

Doctor & Pharmaceutical/Medical Device Industry Relationships

Introduction

Doctors appreciate the contribution that the pharmaceutical and medical device industries make to the practice of medicine. Without the discoveries made by industry, many of the medical advances and products of recent decades would never have been possible. However, there must be appropriate boundaries between practicing doctors and industry. Industry viability understandably requires fiscal integrity and a margin of profit. Doctors' primary motive should be to promote the welfare of their patients.^{1,2} The resultant conflict of interest requires that a doctor deliberately evaluate the ethics of receiving gifts from industry. There are many published standards for appropriate relationships between industry and doctors.³ Many academic medical institutions⁴ and the US Government⁵ have adopted policies on these issues. CMDA, in an effort to give guidance to its members, addresses the question, "What is the appropriate responsibility of a doctor when offered incentives from industry?"

The Current Situation

The choice of what pharmaceutical or medical device to use is largely made by the doctor though this choice is often influenced by institutional or insurance company constraints and incentives. Therapeutic choices must be individualized with due consideration of the best scientific evidence available and costs involved. Industries seek to promote the use of their product to the doctor by providing, among other things, free educational opportunities, gifts, and services. Studies demonstrate that incentives from industry influence recipients more than doctors realize.⁶

Biblical Foundation

A Christian's response must consider several Biblical principles:

- The two great commandments are to love God and neighbor.⁷
 - Jesus warns of the danger of being motivated by a love of money or other things of this world.⁸
 - Jesus directs that our motives be pure and undivided.⁹
 - Christians must "guard their hearts"¹⁰ against undue influence.
- The behavior of a Christian must be "above reproach."¹¹
 - Christians should avoid any form of inappropriate behavior.¹²
 - A reputation for doing what is right is of value.¹³
- Solomon warned that receiving gifts could place people under the influence of others.¹⁴ Even with our best intentions, we may be inappropriately biased toward those who give us gifts.¹⁵

Ethical Principle

Doctors should consider carefully the basis of their therapeutic decisions to assure that they are made in accordance with best possible evidence applied to the welfare of the patient. Personal gain must never be the compelling reason for our decisions. Incentives from industry, intended to influence therapeutic choices, can compromise doctor integrity and behavior.

Recommendations:

Categories of receiving gifts from industry:

1. Unethical practices:
 - a. Contracts that obligate the doctor to prescribe a particular pharmaceutical for reasons of personal gain.
 - b. Failure to disclose the degree to which the industry or institution controls the content of presentations, recommendations, or product placements.
 - c. Failure to disclose to the patient any financial relationships with the industry or institution.
 - d. Selling materials that were gifts, including samples.
 - e. Receiving greater compensation from a company than would be fair and reasonable for services rendered.
2. Practices requiring extreme caution:
 - a. Receiving incentives from industry or institutions to build rapport or promote exposure to their products, e.g., free meals (including staff), entertainment, etc.
 - b. Personal use of product samples.
3. Practices requiring caution:
 - a. Accepting product samples: Product samples are distributed to doctors as a large part of the industry's advertising budget. These are intended to bring attention to the products and allow the doctor some experience in using them. They should be received by the doctor with "no strings attached."
 - i. Appropriate uses include distribution to indigent patients^{16,17} and as a means to introduce a patient to a new product to assess efficacy and side effects before requiring their purchase. Product samples may also be used for dose titration.
 - ii. Inappropriate uses: Product samples must never be given in a way that doctors promote themselves as benefactors.
 - b. Accepting information from Industry. A discerning doctor is wise to look for independent sources of information.¹⁸ One must exercise caution in allowing the following sources to become the basis for therapeutic decisions:
 - i. Sales promotional literature. This material is biased to promote the product. In the United States these materials are regulated by the FDA but are not always in compliance.¹⁹
 - ii. Industry sponsored studies. When using studies that are financed and published by the manufacturer, the doctor must keep in mind that though the work may be done with integrity, the conclusions may be subject to bias. Negative studies may not be readily available and only favorable outcomes emphasized.
4. Generally ethical practices:
 - a. Attending or sponsoring educational activities that have received support from industry where it is clearly stated that industry has no control over the content and any conflict of interest on the part of the faculty is clearly revealed.
 - b. Receiving reprints from peer reviewed journals.
 - c. Requesting industry contribution to charitable efforts.

