

Prevalence and Determinants of Physician Participation in Conducting Pharmaceutical-sponsored Clinical Trials and Lectures

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BACKGROUND: The relationship between physicians and the pharmaceutical industry is controversial because of the potential for conflicts of interest. However, little empirical evidence exists on the extent of physician participation in activities sponsored by pharmaceutical companies.

OBJECTIVES: To determine the prevalence of participation of internal medicine physicians in clinical trials and lectures sponsored by pharmaceutical companies and to describe factors that are associated with such participation.

DESIGN, SETTING, AND PARTICIPANTS: We conducted a cross-sectional regional survey of 1,000 Maryland internal medicine physicians between February 2000 and January 2001 in order to measure the prevalence of physician participation in pharmaceutical-sponsored clinical trials and lectures. We also collected economic and demographic information to examine potential associations between physician characteristics and engagement in such activities.

RESULTS: Of 835 eligible physicians 444 (53%) responded, of whom 37% reported engaging in pharmaceutical-sponsored clinical trials and/or lectures to supplement their incomes. In our multivariable analysis, subspecialists versus generalist physicians (odds ratio [OR], 1.85; 95% confidence interval [CI], 1.14 to 2.99), physicians in private group-single specialty and academic practice versus physicians in solo practice (OR, 2.30; 95% CI, 1.19 to 4.44 and OR, 2.56; 95% CI, 1.17 to 5.61, respectively), and physicians with higher versus lower annual incomes (OR, 1.22; 95% CI, 1.04 to 1.44) had a greater odds of participation in these activities. Additionally, physicians dissatisfied with their income had a 140% greater odds of participation (OR, 2.36; 95% CI, 1.45 to 3.83) than those who were satisfied with their income.

CONCLUSIONS: A substantial number of internists engage in pharmaceutical industry-sponsored clinical trials and/or lectures in an effort to supplement their incomes. Physician dissatisfaction with income appears to partially explain such participation.

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Over the past decade, pharmaceutical company expenditures for clinical research and product marketing have grown rapidly. The industry currently spends approximately \$3.5 billion annually to conduct clinical trials in the United States. A large proportion of these funds are distributed to private entities, such as contract-research organizations and site-management organizations, that may rely on both community and academic physicians for assistance in patient recruitment.^{1,2} In 2000, the pharmaceutical industry also spent approximately \$13 billion to promote products to medical professionals, including significant expenditures on events for physicians (meetings, dinners, etc.).³

There are many reasons why physicians may be attracted to partnering with pharmaceutical companies. First, involvement with the pharmaceutical industry may be desirable for some physicians who wish to expand the breadth of their activities beyond their clinical practice. Second, physicians may enjoy taking an active role in peer education, which may serve to enhance their reputation within their community. Finally, involvement in clinical trials or giving lectures can reap financial rewards and may serve to offset recent declines in practice-derived income or educational debt experienced by many young physicians.^{4,5}

Such relationships between physicians and the pharmaceutical industry are quite controversial,⁶⁻⁸ and may result in significant conflicts of interest.^{9,10} Little is currently known about the extent of physician participation in industry-sponsored activities. Therefore, we designed a study to examine the extent of participation of internal medicine physicians in pharmaceutical company-sponsored clinical trials and lectures. We also sought to determine whether economic or demographic factors were associated with engagement in these activities.

METHODS

Study Design and Population

We conducted a cross-sectional mail survey of 1,000 internal medicine physicians who were randomly sampled from the Maryland American College of Physicians-American Society of Internal Medicine (ACP-ASIM) member registry. To be eligible, physicians had to be full members of the

ACP-ASIM, be 30 years of age or older, and practice either general internal medicine or a subspecialty of internal medicine. Our sampling strategy consisted of systematic alphabetical sampling with a random start. Every third physician on the member registry was asked to participate until we mailed 1,000 surveys. This required two passes through the registry. All surveys were anonymous. We recontacted nonresponders three times by mail and once by fax between February 2000 and January 2001. Sample size was adjusted for surveys that were returned secondary to wrong mailing address or deceased or retired status of the physician. We characterized demographic information on nonresponders by querying the publicly accessible Maryland Board of Physician Quality Assurance website (<http://www.bpqa.state.md.us/>). The study was approved by the Institutional Review Board of the Johns Hopkins Medical Institutions.

