

# Prescribing Under the Influence: Exposure to Pharmaceutical Representatives and the Effect on Physician Attitudes and Prescribing Patterns

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## A. Study Purpose and Rationale

There has been increased interest in the relationship between the pharmaceutical industry and physicians and whether contact impacts the fiduciary relationship between physicians and their patients. More than \$11 billion is spent each year by pharmaceutical companies in promotion and marketing, and just under half that amount goes to pharmaceutical representatives(4). Drug companies allocate an estimated \$8,000 to \$13,000 per physician per year to be spent by pharmaceutical sales representatives(4). How is this money being spent, and to what purpose? The influence of pharmaceutical company marketing on physician behavior, particularly drug prescribing patterns, has not been extensively studied, and what data exists is limited to self-report of behavior as opposed to observation of physician behavior in relation to interactions with specific drug companies. The interaction between medical professionals and pharmaceutical industry can start as early as medical school, residents typically benefit from industry-sponsored meals, free samples and small gifts such as pens and textbooks. This activity declines as physicians enter practice and the frequency of receiving honoraria, conference travel and research funding increases.(4) Multiple studies have shown that physicians generally under recognize the effect of this relationship on their attitudes and behavior. In one study, physicians believed their drug prescribing practices to be based on evidence based medicine, but their understanding of the drug more closely matched advertisement claims(19). Residents also report that their relationship with pharmaceutical representatives (PRs) is limited to accepting small gifts, and that without these gifts, their interaction with PRs would be reduced.(4) Nonetheless, residents were shown to be susceptible to marketing influence as exposure to PRs impacted prescribing practice of residents in terms of prescribing costs, non-rational prescribing and decreased prescribing of generic drugs.(4,9) Chren et al demonstrated an association between interactions with PRs that ranged from meetings to accepting money to perform research and the submission of a formulary request for drugs made by the donor companies(6). Many physicians state that their reliance on evidence based medicine provides them immunity from pharmaceutical industry. However, even the literature has been influenced by drug companies. A 1998 NEJM study found that authors of journal articles supporting the use of calcium-channel antagonists were more likely than neutral or critical authors to have financial relationships with manufacturers of those drugs(11). Additionally, patients perceive physicians to be effected by accepting gifts and financial support more than physicians(12) and one-third of patients felt that the cost of gifts given were passed on to themselves. The cost *is* ultimately passed on to patients, most of whom are unaware of this activity. Acceptance of gifts may further erode the perception of physicians as professionals who serve their patients' best interests.

To avoid the erosion of the fiduciary trust between physicians and patients, multiple guidelines have been proposed to establish the professional and ethical boundaries between industry, physicians and patient care. The FDA has developed guidelines for industry(1), the AMA set guidelines for physicians regarding acceptance of "gifts"(2), institutions have developed campus-wide policies regarding PRs and even some residency training programs have developed guidelines and curricula to address the presence of industry in a scientific and therapeutic environment(3). Comparisons of residency programs with and without these restrictive policies have been made demonstrating that they make a difference regarding perceived benefit of PR activities and the appropriateness of receiving gifts.(5)

New-York Presbyterian Hospital is an institution with a campus-wide policy restricting pharmaceutical representatives' activity. At an ad-hoc meeting of department heads, discussion of the policy concluded that adherence varied according to department enforcement, particularly residency programs as compared to fellowship programs. The Department of Internal Medicine allows limited exposure to PRs with only occasional "G.I. rounds"(afternoon meals) sponsored by drug companies who typically offer small gifts

of pens, textbooks and marketing literature. There are no PRs allowed into the clinic area and no free samples accepted. Off-campus activity occurs when a PR contacts a resident directly to organize a sponsored group meal at an expensive restaurant during off-hours. Departments allow Fellows, such as Cardiology Fellows, to have more contact allowed in order to supplement their meager wages and lack of benefits. Textbooks, journal subscriptions, sponsored lunches and expensive restaurant dinners are more accepted and frequent to this population. Finally, practicing physicians have fewer day to day contacts, but may be the recipients of monetary rewards such as travel fees paid for, honoraria and /or research funding.

