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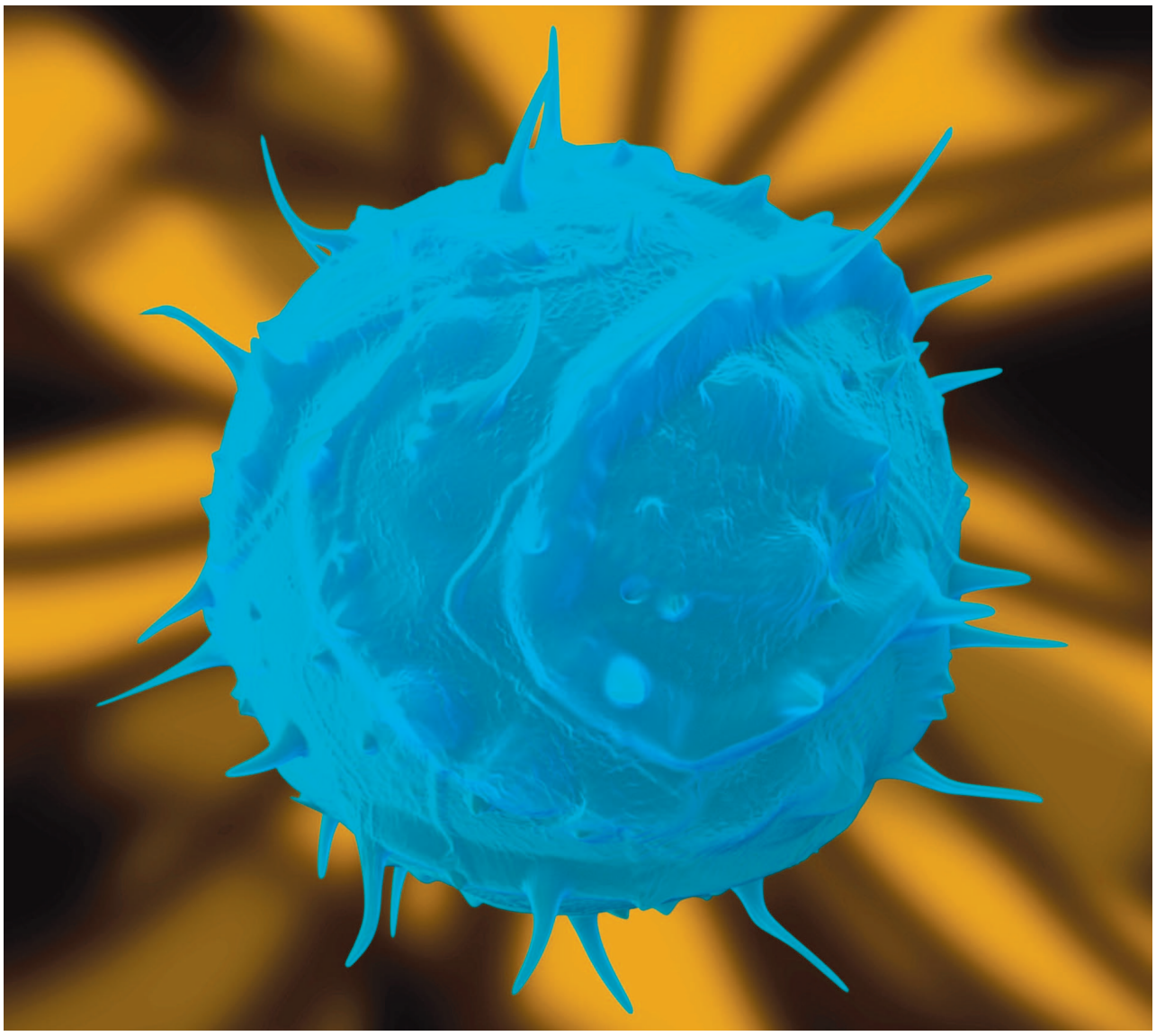

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Legal policies steer direction of stem cell research

AMY ZARZECZNY

Stem cell research is a phrase that stirs controversy, engages imaginations, raises hopes and expectations and targets deeply held moral and religious convictions. As such, it has provided fertile ground for scientific, medical, ethical, philosophical and political debates.

While stem cell research may not always be considered, strictly speaking, a legal issue, it necessarily exists within the boundaries established by law and policy in individual jurisdictions. As is true of every emerging technology that has the potential to significantly affect key societal structures such as our healthcare systems, it requires (and deserves) well-thought-out policy responses that are appropriately grounded in clear and consistent principles. Whether stem cell research has traditionally enjoyed this type of response is an open question.

