Whistleblower protections for US government scientists flounder

In December, after more than a decade of negotiations and hearings, both houses of the US Congress unanimously passed a bipartisan bill aimed at providing legal safeguards for federal employees who disclose alleged wrongdoing occurring in government. The bill, called the Whistleblower Protection Enhancement Act, seemed poised to be signed into law. But late in the afternoon on the final day of the congressional session, an anonymous Republican senator thwarted the antisecrecy reform by placing a secret 'hold' on the bill, which effectively killed the measure.

Now, with a new Congress in session, the bill—which, for the first time, included specific protections for federal scientists—must be reintroduced for a new round of voting and potential roadblocks. And, until it passes, federal scientists preparing to report abuse, waste or fraud in the government may be better off holding their tongues, experts say.

"Under current whistleblower laws, which are very weak in the way they've been enforced and implemented, [scientists] have no recourse if they're retaliated against for complaining," says Celia Wexler, Washington, DC representative for the Scientific Integrity Program at the Union of Concerned Scientists (UCS), a nonpartisan advocacy organization based in Cambridge, Massachusetts.

When government scientists do blow the whistle, they often face demotion, rescinded security clearance, forced relocation or other sanctions. In 2006, for example, Rosemary Johann-Liang, a former manager in the US Food and Drug Administration's drug safety unit, was verbally reprimanded and excluded from safety meetings after recommending that the diabetes drug Avandia include a warning for congestive heart failure.

As a result, many federal scientists are unwilling to come forward to report instances of wrongdoing. In a recent UCS survey of more than 3,000 scientists polled across nine government agencies, around two in five said they feared retaliation for speaking out about their agency's work.

The failed legislative action sought to allay those concerns by explicitly including anticensorship protections for federal scientists who might face retaliation for openly expressing misgivings about suppression or distortion of government research. Under the proposed bill, whistleblowers would also have a right to trial by jury to challenge disciplinary actions taken against them. "It would go a long way toward ensuring scientists are not intimidated and research is not tampered with," says Angela Canterbury, director of public policy at the Project on Government Oversight (POGO), a Washington, DC–based watchdog group.

But until such measures are passed, scientists are better off not exposing themselves, according to Paul Thacker, a POGO investigator and former congressional staffer who spearheaded Republican Iowa Senator Charles Grassley's probes into the financial ties between industry and government-funded scientists. "The best way to protect yourself is not to say anything," he says. "You don't always need to come out and be on the evening news." Instead of going public themselves, Thacker advises scientists with concerns over misconduct to leak key documents to reporters or members of Congress.

Megan Scudellari

Bill to help Canadian companies ship generics has uncertain future

Backed by nongovernmental organizations and the generics industry, the left-of-center New Democratic Party has championed a bill that set out to improve Canada's Access to Medicines Regime (CAMR), a law that enables drug manufacturers in the country to make generic medications for shipment to developing countries to treat illnesses such as tuberculosis and AIDS. The bill, C-393, was introduced to the House of Commons in 2009 and aimed to eliminate many of the CAMR procedures that its supporters consider unwieldy and extend the list of eligible drugs. But the bill has been so gutted that many global health advocates say they cannot support it in its current state, and it is floundering in Canada's parliament.

Under the existing legislation, generic manufacturers that are unable to negotiate a voluntary license from the patent holders can ask the Canadian Commissioner of Patents for a compulsory license to produce an eligible product to address public health problems in another country. If the commissioner says yes, the law then authorizes a one-time license for a named product, along with the country to which it is to be shipped and order size.

CAMR came into force in 2005, almost two years after the World Trade Organization issued a waiver permitting member countries to issue licenses to companies hoping to manufacture and export cheaper versions of patented drugs and medical devices to countries in need. Over 30 countries have enacted similar laws, including China, India, and those in the EU, but Canada's version is considered to be the most detailed. (There is no compulsory licensing procedure in the US for drug exports to developing countries in need.)

To date, only one company has used the measure: in September 2008, the Toronto-based generics maker Apotex shipped nearly 7 million tablets of a triple-combination HIV drug, Apo-TriAvir, to Rwanda. Another batch of tablets followed about a year later. Notably, there have been no exports under comparable rules by other countries.

Despite the opportunity provided by the CAMR, Bruce Clark, vice president of regulatory and medical affairs at Apotex, is "reluctant to use it again" if the law isn't streamlined. "The legislation as it stands now is unworkable," he says. The current legislation, Clark explains, requires companies to apply for licenses on a country-by-country basis, which can be time consuming and impractical.

At the heart of Bill C-393 was a one-license solution that would eliminate the need to seek separate licenses for each export country and each order. No other countries have such a clause.

The brand-name pharmaceutical industry has been opposed to the bill from the start. "We're concerned that it is not good for safety and diversion," says Russell Williams, president of Canada's Research-Based Pharmaceutical Companies, headquartered in Ottawa. In November, in response to concerns from brand-name drugmakers, the committee studying the bill clipped many of the bill's provisions, including the clause that effectively would have allowed generics manufacturers to use a given license to produce an unlimited amount of medicine for an unlimited number of countries in need.

The House of Commons will vote on the bill this spring, but even if it passes there, it must still clear the Senate, which is controlled by Conservatives who generally oppose it.

Hannah Hoag