It is the purpose of this study to investigate the extent of exposure of three groups to pharmaceutical representatives, the attitudes of each of the groups toward this interaction, the appropriateness of receiving gifts, and to establish whether prescribing of marketed drugs is related to exposure to the drug marketers. Our hypothesis is that residents have the most limited exposure, cardiology fellows have more extensive exposure and Cardiology attending physicians in private practice, as a whole, have the most exposure with CME courses, travel honoraria, research, and conference exposure. Because these three groups prescribe the same classes of drugs, they are compared in respect to PR exposure and frequency of prescribing common drugs. The study drugs are chosen from classes with relative uniformity between different drugs within each class. The classes chosen also have definable amounts of marketing associated with each drug over a month-long period and may therefore be ranked accordingly. By asking physicians to report their frequency of prescribing certain drugs, we can evaluate the association with exposure to drug marketing. We have also selected two classes of drugs with no PR in-house marketing, but with extensive television print advertising to which are commonly prescribed to see if one drug is consistently prescribed more than another.

## **B. Study Design and Statistical Analysis**

The study will include NYPH Internal Medicine residents, Cardiology Fellows and board certified Cardiology Attendings in practicing for 10 years. Data collection will be via anonymous self-administered survey sent by mass e-mail. Based on prior studies using self-administered surveys, we expect a 70% response rate. Initial non-responders will be resent the e-mail in 2 weeks. The instrument is adapted from the survey designed by Brotzman and Mark, 1993(5), and was administered to 9 physicians to test for clarity and comprehension. The questionnaire consists of several Likert-scale questions to quantify and characterize exposure to PRs, attitudes regarding benefit of relationships with PRs, utility of literature, perceived appropriateness of accepting gifts and assessment of behavior.

To further evaluate the relationship between exposure to PR and prescribing patterns, common classes of drugs were chosen and evaluated for extent of marketing of the specific drug at NYPH. Drug classes include the statins, calcium-channel blockers and angiotensin converting enzyme inhibitors which all have multiple drugs of presumed equal benefit, but vary according to hours a PR markets that drug in each class per month at NYPH. Information will be obtained from the Hospital Purchasing Department where PRs required to register his/her daily activity, to quantify the number of hours spent marketing each specific drug over a month-long period. Using this information, we will rank each drug according to its potential exposure to a physician by most hours marketed on campus to least. Each physician is asked to rank his/her drugs by frequency of prescription written, and to quantify the number of prescriptions written drug per week and per month. Included in the analysis are two classes of common drugs for which there is no PR exposure in-house, but for which there is extensive print and television advertisement. These include the non-sedating antihistamines and the selective-serotonin reuptake inhibitors. We asked each physician to list the appropriate prescribing frequency to see if there were other modes of influence on prescribing patterns.

### **a. Statistical Analysis**

Statistical methods used to analyze the collected data will include:

- To establish the extent of PR exposure, the mean number of monthly PR contacts will be calculated per study group and compared using ANOVA, with paired t-tests, to determine if there is a statistical difference between residents, fellows and attending physician's exposure to PRs.
- To establish the difference between the attitude, perceived helpfulness and appropriateness of certain behaviors between the different groups, ANOVA with paired t-test will be used.

- To determine if there is an association between exposure to PRs and attitudes regarding PRs within each group of residents, correlation coefficient will be used. With 40 subjects in each group, the correlation coefficient of significance is  $r < -0.43$  and  $r > 0.43$ .
- To evaluate relationship between prescribing patterns and exposure, correlation coefficient will be used within each group

### **C. Study Drugs**

There are no study drugs included in this protocol.

### **D. Medical Device**

There are no medical devices included in this protocol.

### **E. Study Questionnaires**

Please see attached study instrument.

### **F. Study Subjects**

Eligibility for this study extends to all Department of Internal Medicine categorical residents, Cardiology Fellows and Cardiology Attendings with admitting privileges at NYPH who have been board-certified in the last ten years. Exclusion criteria include preliminary residents, as they have a different rotation schedule which may impact the drugs prescribed and characteristics of PR interaction. Visiting fellows will also be excluded for similar reasons. Cardiology Attendings board certified over ten years ago are excluded, as their prescribing patterns may reflect drugs known and accepted prior to the trend of PR direct marketing.

### **G. Recruitment of Subjects**

Subjects will be recruited at New York Presbyterian Hospital – Columbia Campus. Study population will be the Internal Medicine housestaff, Cardiology Fellows and Cardiology attendings in practice for the last 10 years at NYPH as identified by the House Staff Affairs Office who will provide e-mail addresses. Subjects will be identified and contacted by a mass e-mail.

