

Defusing a time bomb

Researchers and their institutions need to dispel a myth about 'independent' research before the media does it for them.

It looks like a done deal: the 2008 version of The Physician Payments Sunshine Act appears set to pass into law with the blessing of many large pharmaceutical and medical device companies, and their industry associations. The Act would require drug and medical device manufacturers to report gifts and payments ("transfers of value") made to medical doctors into a national database that would be publicly accessible online. The Act is comprehensive in the kind of transfers of value it stipulates should be declared and databased. Brown envelopes of cash, checks, gifts, food, entertainment, travel, honoraria, speaking fees and consulting fees would certainly be included, as would anything related to stocks and investments. Other inducements requiring disclosure include participation in industry-sponsored conferences or continuing medical education, funding for clinical trials or funding for other types of research. Only gifts worth less than \$25 are excluded at this point; disclosure is triggered if annual transfers exceed \$500.

The laudable goal of this Act is to make transparent the ties between physicians and biomedical researchers and drug or device manufacturers, ostensibly so that patients can decide for themselves whether a physician's prescribing habits might be influenced by those ties. What the Act and the database it creates will actually do is to expose the naiveté of individual researchers and, indeed, the biomedical community collectively in not revealing the full extent of their involvement with commercial enterprises.

The Senate Bill has been in transit since September 2007 and was revised in May 2008. A comparable bill going through the House of Representative was introduced in March 2008. It now seems highly likely that the legislation will pass, as there's little, if any, opposition to it.

Although industry associations such as The Advanced Medical Technology Association and the Pharmaceutical Research and Manufacturers of America appear comfortable with the Act, academic researchers and their institutions seem completely unprepared. That is already apparent from the high profile cases brought to light by the campaigning Republican senator, Charles Grassley, of Iowa. To do this, Grassley did a simple and really quite elegant experiment. Doctors in universities are supposed to report sources of outside income related to their profession, and the institutions they work in are required to manage any conflicts of interest for recipients of federal money (e.g., US National Institutes of Health (NIH) grants). So Grassley's team looked at the disclosures by prominent clinical researchers and their institutions. And then it compared them with the declarations made by the drug and device companies.

The results of Grassley's experiments make great news headlines. To take just one instance, Grassley examined disclosure related to neurology clinician Karen Wagner at the University of Texas Medical Branch at Galveston, who had undertaken NIH-funded studies on depression involving Prozac (from Eli Lilly) and Paxil (from GlaxoSmithKline, GSK). Lilly reported a payment to Wagner of over \$11,000 in 2002, but Wagner

apparently did not disclose this payment to the university. GSK reported paying Wagner \$160,404 over the 2000–2005 period, but she only reported \$600 from GSK in 2005.

The rights and wrongs of individual cases do not concern us here, but certain realities now need to be faced by everyone. One, the Sunshine database will come into being. Two, it will be searchable and people will search it. Three, few clinicians keep perfect records of their ties to companies. Taken together, those realities create a charter for every national or local newspaper and radio or TV station—and every ambulance-chasing lawyer acting on behalf of a disgruntled patient—to seek to make a story out of a researcher's administrative glitch. And that will sully not only individual reputations but also those of institutions and of the biomedical research community at large.

One response to the Sunshine Act would be to address the administrative burden it creates. University and hospital administrators certainly need to do more to make sure that declarations made by researchers are Sunshine compliant. After all, in recent years, it is the administrators that have been relentlessly pressurizing faculty to go in search of collaborations with the commercial sector. At present, there is no consistency between institutions with respect to the rules of disclosure or their enforcement.

But getting the admin right will not fix the root of the problem. The great unspoken reality is that relationships between companies and researchers are not only becoming the norm, but they are also essential for medicine to progress. Without the exchange of expertise and knowledge between industry and academia, much of medical progress would falter.

This truth remains unspoken because researchers and their institutions like to maintain an aura of lily-white independence from the commercial world. Researchers may feel, and they may be absolutely right, that allowing companies to contribute to payments for trials or research or publications does not threaten their independence of thought or action.

However, that is not how the general public or individual patients see 'independence'. For them, independence implies no financial ties, no associations, not a smidgen of influence from commercial interests. This wholly unrealistic view of angelic independence is an impression that the academic world has fostered, if not actively, then at least through a persistent failure to counter it. And it is this view that the Sunshine Act and its database will blow wide open once and for all.

The way to prevent a public and media backlash is for physicians and researchers (and their institutions) to take immediate and active steps now to explain the interdependence of industrial and academic research. It must be the biomedical community that says "we have to talk to these companies" and "their money really helps push medicine forward." We need to make plain that there can be a win-win-win outcome for doctors, companies and patients alike. That will give patients a better view of the integrated worlds of research and commerce within healthcare and disarm a million trivial investigations based on nothing more than administrative discrepancies.