Capture of Academic Medicine by Big Pharma

By Bruce Patsner, M.D., J.D.

The ongoing saga of the relationship between drug companies and doctors continues with no end in sight to the litany of bad press, reported financial conflicts of interest, allegations of “ghost-writing” of medical articles by pharmaceutical company-employed physicians, and intentional omission of data from critical clinical studies used to support off-label claims for certain therapeutics. Certainly, the topic has received a great deal of attention in the academic medical press over the past five years or more. The history of significant medical literature on the subject easily goes back almost three decades to when Arnold Relman became the first editor of *The New England Journal of Medicine* to use his bully pulpit to write about the dangers of the “medical-industrial complex.” Several medical societies as well as noted health law policy gurus in *The New England Journal of Medicine* and *The Journal of the American Medical Association* have also been critiquing the relationship between academic medicine and big pharmaceutical companies for several years. Ironically, some of the authors of the editorials in these U.S. peer review journals are members of the faculty of the same medical schools as some of the alleged offenders.

The lay press has also zeroed in on this “story of corruption.” Within the past several years at least four books have been published in the U.S. describing the potentially deleterious effects on public health which may result from the deepening financial ties between pharmaceutical companies and academic physicians whose writings often significantly affect the potential market value of new prescription drugs. The problem is not just that some physicians, particularly some in positions of significant academic power at prestigious institutions, have received enormous amounts of money from pharmaceutical companies for giving dozens of talks on behalf of pharmaceutical

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companies promoting those companies’ drug products to other physicians at national medical meetings, hospital department meetings, or specially convened teleconferences all under the umbrella of medical education. Nor is the problem that, at least in some extreme cases, the amounts of money these physicians have received were not properly reported to either the academic institutions they were affiliated with or the Internal Revenue Service, in violation of both medical school academic policy and federal law. The problem now is that there is a serious question about whether such occurrences, and the apparent lax oversight some medical schools and academic medical centers appear to practice, is the result of the medical school’s own conflicts of interest. And it is not just confined to state and private medical schools either; several highly publicized problems with financial conflicts of interest and unapproved transfer of federal intellectual property have also occurred at the National Institutes of Health.

Barriers Between Academic Medicine and Pharmaceutical Companies Continue to Fall

Despite all of the adverse publicity of the past several years, it appears that the barriers between academic medicine and the pharmaceutical industry are continuing to fall despite all of the lip service being paid to institutional ethics rules and talk of new guidelines. Just when you thought things couldn’t get any worse, along comes a story which signifies a new low in the race for the bottom to see which academic medical institution can cement its relationship to a major pharmaceutical company. In a newspaper article published in January in The Wall Street Journal, it was reported that Johnson & Johnson and Vanderbilt University Medical School had agreed to an unusually extensive partnership to develop new drugs to treat schizophrenia.

Unlike the usual agreements between pharmaceutical companies and medical school researchers in which the drug maker typically funds the university’s basic science research in exchange for the first rights to buy any commercially promising drugs which are developed, the reported agreement between Johnson & Johnson and Vanderbilt involves not just discovering potentially valuable new compounds by medical school researchers directly for the pharmaceutical company but also a highly organized, expensive effort at “optimizing” the toxicity profile of the drugs so that they are ready for human testing. Traditionally, this work has been done in-house by the pharmaceutical companies themselves. In exchange for all of this bench and clinical research, Vanderbilt is slated to receive up to $100 million in payments if certain research and clinical

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11 The amount of annual income derived from speaking engagements on behalf of pharmaceutical companies in several cases exceeded $500,000 per annum.
13 A slide shown during a lecture at the semi-annual Gynecologic Oncology Group (GOG) meeting two years ago given to a group of prominent clinical investigators in gynecologic cancer on faculty at major medical schools across the U.S. read “The GOG should partner with industry and do their bidding.”
15 *Id.*
milestones are met.\textsuperscript{16} Dr. Jeffrey Conn, the pharmacology professor who heads Vanderbilt’s drug-discovery program, pledged to publish scientific findings whether the results benefit Johnson & Johnson or not in response to concerns that there is the potential for significant conflicts of interest in the proposed arrangement.\textsuperscript{17}