5. Situations in which it is difficult to refuse gifts from industry.
 - a. Training on certain medical devices provided only by the manufacturer. This is often provided in a setting that involves travel, lodging, meals, etc. as a part of the educational experience. In this context, there may be limited options and the recipient must discern the appropriate response.
 - b. Industry employees may leave incentives for a doctor without giving an opportunity to decline. In this situation, it is imperative that the doctor not allow these incentives to affect their practice.

Conclusion

Christian doctors must be wary of any inappropriate influence industry has over their prescribing behaviors and assure that their practices are guided by what is best for their patients and in accord with biblical principles.

*Approved by the House of Representatives
Passed Unanimously
April 29, 2010. Ridgecrest, North Carolina*

¹ The Hippocratic Oath states, "I will prescribe regimens for the good of my patients according to my ability and my judgment and never do harm to anyone....I will preserve the purity of my life and my arts. In every house where I come I will enter only for the good of my patients."

² Susan L. Cohen PhD writing for the Ethics and Human Rights Committee, American College of Doctors—American Society of Internal Medicine. "Doctors and industry have a shared interest in advancing medical knowledge. Nonetheless, the primary ethic of the doctor is to promote the patient's best interests, while the primary ethic of industry is to promote profitability."

³ The No Free Lunch Web site offers the following examples: American College of Doctors-American Society of Internal Medicine. Position Paper: Doctor-Industry Relations. Part 1: Individual Doctors. Ann Intern Med. 2002;136:396-402. American College of Doctors-American Society of Internal Medicine. Position Paper: Doctor-Industry Relations. Part 2: Organizational Issues. Ann Intern Med. 2002;136:403-406. Canadian Medical Association Policy Summary: Doctors and the pharmaceutical industry. CMAJ, Feb 1, 1992. Council on Ethical and Judicial Affairs, American Medical Association. Gifts to doctors from industry. JAMA, 1991; 261: 501. Council on Ethical and Judicial Affairs, American Medical Association. Guidelines on gifts to doctors from industry: an update. Food and Drug Law Journal, 1992; 47:445-458. Royal College of Doctors: The Relationship between doctors and the pharmaceutical industry. Journal of the Royal College of Doctors of London, 1986. 20(4):235-42.

⁴ An excellent example is that published by the Yale University School of Medicine, Coleman et al, Academic Medicine Vol 81, No 2, Feb 2006 pg 154 as found at <http://www.uthscsa.edu/research/Guidelines%20for%20Clinical%20Faculty%20Pharmaceutical%20Interactions.pdf> Feb 27, 2007.

⁵ <http://oig.hhs.gov/authorities/docs/050503FRCPGPharmac.pdf>

⁶ The internet site "No Free Lunch" (<http://nofreelunch.org/requiredinfluence.htm> February 17, 2007) has done an excellent job in documenting this phenomenon. They reference the following articles: Adair RF, Holmgren LR. Do pharmaceutical samples influence resident prescribing behavior? A randomized trial. Am J Med. 2005 Aug;118(8):881-4.

Avorn J, Chen M, Hartley R. Scientific versus commercial sources of influence on the prescribing behavior of doctors. Am J Med. 1982;73:4-8.

Caudill, TS, Johnson, MS, Rich EC, McKinney, WP. Doctors, pharmaceutical sales representatives, and the cost of prescribing. Arch of Fam Med. 1996;5:201-206. Chew, LD, et al. A Doctor Survey of the Effect of Pharmaceutical Sample Availability on Doctors' Behavior. J Gen Int Med. 2000;15: 478-483.

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Orlowski JP and Wateska L. The effects of pharmaceutical firm enticements on doctor prescribing patterns. Chest. 1992; 102:270-273.

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Wazana A. Doctors and the Pharmaceutical Industry: Is a gift ever just a gift? JAMA. 2000;283:373-80.

⁷ Mark 12:30-31 (ESV) And you shall love the Lord your God with all your heart and with all your soul and with all your mind and with all your strength.' [31] The second is this: 'You shall love your neighbor as yourself.' There is no other commandment greater than these."

⁸ Matthew 6: 24b (NIV) You cannot serve both God and money.

