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Point: Full Disclosure—Presentations and Publications Should Include Dollar Amounts and Duration of Surgeon-Industry Relationships

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Much has been written regarding relationships between practicing physicians, the pharmaceutical industry, and device manufacturers and their interface with the medical and ethical duties we have to our patients. As medical fiduciaries, we are obligated to discharge our responsibilities of trust openly and ethically. It has been suggested that even such trivial items as pens and notepads should be refused, as the acceptance of such items might “endanger patients” through a sense of “reciprocity, the need to give something back to the giver,” and thereby compromise faithful execution of our duties [1].

The primary issue with such concerns is whether such trivial gifts or items of far greater value generate conflicts of interest and thereby might result in compromised decision making and possible harm to patients with resultant erosion of doctor-patient relationships. The Institute of Medicine (IOM) defines conflict of interest as “circumstances that create a risk that professional judgments or actions regarding a primary interest will be unduly influenced by a secondary interest” [2]. Those “secondary interests” noted by the IOM may include items such as professional appointments, academic advancement, lucrative consulting contracts, stock ownership and options, speaker fees, and even the lowly pen and notepad. The issue at play in the present debate deals with effective and appropriate management of these conflicts and attempting to resolve the question of whether true “full disclosure” and complete transparency will be beneficial in the quest for optimal conflict management, and thereby protect us from accusations of intellectual dishonesty and moral compromise.

While it might seem intuitively obvious that “secondary interests” could possibly unduly influence physician behavior and judgments, evidence based on tightly controlled studies is lacking, and even the IOM recognizes that these issues have not and cannot be analyzed by controlled trials [2]. Data are available, but are primarily based upon observational studies [3] and social science analysis [4]. There is solid evidence from social science research that “financial motives distort judgment,” “self-serving bias is unintentional” and “unconscious,” and that it can be “recognizable, but only in others [4].” Based on these observations, many major academic centers (Yale, Harvard, and Stanford, among others) have taken a proactive position in this regard, and prohibit contact between industry representatives and medical

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students and residents in training, but, curiously, have less restrictive guidelines affecting fulltime faculty.

With the preceding as background, it would seem logical and consistent to analyze and review the expectations of and guidance given to those with the highest level of potential conflict of interest, that being those physicians who have contractual/financial relationships (consulting, speaker, or product development), ownership positions (stock or stock options), or potential royalty revenues (based upon intellectual property rights) with device manufacturers or pharmaceutical companies, who also present or publish data pertaining to the efficacy and performance of those companies' drugs or devices. A recent joint position statement from the American Association for Thoracic Surgery (AATS) and The Society of Thoracic Surgeons (STS) specified that "disclosure" is required [5], but the meaning of "disclose" is not defined, bringing to mind a very famous Presidential speculation on "what the meaning of the word 'is' is."

Presently, despite the aforementioned AATS/STS position paper, disclosure continues for the most part to consist of a bland acknowledgment that a "financial relationship" exists, but a more complete disclosure regarding precise dollar amounts involved and the duration of the relationship is absent. Interestingly, the *Journal of Thoracic and Cardiovascular Surgery* editorial staff requires that they be informed as to the dollar amount, but this information is not presented with published papers [6]. It would be informative to learn the extent to which the editorial staff reflects on this information and why they have chosen not to fully disclose it with publication. Can disclosure absent these critical details truly be considered "full disclosure?" Certainly not.

It is important to acknowledge the advancements and benefits our profession and thereby our patients have derived from medical professionals working with device manufacturers on innovative and revolutionary products and with pharmaceutical companies to create life-enhancing drugs. Clearly, many such devices and medications have developed only because of such collaboration, and, unquestionably, full compensation for physicians involved in this manner should not be prohibited or be considered undesirable. Conflict does not arise solely from the work and compensation related to product or drug invention or development, but rather from the advocacy and analysis of the performance or outcomes related to the specific device or drug. There should be no issue with physicians deriving income based upon their unique expertise, but we should have the intellectual honesty to recognize the need for full transparency regarding the extent of the relationships when expounding on the efficacy or preferability of a device, product, or drug. The observer (at a professional meeting) or reader (of a medical journal) should have full access to the extent of possible relationships of the presenter/developer with industry to allow integration of these data into his own analysis of the expert's presentation. This degree of disclosure should also most certainly apply to discussants of presentations at scientific meetings where comments are often sharp, critical, and opinionated, and might unwittingly be influenced by "secondary interests" as defined by the IOM [2].

