Medicine Has Its Own "Conflicts Of Interest"

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Although this may at first seem like an editorial piece, I believe that medical professionals and the public need to know the facts as well as opinion about true (as well as perceived) difficulties in our profession.

I am writing this at the end of December, 2008, as the financial system of the United States continues to struggle over its previous greed and lack of regulation. Some of the present and past medical news also makes one believe that "bias and conflict of interest are endemic in the human condition. We are all products of our language, concepts, needs, experience, goals, and aspirations" as stated by Dr. John Kamp. Let's look at just a few recent medical issues that seem to have been dictated by financial decisions, remembering that no one operates in an economic or moral vacuum.

A recent report in the 11/25/08 PLoS Medicine found nearly a quarter of submitted drug trials were never published. The reason, for most, was that they didn't support the product being tested. They also found that conclusions about drug safety and effectiveness in reports submitted to the FDA were at times changed in the medical literature to favor a drug. Development of a drug may require multiple trials. Among drugs for which findings were published in the medical literature, only 52% disclosed results from all trials. "Full disclosure" is required now by federal law, mandating registration of all clinical trials in a publicly accessible database, ClinicalTrials.gov, run by the National Institutes of Health. There are still loopholes, however, like the fact that safety data are not required. (Science News 12/20/08)

Then there's Medicare's prescription drug benefit program – Part D – that was not exactly without drug pricing issues and "doughnut holes". Granted this was more a political issue, but patients don't always distinguish medicine from politics in their own bottom line. During the "conference" of the final bill, Republican lawmakers stripped Medicare of negotiating powers on discounts for drug prices. It was then publicized in a way to hide the fact that you paid $4,270 of the first $5,871 in prescription costs! And as an example of more cost to the consumer, in the first half of 2006, low-income retirees and their insurers paid an extra $325 million to Pfizer because patients lost discounts in switching from Medicaid to Part D. (Medicaid, state insurance programs, and private employers are dumping beneficiaries into Part D.) Then, of course, the drug companies increased their price of the drugs. Doctors also were well aware of the formularies requiring insurers to offer just one drug per therapeutic class. (Smart Money 9/07)

There are also the anti-competitive generic drug deals. The Federal Trade Commission (FTC) published a summary of settlements between drug companies with unexpired patents and manufacturers who wanted to market generic versions of drugs with soon-to-expire drug patents. In fiscal year 2007, 14 of 33 (42%) of the final settlements included both compensation to the generic drug manufacturer and restriction of its ability to market the product. The majority of these settlements involved payment for delaying production and marketing of the generic. These are bad for consumers as they undermine competition and prevent drugs from being more affordable. (Consumer Health Digest 5/20/08)

What about Continuing Medical Education (CME)? Were you aware that commercial sources are responsible for the funding of approximately half of all CME? (Primary Care Abstracts. April, 2008) Paying for this is the pharmaceutical industry and the medical device manufacturers. These can obviously bias our prescribing and cause treatment changes with our patients in subtle and not-so-subtle ways through the use of this education. Is it even possible in these days of economic difficulty to totally divest ourselves of this financial influence? Could it not be phased out over several years? Finances to support CME should be from the health professionals as well as their employers in the academic sphere and group practices. This also ultimately means academic faculty should not serve on speaker's bureaus or as paid spokesmen and women for drug or device manufacturers.

Then there is the issue of "ghostwriting" by industry employees. Sometimes it is nearly impossible to follow the money line back from the finished medical article, for example, to the company producing the product. Yet over and over we hear of more examples where this is happening. An example of ghostwriting was discussed in the New York Times, December 13, 2008, in which Wyeth was traced according to Congressional letters to have paid ghostwriters to produce articles in favor of its hormone replacement drug (Prempro). At least one article was published even after a federal study found the drug raised the risk of breast cancer. The documents show company executives came up with the ideas for medical articles, titled them, drafted outlines, paid writers to draft the articles, sought academic authors and identified publications to produce the articles. This was done without full disclosure of the company's involvements. Another example is that of the drug rofecoxib (Merck) and the ghostwriting that occurred with that product (JAMA April 17, 2008). The World Association of Medical Editors which defines ghost authorship as a substantial contribution not mentioned in an article also states it as "dishonest and unacceptable".

Other troublesome reports concern, "seeding studies" in which marketing is disguised as research (Archives of Internal Medicine 10/7/08). Family medicine doctors were chosen as the target of Merck to compare Vioxx with Naprosyn. The primary goal here was to get the familiar use of the drug into the heads of the primary providers before and during the drug's launch.

Journal Editors bear some responsibility for companies manipulating publications. However, even when full disclosure is required, manipulation and misrepresentation can occur. However, some journals (e.g. JAMA) are requiring data to be analyzed by independent statisticians. The continued dishonesty could not occur without cooperation of researchers, authors, editors, peer reviews and the FDA. This is obviously eroding public trust in what you and I do in medicine on a daily basis.

Do the preceding issues call for the need of a "bail out" for medicine? Money is not needed to create truthfulness in medicine. (Actually, the love of money is also at the root of this evil.) There is a need for monumental change though, and a call for return of trust and responsibility in medicine. As the JAMA article, April 16, 2008, page 1833 states in "Impugning the Integrity of Medical Science", "the cooperation of everyone involved in medical research, medical editing, medical education, and clinical practice is required for meaningful change to occur." They outline eleven proposals that I suggest we all consider. The trust of our patients in our profession depends on it.

Neither Dr. Peterson nor any member of his immediate family have any relevant relationships to disclose with any corporate organizations associated with the manufacture, license, sale, distribution or promotion of a drug or device.

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