1 John 2:15 (ESV) Do not love the world or the things in the world. If anyone loves the world, the love of the Father is not in him.

1 Tim. 6:10 (ESV) For the love of money is a root of all kinds of evils. It is through this craving that some have wandered away from the faith and pierced themselves with many pangs.

Hebrews 13:5 (ESV) Keep your life free from love of money, and be content with what you have, for he has said, "I will never leave you nor forsake you."

⁹ Matthew 5:8 (ESV) "Blessed are the pure in heart, for they shall see God.

Luke 16:13 (ESV) No servant can serve two masters, for either he will hate the one and love the other, or he will be devoted to the one and despise the other. You cannot serve God and money."

¹⁰ Proverbs 4:23 (ESV) Keep your heart with all vigilance, for from it flow the springs of life.

Proverbs 4:23 (NIV) Above all else, guard your heart, for it is the wellspring of life.

¹¹ 1 Tim. 5:7 (ESV) Command these things as well, so that they may be without reproach.

¹² 1 Thes. 5:22 (ESV) "Abstain from every form of evil." and note that he goes on in vs 23 to say, "Now may the God of peace himself sanctify you completely, and may your whole spirit and soul and body be kept blameless at the coming of our Lord Jesus Christ."

Ephes. 1:4 (ESV) even as he chose us in him before the foundation of the world, that we should be holy and blameless before him. In love

Hebrews 12:14 (ESV) Strive for peace with everyone, and for the holiness without which no one will see the Lord.

2 Cor. 7:1 (ESV) Since we have these promises, beloved, let us cleanse ourselves from every defilement of body and spirit, bringing holiness to completion in the fear of God.

¹³ Proverbs 22:1 (ESV) A good name is to be chosen rather than great riches, and favor is better than silver or gold.

¹⁴ Proverbs 18:16 (ESV) A man's gift makes room for him

¹⁵ Proverbs 19:6 (NASB) Many will entreat the favor of a generous man, And every man is a friend to him who gives gifts.

¹⁶ Medication samples tend to be new products that do not come as generics and are therefore high priced. The danger of using samples to help the indigent is that it allows them to be comfortable with the higher priced medications and then when samples are no longer available they end up purchasing the more expensive brands.

¹⁷ Most pharmaceutical houses have assistance programs. These, not samples, are their primary effort to provide no/low cost medications for the indigent.

¹⁸ The web site No Free Lunch gives the following references to sources of pharmaceutical information not controlled by the pharmaceutical industry. Therapeutics Letter (Canada) <http://www.ti.ubc.ca/>

Established in 1994 by the Department of Pharmacology and Therapeutics at the University of British Columbia "to provide doctors and pharmacists with up to date, evidence-based, practical information on rational drug therapy." Member of the International Society of Drug Bulletins, and free. Drug and Therapeutics Bulletin (UK) <http://www.dtb.org.uk> A monthly publication giving independent evaluations of, and practical advice on, individual treatments and the management of disease. Medical Letter <http://www.medletter.com> Since 1958 has published critical appraisals of new drugs, prescribing recommendations based on expert consensus. It reviews virtually all new drugs. By subscription. Prescriber's Letter <http://www.prescribersletter.com>

¹⁹The following references taken from the "No Free Lunch" web site document some of these issues.

Cooper RJ, et al. The quantity and quality of scientific graphs in pharmaceutical advertisements. *J Gen Intern Med.* 2003 Apr;18(4):294-7. Shaughnessy AF, Slawson DC, Bennett JH. Separating the wheat from the chaff: identifying fallacies in pharmaceutical promotion. *J of Gen Int Med.* 1994; 10:563-8. Stryer, D and Bero, LA. Characteristics of materials distributed by drug companies. An evaluation of appropriateness. *J Gen Int Med.* 1996;11:575-583. Villanueva P, et al. Accuracy of pharmaceutical advertisements in medical journals. *Lancet* 2003; 361: 27-32. Wilkes MS, Doblin BH, Shapiro MF. Pharmaceutical advertisements in leading medical journals: experts' assessments. *Ann Intern Med* 1992;116:912-9. Ziegler MG, Lew P, Singer BC. The accuracy of drug information from pharmaceutical sales representatives. *JAMA.* 1995;273:1296-1298. Comments in *JAMA.* 1995;274:1267-1268.