### **H. Confidentiality of Study Data**

To protect the identity of the subjects and confidentiality of the data, the e-mail addresses will be blinded and the data collected will be coded. The only identifying data will be department affiliation and year of training or board certification. Data will be stored in a secure location only accessible to the investigators.

### **I. Potential Conflict of Interest**

The investigators have no financial, material or proprietary interest in this study.

### **J. Location of Study**

NYPH

### **K. Potential Risks**

There are no perceived potential risks or benefits to conducting or participating in this study.

### **L. Potential Benefits**

As above.

**M. Alternative Therapies**

N/A

**N. Compensation to Subjects**

N/A

**O. Cost to Subjects**

N/A

**P. Minors as Research Subjects**

N/A

**Q. Radiation or Radioactive Substances**

N/A

**R. Consent Form**

N/A

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**Survey (Draft)**

Age: \_\_\_\_\_ Male/ Female

You are a: (circle one) Resident: PGY1 PGY2 PGY3

Cardiology Fellow Year 1 2 3

Cardiology Attending Year of Board Certification

1. Did you come from a medical school with a restrictive policy regarding pharmaceutical representatives?  
Y/N

2. Did your medical school have a curriculum regarding pharmaceutical representatives?  
Y/N

3. Did you train at a residency program with a restrictive policy regarding pharmaceutical representatives?  
Y/N

For the following questions, circle the most appropriate answer:

What is the average number of contacts per month with a PR      0    1-4    5-8    9-12    >12

What number of the above contacts are related to meals?      0    -4    5-8    9-12    >12

What number of the above contacts occur during off-hours?      0    1-4    5-8    9-12    >12

	<b>Strongly Disagree</b>	<b>Somewhat Disagree</b>	<b>Neutral</b>	<b>Somewhat Agree</b>	<b>Strongly Agree</b>
PR contacts are beneficial to residency fellowship/practice experience	1	2	3	4	5
Educational material provided by PR is of good quality	1	2	3	4	5
Social recreation and meal activities provided by PRs are beneficial	1	2	3	4	5
<b>Rate helpfulness of the various materials</b>	<b>Not helpful</b>	<b>Somewhat unhelpful</b>	<b>Neutral</b>	<b>Somewhat helpful</b>	<b>Helpful</b>
PDR	1	2	3	4	5
Micromedex	1	2	3	4	5
Medical Letter	1	2	3	4	5
PR drug literature	1	2	3	4	5
Journal advertisements	1	2	3	4	5
<b>Rate the appropriateness of these gifts</b>	<b>Not appropriate</b>	<b>Somewhat inappropriate</b>	<b>Neutral</b>	<b>Somewhat appropriate</b>	<b>Appropriate</b>
Gifts of <\$50 value (pens, mugs, etc)	1	2	3	4	5
Gifts of > \$50 value (textbooks, etc)	1	2	3	4	5
Personal drug samples	1	2	3	4	5
Meals	1	2	3	4	5
Honoraria	1	2	3	4	5
Paid CME courses	1	2	3	4	5
Social/ recreational outing	1	2	3	4	5
Vacations	1	2	3	4	5

For the below drugs, please rank in order of frequency of prescriptions written (1=most frequent to 5=least)	Rank	# prescriptions/ week	# prescriptions/ month
<b>Statins</b>			
Lipitor / atorvastatin			
Lescol / fluvastatin			
Mevacor / lovastatin			
Pravachol / pravastatin			
Zocor / simvastatin			
<b>ACE Inhibitors</b>			
Lotensin / benzapril			
Capoten / captopril			
Vasotec / enalapril			
Monopril / fosinopril			
Prinivil/Zestril / Lisinopril			
Accupril / quinapril			
Altace / ramipril			
Mavik / trandolapril			
<b>Calcium Channel Blockers</b>			
Norvasc / amlodipine			
Plendil / felodipine			
Procardia / nifedipine			
Cardizem SR / diltiazem			
Calan / Covera SR/ verapamil			
<b>Non-sedating anti-histamines</b>			
Allegra			
Claritin			
<b>SSRIs</b>			
Prozac			
Paxil			
Celexa			
Zoloft			