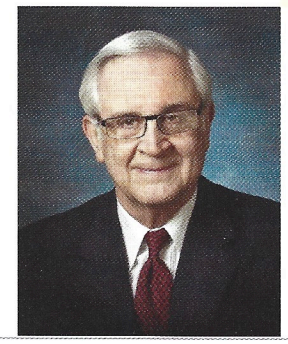
Too Much of a Good Thing?

Lawrence I. Bonchek, M.D., F.A.C.C., F.A.C.S.
Editor in Chief



DISCLOSURE OF CONFLICT OF INTEREST

Until the past decade, little attention was paid to the potential conflicts of interest posed by the gifts, trinkets, luncheons, and travel reimbursements bestowed on physicians by drug companies and medical device manufacturers. Indeed, those payments and gifts were habitual and unremarked, since their purpose seemed mainly to get manufacturer's representatives access to doctors' offices. Physicians of my generation were convinced that, even if they became more receptive to the importunings of some representatives over others, all they were granting was access, and they could not be "bought" by mere ball pens, prescription pads, and dinners. But as medical technology advanced, and new, more expensive devices were marketed to physicians, the stakes were raised. Instead of favors that were rarely grander than dinner at a famous restaurant, or a round of golf at an exclusive club, generous "consulting" fees became increasingly common, and some financial arrangements included such largesse as equity interests in companies, royalty payments, and fees that surpassed six figures annually.

The recent "Patient Protection and Affordable Care Act" has riveted the nation's attention because it promises changes in health care delivery, but it also includes a less prominent provision* that requires disclosure of payments or gifts of value from pharmaceutical and medical device companies to physicians. In this column I will address the implications of this provision only from the standpoint of the medical literature.

Obviously, the most lavish payments are made to physicians who are thought-leaders and early adopters; those most likely to publish or to speak about new and generally expensive drugs and devices. Since "gifts of value" means items with a cumulative value of only $100/year, this requirement should presumably alleviate concern about conflicts of interest. But is that necessarily true?

THE LAW OF UNINTENDED CONSEQUENCES

First, some background. The International Committee of Medical Journal Editors (ICMJE) has adopted a single form[1] for disclosure of conflicts of interest in ICMJE journals (a list that includes most of the journals our readers are likely to peruse). The ICMJE assumes that "the information provided in these disclosures helps the reader to *understand* the relationships between the authors and various commercial entities that may have an interest in the information reported in the published article."[2] It also assumes that the "understanding" either prevents inappropriate payments, or the bias that results therefrom.

I beg to differ.

I contend that the disclosure requirement, at least in regard to publication of articles in medical periodicals, may have a paradoxical effect that demonstrates the law of unintended consequences.

In the earlier era when there was no mandate to acknowledge potential conflicts, the size of "fees" was limited by the fear of embarrassment if large payments were revealed publically. Ironically, though it is now difficult to pick up a free ball pen at a medical convention, stunningly large "consulting" payments are commonplace, and their significance remains difficult for the average physician to discern.

How has this come about? I suggest it is because the mandate to disclose COIs has made such acknowledgments so common and so voluminous that we have become inured to them. The ICMJE form is five pages long. Articles regularly have so many authors that some journals require the lead author to sign an affirmation that each named author played a meaningful role. The result of these trends is often a list of disclosures that seems endless. In the flood of confessions, an individual declaration effectively hides in plain sight. Besides, if the most respected physician-leaders are doing it, surely it must not be wrong. And if everyone is doing it, how are we to find reports about an important new technique or device by a disinterested party? It often

* This section of the bill is a version of a previous stand-alone bill, the Physician Payment Sunshine Act (PPSA), drafted originally in 2007 by Senators Max Baucus (D- Montana) and Charles Grassley (R- Iowa).

seems that everyone writing about some new device is feeding at the manufacturer's trough.

A case in point is the recent report in the *New England Journal of Medicine* about transcatheter aortic-valve implantation for aortic stenosis.[3] With 22 authors, the list of disclosures at the end of the article ran to 240 words (almost as long as the article's abstract) without providing any specific information about the amounts of money involved. Nor was any specific information provided on the NEJM website, where the actual ICMJE forms were displayed, because *no specifics were required.* With such a flood of disclosures, which I have reproduced below,[4] how is one to know whether it is possible for the authors to be unbiased?

How is a physician who deplores such payments to resist the ubiquitous temptation posed by "arrangements" that are ethical and approved, as long as one fills out a disclosure form? Thirty-five years ago a manufacturer's representative with a new pacemaker offered me $1,000 for each one of his new models that I agreed to insert. He represented a major company and I expect that his model was as good as the brand I was then using, but I ushered him out of my office because I considered such arrangements unethical. I imagine most surgeons would have done the same in that era. I believe I would react the same way now, but I cannot *know* because I am not practicing in the current environment when these matters are openly discussed and are *entirely legitimate!*

More on this subject next time, but I am out of space.

IN THIS ISSUE

I am indebted to Dr. Fred Rogers, Medical Director of the LGH Trauma Program, for coordinating the section of articles that explain the exciting developments in trauma care. In addition to his own article that explores the scope of a Trauma Center, Drs. Jennifer Costello and Wichitah Leng explain the crucial role of the clinical pharmacist in the critical care setting; Dr. Daniel Wu describes the training and capabilities of the Acute Care Surgeon; Drs. Eric Bradburn and Heidi Frankel provide an erudite and thorough review of the management of splenic trauma; and Dr. John Lee explains and documents how the *surgically*-directed trauma intensivist model of ICU care at LGH provides important advantages over *medically*-directed trauma ICU care.

Regular readers will recall the comprehensive discussion of the controversy surrounding the role of screening mammography provided in our last issue by Dr. Nitin Tanna, Section Chief of Mammography and Breast Imaging. Since then additional studies have been reported that are grist for the same mill, and we have been fortunate that Dr. Tanna and our regular columnist Dr. Alan Peterson have provided follow-up articles that review the latest studies and clear up the "controversy." It turns out that the matter is much clearer than it seemed in the lay press, and mammography remains a crucial el ement in the early detection of breast cancer. Even if it is difficult to demonstrate a mortality advantage in the 40-50 year age group, evidence is accumulating that annual mammography detects cancers at an earlier stage and smaller size, and the need for mastectomy is significantly reduced for these younger patients.

Finally, in his regular column, Dr. Peterson discusses early closure of small wounds, and—in a Letter to the Editor—Erich Goldstein of the LG College faculty offers the provocative suggestion that fibromyalgia (the subject of my column in the last issue) provides an ideal substrate for studies of the placebo effect.

REFERENCES

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