While the phrase "stem cell research" is often and perhaps unconsciously linked with "human embryonic stem cell research," there are a number of types of stem cell research. The use of adult stem cells and umbilical cord blood stem cells in bone marrow treatments for cancer and other blood disorders are two familiar examples.

More recently, induced pluripotent stem cells derived from adult somatic cells, somatic cell nuclear transfer (SCNT) or "therapeutic cloning" and interspecies somatic cell nuclear transfer (iSCNT) have emerged as scientifically promising techniques. Nonetheless, human embryonic stem cell (hESC) research has largely dominated public discourse and been the focus of most legislative initiatives.

Regulations governing stem cell research vary widely around the world. The legality of the various technologies is an excellent example of this variance. Some policy positions appear to have clear religious groundings, such as predominantly Catholic nations' (for example, Ireland and Italy) prohibitions

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Interpreting standards of proof and review in health law

CYNTHIA KUEHL

Health law litigators are well-versed in the language of "standard of care." However, in 2008, the Supreme Court of Canada released two decisions on the "other" standards — standard of review and standard of proof — that are relevant to those who practise before administrative tribunals.

In *Dunsmuir v. New Brunswick*, [2008] S.C.J. No. 9, the Supreme Court attempted to simplify the law on standard of review by creating a single standard of "reasonableness" for reviewing issues of fact, discretion and policy, thereby eliminating the confusing "patent unreasonableness" standard.

Deference, which imports the notion of respect both for the legislative decision to grant powers to administrative tribunals and for the decisions of those tribunals, is the underlying principle of the reasonableness standard. The court, however, will continue to review jurisdictional, constitutional and most legal issues on a correctness standard.

While the reasonableness standard is not new to the health law field, the practical implication of the *Dunsmuir* articulation of the standard has yet to be fully addressed. Fortunately, some guidance has been provided in the recent Ontario Divisional Court decision in *Yar v. College of Physicians and Surgeons of Ontario*, [2009] O.J. No. 1017.

In *Yar*, the court relied on previous decisions establishing that, on judicial review, the reasons of the tribunal *as a whole* must be evaluated. Like the palpable and overriding error test for reviewing findings of fact made by a trial judge, individual errors or mistakes by a tribunal will not necessarily result in the decision being found unreasonable unless they affect the overall conclusion.

Following *Dunsmuir*, the court in *Yar* noted that there is often a range of acceptable and rational

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Court finds different levels of scrutiny inappropriate

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outcomes from a tribunal that can be defended on the evidence and the law. While the court in *Dunsmuir* noted that reasonableness is "concerned mostly with the existence of justification, transparency and intelligibility with the decision-making process," it also stated that, on judicial review, a court should consider whether the tribunal's decision falls within that range of possible outcomes. If it does, it will likely be found to be a reasonable decision.

One can compare *Yar*, in which the tribunal's decision was upheld, to *Dr. V.L. v. College of Chiropractors of Ontario*, 2008 CanLii 56709, in which the Divisional Court quashed the college's decision as unreasonable. There, the issue was whether a chiropractor, who had an existing intimate relationship with the complainant before she became a patient, was guilty of sexual abuse. The court reviewed whether the treatment was "incidental" to the relationship and found that the college's interpretation of "incidental," as referable to frequency of treatment, was unreasonable.

Applying the language from *Dunsmuir* quoted in *Yar*, this decision arguably either means that the college's interpretation was not within the range of defensible outcomes or that this question lent itself only to one specific result. Leave to appeal has been granted.

> The application of the balance of probabilities test will not happen in a factual vacuum.

In addition to the effect of *Dunsmuir* on future judicial review applications, the recent statement on standard of proof by the Supreme Court in *F.H. v McDougall*, [2008] S.C.J. No. 54 will affect future tribunal decisions at first instance. Since the Divisional Court's decision in *Bernstein v. CPSO*, [1977] O.J. No. 2182, the standard of proof for matters involving professional misconduct has required that the evidence be "clear, cogent and convincing."

The premise of the "*Bernstein* standard" was that the potential impact on career and reputation was so serious that the evidence must meet a certain, arguably heightened, standard. In *F.H.*, the Supreme Court appears to try to eliminate that interpretation of *Bernstein* by clearly stating that there is a single standard of proof, namely balance of probabilities, for all civil cases, including cases in which the allegations are of professional misconduct.

Rather than reject the requirement of clear, cogent and convincing evidence, the court integrated it, finding that regardless of the nature of the civil case, evidence "must always be sufficiently clear, convincing and cogent to satisfy the balance of probabilities test." The decision finds it inappropriate to have different levels of scrutiny of the evidence depending on the gravity of the allegations.