Questionnaire

The survey consisted of 24 multiple-choice questions designed to capture information on participation in pharmaceutical company-sponsored clinical trials and lectures. The specific survey questions to elicit information on participation were as follows: "To supplement your income, do you engage in:" 1) "Clinical trials sponsored by a pharmaceutical company," and 2) "Giving lectures sponsored by a pharmaceutical company." The questionnaire also obtained demographic information (including age, gender, marital status, number of dependents, and year of medical school graduation), practice information (years in practice, practice location/setting, and medical specialty/subspecialty), and economic information (annual income, change in income over the last 5 years, educational debt, income satisfaction, compensation structure, and perception of income in relation to other physicians and nonphysician professionals). The choices for compensation structure included salary alone, salary plus percentage of billing revenue, or billing revenue alone. We designed and piloted the survey with 15 physicians in general internal medicine, after which we solicited feedback and modified the survey accordingly.

Data Analysis

We used descriptive statistics to define the study population demographics and the percentage of the sample participating in clinical trials, giving lectures, or both. We compared characteristics of those physicians who participated in pharmaceutical company-sponsored activities with those of physicians who did not. A one-way analysis of variance (ANOVA) was used for continuous variables, and the χ^2 test was used for categorical variables.

Multivariate analysis was performed using a logistic regression model to assess the presence, strength, and independence of the association between physician characteristics and attitudes and participation in industry-sponsored activities (defined as engaging in clinical trials,

giving lectures, or both). Variables significantly associated ($P \leq .05$) with participation in univariate analyses were included in the logistic regression model. We performed statistical analyses using SPSS 10.0 (SPSS Inc., Chicago, Ill).

RESULTS

Response Rate and Participant Characteristics

Of the 1,000 surveys mailed, 84 were returned undeliverable by the post office, 55 were sent to retired physicians, 10 were sent to deceased physicians, 14 were sent to physicians not engaging in any clinical activity, and 2 were sent to individuals who were not internal medicine physicians. Of the 835 remaining eligible participants, 444 (53%) responded. There were no significant differences between the 444 responders and the 391 nonresponders with regard to gender (76% vs. 73% male) and specialty (56% vs. 52% general internists). However, nonresponders had graduated from medical school about 2.3 years earlier than responders (24.7 vs. 22.4, respectively; $P = .001$).

Respondents had a mean age of 48.1 years. The mean number of years since medical school graduation was 22.4 years. More than half of responding physicians described their specialty as solely general internal medicine, with the remaining physicians reporting another specialty or subspecialty (cardiology, endocrinology, gastroenterology, infectious disease, nephrology, pulmonology, rheumatology, oncology, hematology, or emergency medicine). More than two thirds of participants reported having dependents. When participants were asked about educational debt, more than half had educational debt at some point, but only 13% had current obligation to that debt. More than half of the respondents reported that the income from their primary medical practice remained stagnant or decreased over the past 5 years. More than half reported dissatisfaction with their income, and income satisfaction was strongly correlated with actual income. The odds of a physician being satisfied with his/her income increases by 45% (95% confidence interval [CI], 25% to 67%) per \$50,000 increase in annual income.

Participation in Pharmaceutical Company-sponsored Activities

Overall, 37% of respondents participated in pharmaceutical company clinical trials and/or giving lectures in an effort to supplement their income. Over one fifth reported engaging in clinical trials, while one quarter gave lectures (Fig. 1). Twelve percent of respondents engaged in both activities, while 25% did one or the other.

Characteristics Associated with Giving Lectures or Participating in Clinical Trials

In univariate analysis, male gender, number of dependents, annual income, and number of years in practice

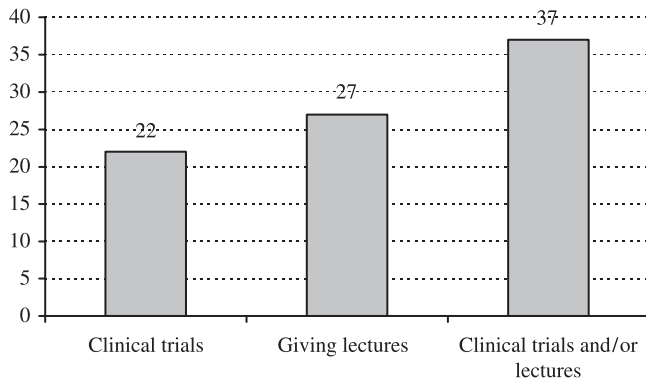


FIGURE 1. Percentage of respondents who participate in pharmaceutical company-sponsored clinical trials and lectures.

