a need for national standards in several areas, as well as a national discussion on the issue of pre-implantation genetic testing. “We’ve lost the ability to create a regulatory framework which I think ultimately would have led to a higher quality of care for Canadians seeking reproductive technology.”

He also believes there’s a need to re-examine the ethical, legal and social issues around cloning, genetic enhancement and stem cell research. Some of the justices got mired, in some of their discussions, around the fear of “cloning in the garage” and other things that were envisioned 20 years ago and haven’t happened, he says, adding that science has evolved in the area and the justices’ arguments did not reflect that.

Caulfield hopes provincial medical associations and national regulatory bodies governing physicians will step into the breach to develop standards governing such things as transparent success rates at fertility clinics, and policies regarding multiple embryo transplants.

Others fret about the absence of any kind of legislative or institutional check on the activities of fertility clinics.

For example, although the law prohibits the buying and selling of gametes, there are still no regulations that define what constitutes a “gift” to potential donors, says Dr. Renza Bouzayen. “It’s so hard to actually not pay a donor,” she says, and as a result, gametes are becoming scarce.

Bouzayen discontinued working with a patient who indicated a willingness to give a \$10 000 “gift” to a donor at a Toronto fertility clinic. “I said, I’m not ready to take the risk” of defending the \$10 000 as a gift rather than a payment, she says. — Laura Eggertson, Ottawa, Ont.

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