Without full and absolute transparency regarding these potential conflicts, we are in danger of losing the trust that the public has in our profession. The key point is to proactively

preserve our professional integrity and reputations rather than attempt to retroactively restore our stature after it has been compromised by embarrassing exposure of financial conflicts. The IOM reflects on the extent of needed information in disclosure: "The disclosure of financial relationships can be effective only if it provides sufficient information for others to use in assessing a relationship and judge the severity of the conflict." Others have echoed this basic tenet: "To better ensure independence, scientific integrity, and full transparency, consulting agreements and unconditional grants should be posted on a publicly available Internet site [7]." Sniderman and Furberg [8] more recently stated: "Currently, simple declaration of all relationships with industry is considered sufficient, although to be meaningful, disclosure must be complete. Present and recent past direct monetary relationships must be divulged in detail, along with any independent investment or contractual relationship conferring potential future financial benefit...once the sum of the benefits is large enough, no matter how it is partitioned, the presumption that physicians are unaffected is not credible." The larger the financial relationship, the greater the potential for conflict and biased analysis, and, hence, the greater need for full disclosure – namely, dollars and duration.

Unfortunately, the lay press has picked up on this issue, and one can cite many egregious examples of unethical behavior seemingly stemming from the vast sums involved. A recent example from the *Wall Street Journal* noted that "Medtronic paid the surgeon accused of falsifying study nearly \$800,000 [9]" In this case, a tenured professor of orthopedics at a prestigious Midwestern University was forced to resign his appointment after being accused of falsifying data regarding the efficacy of a Medtronic bone growth drug and having failed to acknowledge the extent of his consulting fees to the University and to the publishing journal (*Journal of Bone and Joint Surgery*) [10]. If this journal had known upon submission of the article the extent of potential financial conflict, the editors might have vetted the data differently or more thoroughly before publication and thereby avoided this professionally humiliating and destructive circumstance.

I have already acknowledged that data utilized to support my opinions have not been derived from randomized, controlled trials, but to dismiss them solely upon this criterion seems irrational. Furthermore, how could one ever construct such a trial? It is rational that we attempt to manage conflicts of interest internally, and certainly if we do not, the Federal government will become even more intrusive than it is presently. In fact, if one argues that our current standards are acceptable, and no changes are necessary or appropriate, consider the following two points.

First, the Physician Payment Sunshine Act was signed into law as a significant component of the Patient Protection and Affordable Care Act of 2010 (PPACA). Under the provisions of this law, device manufacturers, drug makers, and others will be required to track any payments or gifts of \$10 or more made to physicians or academic medical centers, and the federal government will store, collate, and disseminate this information to the public through an electronic database beginning in 2013. Interestingly, this act signed March 23, 2010, does require full financial disclosure, but puts no limits on financial relationships. Since this information will be available to all members of our profession and our patients alike, we should be proactive and position ourselves out in front of the issue as opposed to dealing

with the fallout and potential bad publicity after this information is publicly released. Furthermore, as there are no limits on compensation or ownership positions, the argument that disclosure would stifle innovation seems hollow.

Second, inevitably our patients will demand more information as they become increasingly aware of and more sophisticated regarding the extent of physician/industry relationships. Guy Chisolm, PhD, Vice Chair of the Lerner Research Institute at the Cleveland Clinic, recently related that polling of 2,300 Clinic patients dealing with this specific topic generated a response rate of greater than 50%. Most respondents suggested that more information with greater specificity regarding the details of the relationships was desirable and important to them (personal communication). Other studies have likewise pointed out that most patients being enrolled in clinical trials want to know relevant financial relationships pertaining to the investigators. The authors do acknowledge that many obstacles to achieving effective disclosure exist, yet also note that trial enrollment is not necessarily adversely affected by these efforts [11].