were positively associated with participation (Table 1). Internal medicine subspecialty, private group-single specialty and academic practice settings, plans to stay in current practice for the next 5 years, and dissatisfaction with current income were also positively associated. Age (odds ratio [OR], 1.00; 95% CI, 0.98 to 1.02), number of years since graduation (OR, 1.00; CI, 0.98 to 1.02), marital status, practice location, current educational debt, compensation structure, and change in income were not associated with participation. In multivariate analysis, gender did not remain independently associated with participation after adjustment ($P = .5$). Subspecialty practice and practice setting remained strongly and independently associated with physician participation in pharmaceutical company activities. Specialists had a 90% greater odds of engaging in pharmaceutical-sponsored clinical trials and lectures than did generalists. Physicians in private group-single specialty and academic practice, physicians who were in practice for 11 to 15 or 16 to 20 years, and physicians who were dissatisfied with their incomes were also more likely to participate in such activities. Further stratified analysis suggested that the odds of engaging in pharmaceutical-sponsored activities were greater for physicians dissatisfied with their incomes regardless of gender, specialty, or recent change in income. Finally, for every \$50,000 increase in income, physicians had a 1.2-fold odds of participation. All variables combined explained 11% of the variation in physician participation and the area under the receiver operating characteristic curve was 0.72.

Comment

In our study, more than one third of internists engaged in clinical trials and/or lectures supported by pharmaceutical companies to supplement their incomes. These findings are consistent with a recently published study that reported that nearly 47% of institutional review board members serve as consultants for industry.¹¹ Our data, however, extends beyond academia, and suggests that physician-industry relationships are also prevalent in nonacademic

settings. Characteristics that we found to be associated with participation included subspecialty training, practice setting (academic or private group-single specialty), number of years in practice (between 11 and 20), higher annual income, and dissatisfaction with income.

The implications of these relationships between physicians and pharmaceutical companies are important. The benefits to individual physicians may be both noneconomic and economic. Relationships such as these may offer some physicians a mechanism to enhance prestige and knowledge in a manner that can bolster their professional reputation, allow them to engage in an academic pursuit, add variety to day-to-day clinical practice, and bring new innovations and up-to-date knowledge to patients. The greater involvement by academics may indicate that scholarly pursuits are a goal or that academics are experiencing less institutional support for teaching and other scholarly activities. Additionally, physician involvement in clinical trials may benefit patients by offering them treatment options for end-stage disease and make some disenfranchised patients eligible for care and follow-up.

There are, however, potential adverse consequences from such involvement. The ability of physicians who have financial relationships with industry to remain objective is uncertain. The incentives of physicians and pharmaceutical companies are not always aligned. Physicians and companies are, in part, economic agents. Both have a responsibility to act in the best interest of patients, but pharmaceutical companies have a primary responsibility to their shareholders to increase stock value by selling products, increasing revenue, and increasing profit margins, which may sometimes conflict with the best interests of patients. Although many physicians do not believe that they are influenced by drug company promotion,^{12,13} evidence suggests that the opposite may be true. Physicians who accept money to speak at symposia or to perform company-sponsored research have been shown to be more likely to request that the company's drugs be added to the hospital formulary.¹⁴ Additionally, frequent contact between physicians and pharmaceutical representatives has been associated with a greater willingness to prescribe new drugs and higher prescribing costs.¹⁵⁻¹⁷

Participation in clinical trials can involve recruitment of patients from a physician practice (e.g., payment per patient or group of patients enrolled) or trial oversight capacity without active recruitment. Remuneration for recruitment of patients into clinical trials beyond office expenses is an ethically tenuous proposition, which may tempt physicians to violate the principles of acting in the patient's best interest, protecting the patient from harm, and failing to disclose financial relationships. The responsibility of physicians to disclose potential conflicts of interest with patients is subject to debate.¹⁸ Some physicians may argue that their income is a private matter that should not be subject to public scrutiny. Others may argue that patients have a right to full disclosure because such relationships can influence professional objectivity. Failure to

