

## ETHICS FEATURE

# Breaking Up is Hard to Do: Lessons Learned from a Pharma-Free Practice Transformation

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**Background:** Academic medical centers are examining relationships with the pharmaceutical industry and making changes to limit interactions. Most doctors, however, practice outside of academic institutions and see pharmaceutical detailers and accept drug samples and gifts. Little guidance for practicing physicians exists about transforming practices to become pharma-free. Consideration must be given to the impact on practice culture, staff views, and patient needs.

**Methods:** A small private practice, setting out to transform into a pharma-free clinic, used a practice transformation process that examined the industry presence in the clinic, educated the doctors on potential conflicts of interest, and improved practice flow. Staff were given the opportunity to share concerns, and their issues were acknowledged. Educational interventions were developed to help providers keep current. Finally, efforts were made to educate patients about the policy.

**Results:** The clinic recorded the degree to which it was detailed. Loss of gifts, keeping current with new drugs, and managing without samples were noted concerns. Policy change champions developed strategies to address concerns.

**Discussion:** A shift in practice culture to a pharma-free clinic is achievable and maintainable over time. Barriers to success can be identified and overcome with attention given to careful gathering of information, staff input, and stakeholder education. (J Am Board Fam Med 2013;26:332–338.)

**Keywords:** Conflict of Interest, Drug Industry, Medical Ethics, Practice Management

The precarious relationship between the pharmaceutical industry and the individual physician was first described by Charles May in 1961 in a paper entitled “Selling Drugs by ‘Educating’ Physicians.”<sup>1</sup> After more than 50 years and the accumulation of extensive literature on the subject, much of the responsibility still remains with the individual practitioner to ensure he or she is not subject to undue industry influence.

The pharmaceutical industry spends between \$12 and \$57 billion per year on promotional activities.<sup>2,3</sup> A majority of this money goes to the provision of drug samples and face-to-face product detailing by pharmaceutical representatives to physicians. Although many companies have scaled back their sales force, as of 2009 pharmaceutical companies employed a sales force of 92,000, or 1 drug representative for every 8 physicians.<sup>4–7</sup>

The powerful influence of pharmaceutical marketing on the prescribing patterns of physicians has been documented and has led to calls for reform at the institutional, professional, and individual levels to minimize this impact.<sup>6,8–12</sup> In the past decade several states and many major academic medical centers have enacted policies that either restrict or mandate disclosure of financial relationships with industry.<sup>13,14</sup> Most notably, the Affordable Care Act of 2010 contains the Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, and biologics paid for by Medicare or Medicaid to report all payments to physicians and

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teaching hospitals to a publically accessible database starting August 2013.<sup>15</sup> Others have proposed more stringent guidelines for managing clinician-industry interactions and substantial federal investment in research to promote noncommercial, evidence-based practices.<sup>16</sup> Where does that leave the long-established relationship between pharmaceutical representatives and practicing physicians? While significant progress at the state, federal, and institutional levels has been made to curb these problematic relationships, little guidance exists for physicians and other clinicians in small, independent practices.<sup>17</sup>

Against this historical and cultural backdrop, a small, private, family medicine clinic examined the degree to which pharmaceutical representatives detailed and provided samples to the practice. After this internal audit and self-study, the practice partners decided by consensus to pursue a policy prohibiting pharmaceutical industry interactions, including accepting and distributing drug samples. Despite the consistent evidence suggesting a negative effect of the physician-pharmaceutical relationship,<sup>6,8,12</sup> little guidance on how to transform a practice from being heavily detailed to pharma-free exists for those contemplating a policy change. Accounts of how various practices handle their drug sample inventories have been described,<sup>18–20</sup> but the literature is relatively silent on the steps practices can take to extricate themselves completely from interactions with the pharmaceutical industry. The objective of this article is to describe the efforts of this small private practice of 5 physicians and a physician assistant as it embarked on an intentional and carefully considered path to discontinue seeing pharmaceutical representatives and to stop accepting and distributing drug samples.

## Methods

Madras Medical Group is a privately owned family medicine practice located in rural Oregon. There are 5 family physicians and a PA-C who provide the full spectrum of family medicine services, including obstetrics. The clinic also employs 18 supporting staff. Madras Medical Group is the largest medical provider in a catchment area serving 20,000 people.