While the Supreme Court specifically rejects any formulation of standard of proof other than balance of probabilities, the application of the balance of probabilities test will not happen in a factual vacuum. Thus, tribunals will inevitably consider whether the potential outcomes to the health professional are relevant to the consideration of whether the evidentiary threshold is met.

In the year ahead, courts and tribunals will need to integrate the "other" standards into their decisions and, in doing so, determine whether the effects of *Dunsmuir* and *F.H.* will change the existing law or, in the health law context, amount only to a restatement of it. ■

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Lawddities

A legal oddity in ***Health Law***

Yogurt company 'thirsts for revenge'

A debate rages over DanActive, a new drink from the makers of Activia yogurt. The question: Do you drink it or do you eat it?

Danone, a Canadian yogurt company, planned to import the product from the U.S. and sell it in Canada, according to *Maclean's*. If DanActive proved popular, Danone would open a factory in Quebec to produce it. But was Danone encouraged for its plan that would create jobs in Canada? Treated like royalty for its idea that would stimulate the foundering economy? In short, no. Although all went well in the initial stages of the project, things fell apart when the company decided to clear the plan with the Canadian Border Services Agency (CBSA).

At first, the CBSA concluded DanActive was a "beverage containing milk," making it duty-free under NAFTA. Then, in its infinite wisdom, the CBSA changed its mind and labeled DanActive a "liquid yogourt," making it a food, not a drink — with a gigantic 237.5 percent duty.

Activia is now engaged in pricey litigation to prove that DanActive is, in fact, a beverage containing milk, notes *Maclean's*. If the ruling goes the other way, the company may have to scrap its entire plan.

Let's hear it for chugging rather than chewing! — *Natalie Fraser*

Contrasting trends in funding raise concerns of 'brain drain'

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on the derivation of hESC lines within their borders.

However, where countries with relatively similar cultural, political and religious positions have taken starkly different approaches, the links are less clear. For instance, the U.K. permits both SCNT and iSCNT; Australia permits SCNT but prohibits iSCNT; and Canada explicitly prohibits SCNT but likely implicitly allows iSCNT. Other jurisdictions function in the absence of regulation.

Such differences are important for a number of reasons, including the impact they have on international collaboration. This is particularly relevant given the increasing tendency for technologies, scientists and, in the case of medical tourism, even patients, to cross national borders.

Other areas of policy divergence are equally relevant, including patent laws, compensation rules for gamete donors and consent requirements for donors and research participants — which is particularly important as the field moves towards clinical translation.

Also of central importance are funding structures, and, in particular, rules and restrictions governing the use of public funds. Funding is central to the success of scientific research, but its relationship with regulation can be complex. By way of illustration, despite the fact that SCNT is now permitted in the U.K. following amendments to the *Human Fertilisation and Embryology Act*, this research now appears to be impeded by lack of funding.

Recent changes in U.S. federal funding rules, namely President Obama's lifting of the ban on federal funding being used to support research on hESC lines derived after Aug. 9, 2001, have received much attention. The response in some states has been the introduction of legislation to restrict the use of state funds or otherwise prevent hESC research (for example, Texas, Mississippi and Oklahoma), in much the same way other states (for example, California, New Jersey and Connecticut) responded to President Bush's funding restrictions by making funds for hESC research available on a state level.

> Talented scientists and their teams will migrate to jurisdictions that provide them with the resources they require to do their work.

While many of the issues being discussed in these contexts are familiar, the global economic crisis raises new and significant implications. On one hand, some jurisdictions have made investment in science a priority in their stimulus endeavors.

Conversely, the trend in other jurisdictions appears to be a retraction of funding. An emerging issue associated with these contrasting trends is the concern about "brain drain." This issue has traditionally been associated with the permissiveness or restrictiveness of jurisdictions' regulatory positions. Now the emerging concern is that talented scientists and their teams will migrate to jurisdictions that provide them with the resources they require to do their work.

All in all, we are witnessing exciting and challenging times for stem cell research, law and policy. The variety and depth of the issues facing policy makers around the world today are remarkable. It will be fascinating to see how matters unfold and how law will be used as a shaping tool, particularly given that the legal implications of stem cell research cannot be separated from the broader policy context. For instance, the legislated review period for Canada's *Assisted Human Reproduction Act* has arrived.

Will Canada's position shift? Only time will tell. As we move forward, we should avoid sensationalizing this area. While stem cell research certainly raises various unique issues requiring novel consideration and innovative responses, we must also be cognizant of how existing principles and policies addressing analogous issues can guide our steps.

Ideally, informed discussion and debate will encourage a thoughtful and principled approach to policy making in the days ahead. ■

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