Table 1. Characteristics of Physician Respondents and Association Between Physician Characteristics and Participation in Pharmaceutical-sponsored Activities

Characteristic	Respondents* N (%)	Participating in Activities N (%)	Unadjusted Odds Ratio (95% CI)	Adjusted Odds Ratio† (95% CI)
Gender				
Female	107 (24)	28 (26)	1.00 (reference)	1.0 (reference)
Male	337 (76)	135 (40)	1.90 (1.18 to 3.09)	1.17 (0.64 to 2.13)
Marital status				
Single	51 (12)	16 (31)	1.00 (reference)	NA
Married	392 (88)	147 (38)	1.28 (0.68 to 2.39)	NA
Dependents				
None	124 (28)	36 (29)	1.00 (reference)	1.00 (reference)
One or more	316 (71)	127 (40)	1.63 (1.04 to 2.54)	1.14 (0.67 to 1.94)
Specialty				
General internal medicine	250 (56)	72 (29)	1.00 (reference)	1.00 (reference)
Internal medicine subspecialty	194 (44)	91 (47)	2.16 (1.46 to 3.20)	1.85 (1.14 to 2.99)
Practice setting				
Solo practice	77 (17)	21 (28)	1.00 (reference)	1.00 (reference)
Private/group—single specialty	159 (36)	71 (45)	2.11 (1.17 to 3.82)	2.30 (1.19 to 4.44)
Private/group—multispecialty	54 (12)	19 (35)	1.42 (0.67 to 3.01)	1.68 (0.73 to 3.88)
Academic	94 (21)	42 (45)	2.11 (1.11 to 4.04)	2.56 (1.17 to 5.61)
Staff model HMO	12 (3)	2 (17)	0.52 (0.11 to 2.59)	0.90 (0.16 to 4.94)
Other	45 (10)	7 (16)	0.48 (0.19 to 1.25)	0.65 (0.22 to 1.91)
Practice location				
Urban	194 (44)	73 (38)	1.00 (reference)	NA
Suburban	203 (46)	74 (36)	0.95 (0.63 to 1.43)	NA
Rural	43 (10)	16 (37)	0.98 (0.50 to 1.95)	NA
Number of years in practice				
≤5	50 (11)	12 (24)	1.00 (reference)	1.00 (reference)
6 to 10	97 (22)	32 (33)	1.54 (0.71 to 3.33)	2.00 (0.85 to 4.68)
11 to 15	77 (17)	34 (44)	2.45 (1.11 to 5.38)	2.53 (1.07 to 6.01)
16 to 20	67 (15)	33 (49)	2.99 (1.34 to 6.68)	2.60 (1.03 to 6.59)
>20	149 (34)	52 (35)	1.73 (0.83 to 2.60)	1.53 (0.66 to 3.59)
Compensation structure				
Salary alone	176 (40)	57 (32)	1.00 (reference)	NA
Salary plus billing revenue	95 (21)	36 (38)	1.27 (0.76 to 2.15)	NA
Billing revenue alone	166 (37)	68 (41)	1.45 (0.93 to 2.25)	NA
Income satisfaction				
Satisfied with current income	198 (45)	57 (29)	1.00 (reference)	1.00 (reference)
Dissatisfied with current income	236 (53)	101 (43)	1.85 (1.24 to 2.77)	2.36 (1.45 to 3.83)
Current educational debt				
No obligation	386 (87)	139 (36)	1.00 (reference)	NA
Obligation	56 (13)	24 (43)	1.33 (0.76 to 2.35)	NA
Practice plan over the next 5 years				
Leave current practice	197 (44)	62 (31)	1.00 (reference)	1.00 (reference)
Remain in current practice	247 (56)	101 (41)	1.53 (1.03 to 2.26)	0.83 (0.52 to 1.33)
Change in income over last 5 years				
Decreased or unchanged	255 (57)	93 (36)	1.00 (reference)	NA
Increased	161 (36)	59 (37)	1.01 (0.67 to 1.52)	NA
Annual income‡				
≤\$100,000	116 (26)	27 (23)	1.00 (reference)	1.00 (reference)
\$101,000 to \$150,000	152 (34)	55 (36)	1.87 (1.09 to 3.22)	1.64 (0.89 to 3.01)
\$151,000 to \$200,000	75 (17)	32 (43)	2.48 (1.32 to 4.65)	1.90 (0.93 to 3.89)
\$201,000 to \$250,000	36 (8)	20 (55)	4.17 (1.90 to 9.14)	2.63 (1.09 to 6.34)
>\$250,000	52 (12)	23 (44)	2.64 (1.31 to 5.30)	2.16 (0.90 to 5.13)