To better understand the nature of the interactions between the clinic and pharmaceutical representatives, objective data were collected documenting the nature and magnitude of industry connections. First,

from March to August 2005, the practice recorded the number of visits to the practice by pharmaceutical detailers and the number of lunches provided. In this clinic, pharmaceutical representatives did not detail on a scheduled basis but visited the clinic on a drop-in basis only. The record keeping was done by the office manager as part of a routine practice of noting all visits from nonpatient clinic visitors (eg, drug representatives, repair persons, delivery persons). The office manager was not aware that the record of pharmaceutical representative visits or lunches was to be used as part of this evaluation.

In addition, accepted drug samples were recorded. To estimate the value of the samples, historical average wholesale price data were obtained and the monthly cost was determined based on Oregon Medicaid reimbursement rates. For comparative purposes a potential generic or lower-cost alternative for each sample medicine was identified, and the monthly cost of that was estimated in a similar manner.

Finally, three physician partners (including one of the authors, DE) held group and individual interviews with both clinical and front office staff to identify their concerns about a potential change in practice culture as well as share the data collected about the frequency of industry detailing and drug samples. Madras Medical Group has a history of conducting informal interviews with clinic staff regularly to evaluate attitudes about clinic operations and policies for quality improvement purposes. For this project, interviews were conducted between September 1 and December 1, 2005. Questions asked of clinicians and nonclinical staff centered around the value of drug detailer visits to patients and the clinic, perceived staff benefits of visits to the staff, and losses if the clinic became pharma-free. Providers also were asked to evaluate qualitatively the usefulness of sampled medicines. Responses to interviews were summarized by interviewers and presented to the provider group to identify common themes and concerns from providers and staff. In particular, the provider group sought to understand the relative value and risks of continued interactions with industry representatives. Results of this process were used to inform the proposed policy restricting drug detailing and samples that was implemented January 1, 2006.

Because this work was conducted as part of routine clinic quality improvement, informed consent was not obtained. Subsequent evaluation of this

policy and these data were approved by the Oregon Health & Science University Institutional Review Board (IRB-4596).

## Results

During the 6 months immediately preceding the decision to change the pharmaceutical detailer policy, the practice was visited 199 times (an average of 33.17 times per month; minimum, 29 times; maximum, 37 times) by pharmaceutical representatives. Drug companies sponsored 23 in-clinic lunches from February to November, an average of 2.3 lunches per month.

Inventory of the sample cabinet showed very few first-line drugs available for the most common illnesses seen in the practice. The inventory of sampled medicines along with reasonable first-line alternatives is shown in Table 1. The estimated average price per month of the sampled medicines was \$90. Reasonable less expensive alternatives could be identified for 38 of 46 sampled drugs. At an average of \$22 per month, using a less expensive, often generic alternative would save the ultimate payer \$70 per therapy per month.

During the individual and group interviews, four themes emerged. The physicians were concerned about (1) the practice culture of seeing detailers, (2) the effect they had on staff morale, (3) sample expectations of patients and physicians, and (4) being current on new drugs. Efforts were made to mitigate these issues. Not all providers in the practice initially were willing to discontinue seeing drug detailers and accepting samples. There were two provider champions of the proposed policy, two who leaned toward making the change, and two who did not want to change the policy. Small interim steps were taken while the practice engaged in clinician education. These steps included limiting lunches to once per month. Detailers were asked to only present peer-reviewed materials during visits.

Interviews with staff identified several other concerns. First, staff enjoyed the promotional items that are distributed frequently by drug representatives, such as pads of paper, pens, and mugs. Many of the branded items were taken home by staff members. Second, physicians, staff and their family members personally used samples in the cabinets. Most important, staff enjoyed the opportunity to get together socially for lunch when it was provided for them.

The clinic proactively made several steps to alleviate staff and physician concerns about the policy change. First, provider champions began a process to educate both themselves and other clinicians on the literature related to the ethics of the physician-industry relationship and its effect on practice. During monthly morning clinic meetings, peer-reviewed literature was presented regarding the influence of pharmaceutical detailing and drug samples on prescribing patterns, prescribing safety, increased drug costs, and the ethics of gifting. *The Truth About the Drug Companies* by Marcia Angell<sup>21</sup> was read and discussed. The fallout from the effects of rofecoxib on cardiac health and the subsequent congressional investigation was researched and discussed actively among the physicians. These efforts resulted in the consensus adoption and implementation of a pharma-free policy, which went into effect on January 1, 2006.