If the government is going to mandate it and our patients already want it, what is the legitimate argument against transparency and precise details regarding financial relationships? The first would seem to be that it is personally intrusive and is an unnecessary invasion of privacy. Those who express discomfort with the prospect of full reporting (dollars and duration) seem to validate the feeling that a problem does exist. The numbers of relationships acknowledged by specific persons before presentations can be staggering and brings to mind the appearance of a logo-laden NASCAR vehicle or the jersey of a professional cyclist. To use a baseball analogy, a person can be a highly paid and critically important player for a major league team, win games for the manager, and drive millions of dollars of revenue to the owner's bottom line, yet it would be completely inappropriate and inconceivable that this same star would be permitted to call the game's balls and strikes or do broadcast analysis from the dugout and comment on the team's performance and future championship potential.

The second argument against full disclosure relates to the costs and difficulties involved with collating and reporting the data. Obviously, consulting and speaker's fees that result in the issuance of 1099 forms will not be problematic as these are submitted to the recipient and to the Internal Revenue Service by the involved corporation on an annual basis. Equity and royalty positions might be somewhat more difficult, but certainly should not create insurmountable challenges. Pricing "intellectual property" seems a somewhat more daunting task, but again guidelines can be established, and clearly this particular concern is not the most significant aspect of the issue. In future reporting, uniform templates for disclosure are needed to guard against a lack of conformity and consistency, and these should be designed without delay by our Societies. When government-mandated disclosure arrives, having an active and effective program in place to report data should obviate any embarrassing discrepancies between reports issued by individual physicians and those submitted publicly by corporations.

The issue of full transparency and full disclosure of potential conflicts of interest comes down to managing fiduciary obligations and preserving our trust with our patients. We must

also acknowledge that full disclosure does not mitigate the potential for bias. It does, however, provide program committees, editorial staffs, and the listening and reading medical professionals important information that can be used in their analysis of data and positions presented and advocated. Conflicts do and will exist, and it is important that we manage them properly, for if we do not, they will undermine the reputation and stature of our profession, and erode the bond between ourselves and our patients. We would not allow a physician fully employed by industry to make a scientific presentation or publish an article for a peer-reviewed journal related to his or her company's device or drug, yet we know from previously released orthopedic surgeon related data that many physician lecturers and writers are receiving yearly "consulting fees" and "royalty arrangements" that greatly exceed what is paid to physicians employed by device manufacturers—many above \$1 million/year [12–14]. If publicly reporting these numbers places some in an uncomfortable position, so be it. This information is critical in the analysis of the clarity, sanctity, and scientific integrity of information and data presented. Collaboration has been valuable, but full transparency is critical to open, unbiased scientific dialogue and exchange.

There has been push back to the above positions, however, and recently a newly organized professional organization—the Association of Clinical Researchers and Educators (ACRE)—suggested that "the push to police financial relationships has gone too far" and will "impede physician-industry collaboration [15]." Thomas Stossel, MD, a Harvard professor of medicine, stated that critics of current conditions "aim to bring about a conflict-of-interest police state [15]." Transparency and full disclosure might be challenging and discomfoting, but it certainly is not draconian and is not in any way a prohibition to collaboration and the future development of relationships between physicians and industry.

The ideas and suggestions advocated herein are by no means new or unique. Jerome Kassirer, MD, has articulated these views for years, and most explicitly in his book "On the Take" [16]. Among his observations are these: Most physicians who are close to industry swear that they are not and could not be influenced by a financial conflict of interest, yet this posture ignores what we know about human nature and the powerful influence of money. Dr Kassirer further opines on the issue of disclosure: although disclosure is not a particularly high standard, and has flaws, it is better than no disclosure at all. Addressing the "precise meaning of disclosure," he states that there should be a requirement for full, detailed disclosure in legible handouts at all teaching events of the type (drug or devices), dollar amounts, and duration of the lecturer that relate to the subject at hand.

