Testimony on disclosing pharmaceutical samples

Richard G. Pinckney, MD, MPH
Office of Primary Care
University of Vermont College of Medicine

On October 27th 2009, Dr. Pinckney provided oral testimonial. This document represents an expanded version of this testimonial with references.

Professional background:

The team at the Office of Primary Care has a wealth of expertise in the relationship between the pharmaceutical industry and clinical practice in Vermont. Their accomplishments include the development of the Vermont Academic Detailing Program, which serves to provide unbiased condition-specific information to primary care practitioners with the goal of supporting cost effective, evidence-based prescribing. They have also received an award from Attorney General Consumer and Prescriber Grant Program. With this award they developed educational programs to inform prescribers about the impact of marketing on clinical practice and study the impact of samples, marketing, and educational programs on prescribing.

Scope of the samples problem:

The pharmaceutical industry invests heavily to provide sample medications to prescribers. The retail value of medication samples distributed in the United States exceeded $18 billion in 2005, an amount that has tripled in 10 years.[1] These free medications reach many prescribers and patients. In 2003, 12% of all Americans received a sample medication,[2] and in 2004, nearly half of all Medicare beneficiaries asked for or received samples.[3] Furthermore, 92% of physicians stated that they had received samples from pharmaceutical representatives at least once in their career, according to a national representative survey.[4]

Research suggests that samples result in the increased prescribing of brand name medications when more evidence-based, less costly generic or over-the counter alternatives exist. A survey study, using vignettes to simulate prescribing decisions, found that use of samples led physicians to dispense and write subsequent prescriptions for medications that differed from their preferred agents.[5] This finding has been confirmed in observational research.[6] Furthermore, observational studies have shown that physicians who provide samples to their patients are less likely to recommend over-the-counter medications,[7] prescribe preferred medications,[8,9] and they were more likely to prescribe advertised medications.[7]

Vermont prescriber attitudes about samples:

As part of our educational programs, we talk to prescribers about marketing and the topic of samples has frequently come up. Samples appear to have several benefits in medical practice: they allow patients to try medication and assess efficacy and side effects before committing to a full prescription, and they help patient who can't afford medication to receive this medication for free. For about 4 years Richard Pinckney practiced medicine in walk-in care settings and in this setting, providing samples to patients was a life-saving intervention. As we informally surveyed prescribers throughout the state, the experience was similar: the major drive to accept samples in clinics is to provide free medications to impoverished patients.

We formally surveyed attitudes about samples in our survey of Vermont prescribers (see figure). We had 206 prescribers out of the total population of 631 primary care prescribers return the survey that met the eligibility criteria. The majority of prescribers agreed that samples do alter treatment plans and the majority of those with samples in their clinics believe they help patients that can't afford their medications. As was suspected from our experience, the helpfulness of samples to determine the efficacy of a medication was not as strong of a belief.

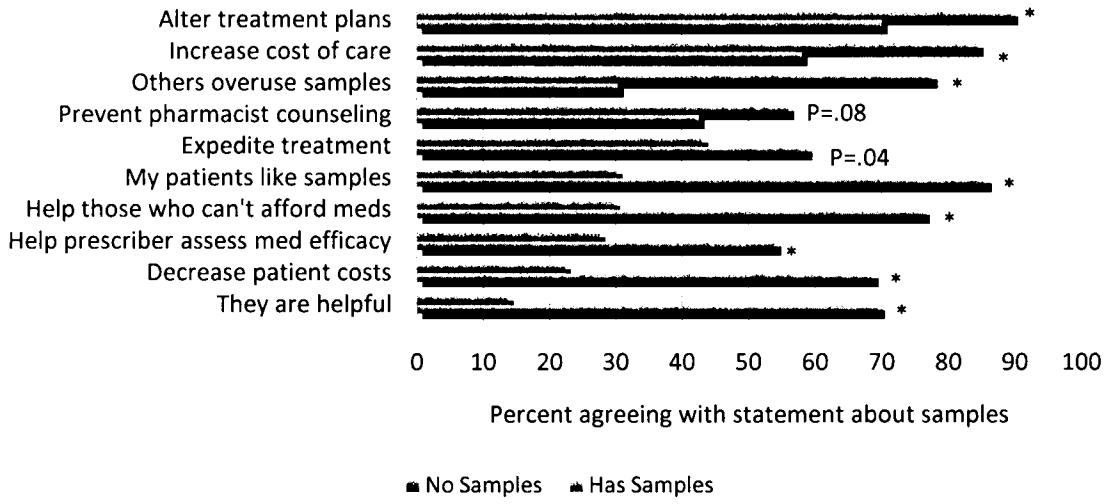

Figure: Comparison of attitudes about sample use in prescribers who do and don't have samples in their clinics. * = P<.01

Therefore the use of samples is a complex and mixed phenomenon. It appears to be an important resource for some patients who cannot afford their medication, but it influences subsequent prescription writing. Research has shown that samples influence prescription writing on patients who can afford medications

a number of ways. First, patients with insurance/money are actually more likely to receive samples than poor patients[2] and once a patient is given a sample, they are likely to receive a prescription for the same medication.[5] Second, our unpublished research has shown that prescribing strategies are shifted even for patients who are not given samples, so that it increases the cost of care and leads to deviation from evidence-based practice.