The practice implemented a monthly all-clinic lunch with protected time for staff. The cost of this lunch ranges from \$60 to \$80. While the providers acknowledged that the staff enjoyed gifts and the use of samples, no efforts were made to replace these. Branded office supplies that were found in the clinic were disposed of and replaced with supplies purchased at local businesses, when possible, at a cost of less than \$200. Nonindustry drug information sources were identified, and a monthly educational provider meeting was established to discuss both new and old drugs. Patient educational materials describing the transition were developed and distributed. Finally, the local press was notified of the policy change. A press release describing the policy change and the reasons behind it was issued. Two articles were published in the local and regional newspapers.

## Discussion

Considerable progress has been made over the past several years in describing the physician-pharmaceutical relationship, its effects on care, the veracity of information distributed, and qualifying its effect on prescribing.<sup>8,12</sup> A large amount of literature suggests that interaction with industry is associated with substantial negative consequences on patient safety, cost of drugs to patients, generic prescriptions, and evidence-based prescribing.<sup>12</sup> Although physician interactions with industry have declined in recent years—likely because of in-

**Table 1. Inventory of Sampled Medicines, Potential Alternative Drugs, and Estimated Monthly Costs**

Sampled Drug	Generic Name	Average Monthly Cost (\$)	Potential Alternative Drug	Average Alternative Drug Monthly Cost (\$)	Difference (\$)
Psychotropic/neurologic					
Cymbalta	Duloxetine	107	Fluoxetine	10	−96
Lexapro	L-citalopram	75	Fluoxetine	10	−65
Paxil CR	Paroxetine	79	Fluoxetine	10	−69
Zoloft	Sertraline	81	Fluoxetine	10	−71
Imitrex	Sumatriptan	21*	NA		
Namenda	Memantine	145	NA		
Cardiovascular					
Advicor	Niacin	76	Niacin / lovastatin	39	−37
Altace	Ramipril	46	Lisinopril	16	−30
Altoprev	Lovastatin	89	Lovastatin	38	−51
Avapro	Irbesartan	50	Lisinopril	16	−34
Benicar	Olmesartan	50	Lisinopril	16	−34
Coreg	carvedilol	99	Metoprolol	7	−92
Cozaar	Losartan	54	Lisinopril	16	−38
Diovan	Valsartan	55	Lisinopril	16	−39
Hyzaar	Losartan/HCTZ	59	Lisinopril / HCTZ	15	−43
Lipitor	Atorvastatin	94	Lovastatin	38	−56
Micardis	Telmisartan	55	Lisinopril	16	−38
Niaspan	Niacin Extended Release	58	Niacin	4	−54
Norvasc	Amlodipine	57	Felodipine	49	−9
Pravachol	Pravastatin	90	Lovastatin	38	−52
Teveten	Eprosartan	39	Lisinopril	16	−23
Tricor	Fenofibrate	65	Gemfibrozil	19	−46
Vytorin	Simvastatin/ezetimibe	85	Lovastatin	16	−68
Zocor	Simvastatin	94	Lovastatin	16	−78
Endocrine					
Actos	Pioglitazone	155	Glyburide or glipizide or metformin	9	−147
Avandia	Rosiglitazone	103	Glyburide or glipizide or metformin	9	−94
Starlix	Nateglinide	105	Glyburide or glipizide or metformin	9	−97
ACTOPLUS MET	Pioglitazone/metformin	150	Glipizide/metformin	49	−101
Avodart	Dutasteride	81	Terazosin	40	−41
Boniva	Ibandronate	60	NA		
Enablex	Darifenacin	91	Oxybutynin	15	−76
Flomax	Tamsulosin	58	Terazosin	40	−19
Fosamax	Alendronate	84	NA		
Prempro	Estrogen/medroxyprogesterone	42	NA		
Sanctura	Trospium	45	Oxybutynin	15	−30
Vesicare	Solifenacin	95	Oxybutynin	15	−80
Musculoskeletal					
Skelaxin	Metaxalone	228	Baclofen	31	−197
Ultracet	Tramadol/APAP	50	Hydrocodone/APAP 5/500	7	−43
Respiratory/allergy					
Asmanex	Mometasone	369*	Qvar™(beclomethasone)	69	−300
Singulair	Montelukast	91	NA		
Spiriva	Tiotropium	127*	Atrovent™ (ipratropium)	62	−65

Table 1. Continued

Sampled Drug	Generic Name	Average Monthly Cost (\$)	Potential Alternative Drug	Average Alternative Drug Monthly Cost (\$)	Difference (\$)
Xopenex	Levalbuterol	165*	Albuterol	14	-151
Zyrtec	Cetirizine	66	Loratadine	14	-52
Miscellaneous					
Viagra	Sildenafil	13 <sup>†</sup>	NA		
Zelnorm	Tegaserod	170	NA		
Omnicef	Cefdinir	50	Cefaclor	24	-26
					Average Difference = -\$70

Drug costs estimated by Oregon Medicaid reimbursement data in 2005. Costs of brand-name drug costs = average wholesale price  $\times$  0.85; generic drugs = maximum allowable cost.