Although these statements are based on his opinion and observational studies rather than on randomized studies, they are precise in their intent and are reflective of an increasingly recognized and accepted ethical position. The possibility of any randomized trials resolving the debate seems remote and impractical.

We should leave the parsing of the "precise meaning of disclosure" to the professionals with legal degrees. We should "fully disclose" because not only is it right and honorable, but also it is inescapable as our government has legislated it and our patients will soon have access to it. We need to clearly stake out our position and plan of action before the public reporting coming in 2013. This is a "no brainer," and the time for action is now.

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References

1. Iserson KV, Cerfolio RJ, Sade RM. Politely refuse the pen and note pad: gifts from industry to physician harm patients. *Ann Thorac Surg.* 2007; 84:1077–84. [PubMed: 17888951]
2. IOM (Institute of Medicine). Conflict of interest in medical research, education, and practice. Washington, DC: National Academies Press; 2009.
3. Wazana A. Physicians and the pharmaceutical industry: is a gift ever just a gift? *JAMA.* 2000; 283:373–80. [PubMed: 10647801]
4. Dana J, Loewenstein G. A social science perspective on gifts to physician from industry. *JAMA.* 2003; 290:252–5. [PubMed: 12851281]
5. Mack MJ, Sade RM, American Association for Thoracic Surgery Ethics Committee and The Society of Thoracic Surgeons Standards and Ethics Committee. Relations between cardiothoracic surgeons and industry. *Ann Thorac Surg.* 2009; 87:1334–6. [PubMed: 19379860]
6. Journal Thoracic and Cardiovascular Surgery disclosure statement. Available at: <http://www.editorialmanager.com/jtcvs/>. Accessed December 30, 2010
7. Brennan TA, Rothman DJ, Blank L, et al. Health industry practices that create conflicts of interest. A policy proposal for academic medical centers. *JAMA.* 2006; 295:429–33. [PubMed: 16434633]
8. Sniderman AD, Furberg CD. Why guideline-making requires reform. *JAMA.* 2009; 301:429–31. [PubMed: 19176446]
9. Armstrong, D.; Burton, TM. Medtronic paid the surgeon accused of falsifying study nearly \$800,000. *Wall Street Journal.* Jun 18. 2009 Available at: <http://online.wsj.com/article/SB124527830694724953.html>. Accessed December 30, 2010
10. Kumar, K. Surgeon accused of lying quits Washington University. *St Louis Post-Dispatch.* Aug 10. 2009 Available at: <http://www.allbusiness.com/education-training/education-administration-university/12701347-1.html>. Accessed December 30, 2010
11. Weinfurt KP, Hall MA, King NM, Friedman JY, Schulman KA, Sugarman J. Disclosure of financial relationships to participants in clinical research. *N Engl J Med.* 2009; 361:916–21. [PubMed: 19710491]
12. Feder, BJ. New focus of inquiry into bribes: doctors. *New York Times.* Mar 22. 2008 Available at: <http://www.nytimes.com/2008/03/22/business/22device.html>. Accessed December 30, 2010
13. Burns G. Partnerships between surgeons, implant makers raise ethical concerns. *Chicago Tribune.* Oct 26.2008
14. Carryerou, J.; McGinty, T. Top spine surgeons reap royalties, Medicare bounty; *Wall Street Journal.* Dec 20. 2010 p. A1 Available at: <http://online.wsj.com/article/SB10001424-052748703395204576024023361023138.html>. Accessed December 30, 2010
15. O'Reilly KB. Industry gift bans slammed for overreaching. *Am Med News.* 2009; 52:19. Available at: <http://www.ama-assn.org/amednews/2009/08/10/prl20810.htm>. Accessed December 30, 2010.
16. Kassirer, JP. On the take: how medicine's complicity with big business can endanger your health. New York: Oxford University Press; 2005.