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Trust, but verify

Collaborations between researchers and industry are essential to biomedical progress. But relations have to be completely open.

Among the lessons learned from the two-year-long investigation of financial disclosure in US biomedicine by Senator Charles Grassley (Republican, Iowa) (see page 330) is that an honour system is only as good as the clarity of its rules — and the effectiveness of the oversight.

Witness the *de facto* honour system that governs the financial activities of researchers receiving support from the US National Institutes of Health (NIH). Under conflict-of-interest rules in place since 1995, extramural grant applicants must report industry payments of more than US$10,000 per year if those payments would "reasonably appear to be affected by the research" for which NIH funding is sought. The same disclosure rule applies to equity holdings of more than $10,000, or more than 5% ownership in a company. The reports go to the researchers' home institutions, which in turn must report the existence of a conflict to the NIH, and assure the agency that they have managed, reduced or eliminated it.

After much investigation, however, Grassley and his staff have alleged that some academic researchers have taken a relaxed approach to this reporting requirement, and that some institutions have been just as casual in monitoring their researchers. The ensuing bad publicity has threatened to undermine the public's faith in the $24-billion extramural research effort of the NIH.

But the efforts of Grassley's team have had one positive effect: after years of ignoring warnings about sloppy conflict-of-interest enforcement — in a 2001 report by the Association of American Universities in Washington, DC, among others — research institutions are hastening to enforce the NIH rules aggressively. Some have even instituted more stringent rules of their own. Soon, they could have a new enforcement tool: the Physician Payments Sunshine Act of 2009, which Grassley has inserted into health-reform legislation now circulating on Capitol Hill. The act would require drug and device firms to post any payments to a physician in excess of $100 annually on a public website

Given the recent rash of publicity, some researchers fear that the very appearance of their names on such a website would imply wrongdoing, as if they were inherently compromised by any collaboration with industry. That risk is real enough. Any website should thus make it very clear that industry–academic collaboration is a valuable, indeed an essential, driver of biomedical innovation; that the translation of basic research to the clinic depends on it; and that it is encouraged both by US law — specifically, the Bayh–Dole Act of 1980 — and by the NIH.

That said, the ubiquitous interconnections between industry and academia — and the very desirability of a permeable boundary between the two — are probably the most compelling argument for the Sunshine Act. The transparency it would provide is a long overdue corrective to a culture that has too often seemed to look the other way when it comes to potential conflicts of interest. Such transparency would both shore up public trust and prompt researchers to tougher self-scrutiny as they complete their disclosures.

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It's important to note that Grassley's Sunshine Act does not apply to non-physician scientists; he drafted it with medication-prescribing doctors in mind. Yet PhD scientists, too, play a vital part in many industry collaborations. For the sake of fairness and consistency, the act should apply to them as well.

Whether or not the Sunshine Act becomes law, the NIH is moving on a parallel track to tighten its own reporting rules for extramural researchers. A lowering of its $10,000 threshold for reporting is expected before the end of the year, for example. The agency should bear another principle in mind as it finalizes such changes: clarity in what is and is not reportable, with rules spelled out unambiguously. Increased clarity would protect NIH-funded researchers and the public they serve. ■

Taking the NICE path

The United States can learn from the UK body that rates the effectiveness of medical procedures.

In the highly polarized debate over US health-care reform, opponents of increased government involvement in the system frequently caricature Britain's National Health Service (NHS) as the disaster they want to avoid — an impenetrable snarl of red tape that keeps ailing pensioners on years-long waiting lists for even the most essential procedures. And at the heart of their nightmare is the UK National Institute for Health and Clinical Excellence (NICE), portrayed as a bunch of callous government bureaucrats ruling life-saving medications as off-limits to dying patients.

Globally, however, NICE is widely regarded as a world leader in comparative-effectiveness studies: research that aims to show which of the available medical options is most effective at treating any given condition, and which is worth the money — what US reform opponents might call 'health-care rationing'. Faced with an overwhelming yet incomplete medical literature, most medical professionals welcome NICE's best-practice guidelines on everything from early testing for breast cancer to child nutrition.

NICE's politically and emotionally fraught function can arouse intense feelings. In one example last year (see page 336), NICE had to make a Solomonic choice: should the NHS spend an extra £31,000