* Some percentages do not sum to 100 percent due to missing data: 1% for dependents, 1% for practice setting, 1% for number of years in practice, 1% for practice plan over the next 5 years, 2% for compensation structure, 2% for income satisfaction, 3% for annual income, and 7% for change in income over last 5 years.

† Adjusted for gender, dependents, specialty, practice setting, number of years in practice, practice plan over next 5 years, income satisfaction, and annual income.

‡ Annual income was also analyzed as a continuous variable in multivariable analysis. For every \$50,000 increase in income, physicians had a 1.2-fold odds of participation (OR, 1.22; 95% CI, 1.04 to 1.44).

OR, odds ratio; CI, confidence interval; NA, not addressed.

do so can be seen as a violation of the principle of patient autonomy.⁹

Our study suggests that dissatisfaction with income partially explains participation in these activities. This finding in the 53% of physicians who are dissatisfied would be consistent with the target income hypothesis, which states that physicians will alter their behavior to achieve a desired income level.¹⁹ A recently published study has supported this theory, suggesting that physicians are becoming more entrepreneurial in an effort to combat economic pressures.²⁰ It is possible that physicians who are dissatisfied with their incomes and have not been able to attain their "targets" by increasing volume or charges may turn to alternative sources of revenue outside of their clinical practice to achieve their goals. Such physicians may be at greater risk for conflicts of interest with patients. Surprisingly, in our study, change in income was not associated with participation. Perhaps some physicians whose income decreased desired this change in an effort to work less.

Several limitations to this study deserve mention. First, our sample is limited to internal medicine physicians who were ACP-ASIM members in the state of Maryland. Physicians in other specialties and other states may practice in settings where pharmaceutical company presence and practice income is different and therefore may be more or less likely to engage in relationships with industry. We chose to survey ACP-ASIM members because we thought they represented a good mix of general internists, subspecialists, private practitioners, and academic physicians. Although these physicians may not be representative of all internists in Maryland, the percentage of respondents that were generalists versus specialists were similar to the breakdown of board-certified internists for the entire state.²¹ Additionally, by limiting our sample to ACP-ASIM full members over the age of 30, we can make no conclusions about the relationship between physicians-in-training and pharmaceutical companies. Second, nonresponse bias is a concern in any study such as this that uses systematic survey methods with potentially sensitive subject matter (e.g., income). Although it was reassuring that responders and nonresponders were similar with regard to gender and specialty, they may differ on other unknown characteristics. Third, our response rate of 53% was not optimal, although it is comparable to the mean response rates of mailed physician surveys of similar size.^{22,23} Fourth, our study may underestimate the relationship between academic faculty and the pharmaceutical industry by limiting our analysis to full-time academic physicians. It is likely that a number of the physicians from other practice settings hold part-time academic appointments or are involved in teaching medical students, residents, or fellows. Finally, we do not have data on the level of payment for or the quality of pharmaceutical-sponsored activities in which the physicians engaged. The honoraria amounts and degree of autonomy allowed to physicians in delivering lectures and performing and reporting clinical trials may

vary significantly among physicians and individual pharmaceutical companies.

In summary, the significant involvement of physicians in pharmaceutical company-sponsored activities demonstrated in this study and the factors associated with this involvement are important. The benefits that such relationships may have must be weighed against the harms that could affect patient care. The finding that over one third of internists engage in these activities suggests that participation may be considered standard practice, especially within some subgroups of physicians. Existing guidelines for physician conduct clearly state that "physicians have an obligation to recognize, disclose to the general public, and deal with conflicts of interest that arise in the course of their professional duties and activities."²⁴ Yet, studies of physician attitudes suggest that most physicians do not view relationships with industry as ethically problematic.^{10,25} Such acceptance may pose a significant barrier to meaningful discussion of the topic. The impact of the relationship between physicians and industry on professionalism and patient welfare deserves further consideration for maintaining patient trust in the health professions.

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