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Call for arm's-length national research integrity agency

t's the classic Canadian response to a problem like scientific misconduct, says Toronto physicianscientist Dr. Paul Pencharz. "Deny, deny, deny. Sweep it under the carpet."

Inevitably, though, Pencharz forecasts Canada will have little alternative but to overcome its recalcitrance and create an independent National Research Integrity Agency. That's exactly what he urged in a report commissioned by Memorial University to assess its practices and policies for handling misconduct in the wake of the highly-publicized case of Dr. Ranjit Chandra, who is alleged to have fabricated data on nonexistent babies for his infant formula studies.

The birth of that agency may be well off on the horizon, however, as sponsors of a late January national Research Integrity Workshop say there's little appetite for the bureaucracy, cost or regulation implicit in the creation of an agency.

But Pencharz, staff physician of the Division of Gastroenterology Hepatology and Nutrition, senior scientist at the Hospital for Sick Children, and professor of paediatrics and nutritional sciences at the University of Toronto, says the growing incidence of misconduct cases alone justifies the creation of an agency similar to the US Office of Research Integrity or its sister agencies in Europe. The former was created in 1993 as primarily an investigatory body but has since become more an oversight body, relying on local institutions to conduct investigations and stepping-in only in rare instances. In Europe, agencies range from strict investigatory bodies to advisory bodies which craft guidelines that are implemented locally. It's been conservatively estimated that 0.001%-1.0% of research involves misconduct (Science and Engineering Ethics 2006; 12:53-74).

Canadian taxpayers deserve a measure of accountability in exchange for footing the research bill, Pencharz adds. "The fact that some people will cheat, people will accept.... We know that politicians cheat. We know that ministers of the church cheat, etcetera. But what the public will ultimately not tolerate is failure to deal with the cheats."

Moreover, an arm's-length agency, ideally including a senior member of the judiciary (as is the case in Denmark) would ensure that an accused scientist has due process and is treated fairly, Pencharz argues. It would also have a measure of institutional memory and experience in handling charges, "unlike most universities."

Arguing that all research, whether publicly or privately funded, should fall under the agency's rubric, Pencharz contends that such a regime would prevent conflict situations like the widely publicized Apotex/Nancy Olivieri affair, in which the U of T investigated one of its own while simultaneously accepting money from the pharmaceutical firm that sponsored her research. "There are 2 sides to this and once you start to have something at a national level, you're more likely to have people who do not have a conflict-of-interest. They're more likely to be objective."

The research community, however, seems resistant to the notion.

Canadian Association of University Teachers (CAUT) executive-director Jim Turk says the bulk of delegates to a 2-day workshop sponsored by CAUT, Health Canada and other members of the recently-formed Canadian Research Integrity Committee (CRIC, a loose affiliation of 16 research and academic bodies, including the 3 granting councils and the Association of Faculties of Medicine of Canada) were entirely lukewarm to the prospect, particularly if it took the form of a government agency.



Research misconduct made headlines when South Korean stem cell researcher Hwang Woo Suk fooled the editors of *Science* into believing he had cloned human embryos and derived 12 stem cell lines. He most likely did clone Snuppy, above.

"There wasn't an appetite for saying: we want Health Canada, or an arm of the federal government, to assert its authority, which it doesn't have, to deal with this," Turk says. "On the other hand, a lot of us felt it was wholly inappropriate to leave all of this to provincial jurisdiction, because then each province is going to have to wrestle with this and that's not a practical or useful approach."

Besides, Turk argues, a regulatory agency wouldn't address the underlying causes of misconduct, like the "productivity driven research culture" that has taken root in universities or the push to generate more external

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sources of revenue. As researchers venture into corporate circles, they're discovering "some private sector funders want to be able to put restrictions on access to data. Others want to put restrictions on right to publish. Some want to impose confidentiality agreements or they don't want negative findings published."

A national agency would also severely narrow the focus on fabrication, falsification, plagiarism and conflict of interest, Turk adds. "Anything beyond that would be outside the scope of its legislative authority. Yet, there is a whole range of things relating to integrity, or that undermine the integrity of scientific work, that can't be addressed in that way."

Those would include such sublime forms of misconduct as ghost writing by pharmaceutical firms and shot-gunning (simultaneously publishing an article in multiple journals to create the illusion that evidence in favour of a proposition is overwhelming).

The delegates believe that Canada should take time to make a comprehensive examination of international models of handling misconduct to determine what degree of regulatory stick, if any, is needed, Turk says. "We're still very much in an embryonic stage."

Health Canada policy analyst Dr. Gordon Lawson says the government has no immediate plans to move with legislation or regulation. "We're just trying to get a better sense of the lay of the land."

Currently, the investigation of misconduct allegations is the domain of universities, even in instances involving federal research grants and an alleged breach of extremely broad integrity guidelines adopted in 2003 by the 3 granting councils (the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council, and the Social Sciences and

Humanities Research Council). Lacking statutory authority to act as a quasijudicial body or regulator, the councils refer all complaints to the university that employs the alleged miscreant for investigation.

CIHR received 54 such complaints between 2000 and 2006. Some 36 were deemed worthy of investigation and 21 found to have violated council guidelines. Three remain under investigation. CIHR spokesman Dave Coulombe says sanctions can range from refusing to consider applications from the researcher to withdrawal of remaining installments of an award. The granting councils are expected to bolster an aspect of their integrity guidelines this spring by signing a Memorandum of Understanding with universities regarding conflict of interest. — Wayne Kondro, **CMAJ**

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