Disclosure and other interventions to address the problem:

The current disclosure plan would be a required report by pharmaceutical industry of the quantity and type of medications provided to offices. This information would be useful for tracking the amount of samples and for planning and possibly evaluating interventions. However, it alone would not likely lead to significant improvements. It fails to measure how samples are being used, and also fails to measure how other prescription writing is being influenced. Also samples are usually seen as socially/ethically acceptable by both prescibers and patients,[10] so there is likely to be little embarrassment in the disclosures, that would likely lead to behavior change. As our prior research has shown, the real potential detriment to medical practice is not directly related to the samples themselves, but how subsequent prescription writing is affected.

If the state is interested in reducing the detrimental affects of samples on medical practice, it could consider not only a sample disclosure statute, but some of the other interventions that have been previously described. These include removing samples from clinics,[7,9,11] stocking generic samples,[12-15] use of generic vouchers, [16] and sample formularies.[17] Ultimately the best strategy will be to maintain a safety net for our economically at risk patients while encouraging evidence-based, cost effective care for all.

References

1. Donohue JM, Cevasco M, Rosenthal MB. A decade of direct-to-consumer advertising of prescription drugs. N Engl J Med 2007;357:673-81.

2. Cutrona SL, Woolhandler S, Lasser KE, et al. Characteristics of recipients of free prescription drug samples: a nationally representative analysis. Am J Public Health 2008;98:284-289.

3. Tija J, Briesacher BA, Soumerai SB, et al. Medicare beneficiaries and free prescription drug samples: a national survey. J Gen Intern Med 23:709–14.

4. Henry J. Kaiser Family Foundation. National Survey of Physicians, part II: Doctors and prescription drugs. 2002. Available from

http://www.kff.org/rxdrugs/loader.cfm?url=/commonspot/security/getfile.cfm&pageID=13965.

5. Chew LD, O'Young TS, Hazlet TK et al. A physicians survey of the effect of drug sample availability on physicians' behavior. J Gen Intern Med 2000;15:478-483.

6. Symm B, Averitt M Forjuob SN, Preece. Effects of using free sample medications on the prescribing practices of family physicians. J Am Board Fam Med 2006;19:443-9.

7. Adair RF, Holmgren. Do drug samples influence resident prescribing behavior? A randomized trial. American Journal of Medicine. 2005;118:881-884.

8. Miller DP, Mansfield RJ, Woods JB et al. The impact of drug samples on prescribing to the uninsured. Southern Medical Journal. 2008; 101:888-893.

9. Boltri JM, Gordon ER, Vogel RL. Effect of antihypertensive samples on physician prescribing patterns. Fam Med 2002;34:729-31.

10. Gibbons RV, Landry FJ, Blouch DL, et al. A comparison of physicians' and patients' attitudes toward pharmaceutical industry gifts. J Gen Intern Med. 1998;13:151-154.

11. Brewer D. The effect of drug sampling policies on resident prescribing. Fam Med 1998;30:482-6.

12. Scott AB, Culley EC, O'Donnell J. Effects of a physician office generic drug sampling system on generic dispensing ratios and drug costs in a large managed care organization. *J Manag Care Pharm.* 2007; 13(5):412-19.

13. Conklin, MH, Culley EJ, O'Donell J. Case study of the effects of office-based generic drug sampling on antibiotic drug costs and first-line antibiotic prescribing ratios. J Manag Care Pharm. 2009;15:55-61.

14. Mukamal KJ, Markson LJ, Flier SR, Calabrese. Restocking the sample closet: Results of a trial to alter medication prescribing. J Am Board Fam Pract 2002;15:285-9.

15. Rationale and design of the study assessing the effect of cardiovascular medications provided as low-cost, evidence-based generic samples (Samples) trial. Shrank WH, Choudhry NK, Solomon DH et al. American Heart Journal. 157:613-619.

16. Vermont General Assembly. Act 80: Chapter 91, (2008) Montpelier, Vermont

17. STFM Group on Pharmaceutical Industry in Family Medicine. Guidelines for residency program relationships with pharmaceutical and other proprietary companies. Kansas, Mo: Society of Teachers of Family Medicine; 1994.