\*Cost per inhaler.

<sup>†</sup>Cost per dose.

creased scrutiny and regulation—the proportion of primary care physicians with industry relationships remains stubbornly high (84%).<sup>22</sup> To date, practice transformation related to industry conflicts of interest has been dictated to clinicians largely through administrative changes at large academic medical centers and large health systems.<sup>9</sup> In 2008, the Association of American Medical Colleges published recommendations to assist medical centers in developing policy to minimize undue industry conflicts of interest and encourage high standards of medical professionalism.<sup>23</sup> However, of the approximately 800,000 doctors in the United States, only 22% practice in academic settings. To our knowledge this is the first report documenting a process that small private practices can consider when contemplating restrictions in how they interact with the pharmaceutical industry. This description of an internal practice change contributes to the ongoing discussion of the potential clinical influence and the ethics of the relationship between practicing physicians and pharmaceutical marketing.

#### ***Quantifying the Clinic-Industry Relationship***

A key aspect of the success of this policy change was the preliminary work of evaluating exactly how often and in what manner the clinic was visited by drug detailers. The clinic was visited, on average, 33 times per month, or approximately 6 times per clinician per month, which is consistent with published national representative 2004 estimates (median visits, 8).<sup>22</sup> Furthermore, qualitative and quantitative analyses of the samples available played an

important role. Providers were able to see that most sampled medicines were brand drugs for which less expensive options often were available. This foundation of information allowed the champions of the policy to rationally discuss changes with the other providers. This data also allowed the clinic providers to put the results of the discussed peer-reviewed literature into the context of their everyday clinical experience.

#### ***Anticipating Clinician and Staff Concerns***

Cultural change in any institution, including a small family medicine practice, requires buy-in at all levels of the organization. Substantial upfront education of the partner decision makers was vital to downstream success. Soliciting staff input and including that input in policy discussions enabled staff not only to accept the policy change but to express some pride in the clinic's position.<sup>24</sup> Despite the providers' inability to address all staff concerns, they were able to fulfill the need for socialization by dedicating protected time for a group lunch.

Provider concerns included the need to stay current with new pharmacologic therapies previously brought forward by detailer visits. The institution of monthly clinical meetings with expected attendance addressed this need and evolved into a more thorough discussion of a variety of medical topics. Many advocate a model of presenting independent and unbiased prescribing information delivered from noncommercial sources through academic detailing programs.<sup>25</sup> Although these programs are not widespread, they may provide a valuable role in



filling the “educational” void left by the absence of the pharmaceutical industry. The Agency for Health care Research and Quality is currently funding a nationwide academic detailing program aimed at delivering educational content synthesized through their Effective Health Care Program.<sup>26</sup>

### ***Educating Patients and the Public***

Multiple studies document patient awareness and concerns about undue influence of the pharmaceutical industry on physicians and their prescribing patterns.<sup>6,24,27</sup> The distribution of press releases to local and regional media outlets and the accompanying articles greatly eased the transition for patients and the public. Patients generally voiced an understanding of the new policy, and no ill effects were observed.

### ***Study Limitations***

The original intent of this internal examination was not a study for publication. The practice leaders set out to study their relationship with the drug industry and how it could most effectively implement a policy to change the practice’s culture with minimal negative impact on their staff and practice. Although methodology could be improved with more rigorous interviews with staff and analysis of data from those interviews, we believe that the observations and experience during this process provide valuable lessons for other practices. In addition, this practice transformation occurred at a smaller private practice with strong institutional pride, physician and staff loyalty, and a commitment to providing excellent patient care. Long-term working relationships among the provider decision makers allowed for a respectful process of education and the ensuing conversation about dissenting viewpoints. Strategies for institutional change employed at this practice, while generally accepted, may not be applicable in other practice settings.

With these limitations in mind, this study demonstrates that a shift in practice culture from a highly detailed practice to a pharma-free clinic is achievable. Barriers to success can be identified and overcome when attention is given to careful information gathering, inclusion of staff input, and both clinic and patient education.

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