It remains to be seen whether the promise to publish negative results will actually take place since the precise details of the contractual agreement have not been made public. It is not clear who actually “owns” the data, nor is it obvious that publishing “negative” data is sufficient counterweight to the enormous financial stake the medical school now has in ensuring that newly developed compounds successfully complete clinical trials and ultimately reach consumers. The agreement between Vanderbilt and Johnson & Johnson is also being inked despite that fact that Alastair J.J. Wood, currently Associate Dean at Vanderbilt Medical School, has been one of the strongest critics of current U.S. Food and Drug Administration (FDA) policies on new drug approval, post-marketing surveillance, and academic medical-industry relations.\textsuperscript{18}

\textbf{No Federal Rules, Only Standards and Guidelines}

All of the recent news on financial conflicts of interest in the growing partnering of academic medicine and the pharmaceutical industry raises troublesome questions about the ability of either the medical profession or private industry to self-regulate their conduct. Indirectly, it remains to be seen whether new agreements between academic medicine and big pharmaceutical companies such as those between Vanderbilt and Johnson & Johnson will further interfere with FDA’s ability to fulfill its mission of protecting the U.S. public from unsafe medical products.

Addressing the problems of potential financial conflicts of interest and the well-documented problems of transparency of clinical trial information will not be easy. Although both medical professional societies and NIH have issued statements on industry-academic relations, these proclamations only rise to the level of standards and guidelines. Even if such institutional guidelines are binding on the scientists and clinical investigators they employ, they are only as effective as the enforcement actions undertaken when there are violations. If penalties are mild, standards are lax or are rarely enforced, or the guidelines vary too much from academic medical institution to institution it is doubtful the current situation will change. This raises the question of whether more federal oversight is required, as some have proposed.\textsuperscript{19} The other unanswered question is whether the situation is likely to change given the harsh economic realities of progressively declining federal funding for academic medical research and changes in federal rules years ago which helped create the current situation.

\textsuperscript{16} Id.
\textsuperscript{17} Id.
\textsuperscript{18} Statement by Alistair Wood at U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee, February 16, 2005.
Where Things Might Be Headed

Are things going to change? With a new Democratic administration in Washington, D.C. that promised more regulatory oversight of industry during the Presidential campaign, it might be possible.

The pharmaceutical industry has already anticipated that the playing field will likely change in physician-pharmaceutical relationships and that new stronger federal rules may be on the way. Several large pharmaceutical companies (Eli Lilly and Merck) have already indicated that they will voluntarily begin to disclose payments they make to physicians.\(^{20}\) In 2007, the Physician Payments Sunshine Act\(^ {21}\) (so named because legislation such as this is designed to “let the sun shine in” and reveal otherwise private information) was introduced by Sen. Charles Grassley (R-IA). This proposed law was designed to prevent the violations of federal and university conflict-of-interest rules and to replace the hodge-podge of state laws and voluntary compliance systems at medical schools.\(^ {22}\) Although this bill never became law because it had not been passed before the end of that session of Congress, it is likely that the bill will be introduced again.\(^ {23}\)

Some medical schools have taken more aggressive steps to limit the access pharmaceutical companies have to medical students and physicians in training.\(^ {24}\) They have begun revising physician-in-training educational programs so that the medical schools, not pharmaceutical companies, are the primary sources of post-graduate education of physicians,\(^ {25}\) and have developed on-line public disclosure of academic physician-pharmaceutical industry financial and research relationships.\(^ {26}\) What impact these changes may have is currently unknown.


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\(^{20}\) Benedict Carey, Two Big Drug Makers to Begin Disclosing Payments They Make to Doctors, THE NEW YORK TIMES, September 25, 2008 at A16.

\(^{21}\) S. 2029, 110\(^ {th}\) Congress, “Physician Payments Sunshine Act.” This bill would have amended title XI of the Social Security Act to provide for transparency in the relationship between physicians and manufacturers of drugs, devices or medical supplies for which payment is made under Medicare, Medicaid, or SCHIP.


\(^{25}\) Id.