Doctors and the Drug Companies:

A Study to Determine the Opinions of Surgical Residents Regarding Interaction with the Pharmaceutical Industry

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Abstract

While the potential for conflict of interest exists in all occupations and professional interactions, none have held the current concern or interest of the popular press and society as much as the potential conflicts that exist between physicians and the pharmaceutical industry. Of particular interest in the debate have been the conflicts that exist between physicians and researchers in academic medical centers and the pharmaceutical companies that promote their products and reap the benefits of new molecules and technologies that emerge from these institutions. To determine the current attitudes and beliefs held by physicians toward representatives of the pharmaceutical industry a survey was conducted at a major academic medical institution. Surgery residents at the institution were asked a series of 19 questions to determine their opinions regarding the quality of their interactions with sales representatives, departmental policy, regulation and research. A total of 34 residents responded to the survey. Results were calculated on the class as a whole and a sub-analysis was conducted to determine if responses varied between first and second, third, or fourth year residents. Overall surgical residents favored policies that allow pharmaceutical representatives to continue to detail and promote their products within the institution. A large majority of physicians felt the literature and educational resources presented in the institution were both accurate and valuable. The majority of physicians felt the current institutional policies regarding interactions with representatives of industry were adequate. Attitudes among surgery physicians changed slightly during their four year residency. A majority (90%) of all fourth year residents agreed that pharmaceutical representatives should be allowed to detail or interact with physicians at the institution versus 78% of first and second year residents and 83% of third year residents. Though the potential for conflict of interest obviously occurs in academic medicine, as it does is a vast number of other occupations, the results of this survey suggest that physicians believe the relationship between academic physicians and the pharmaceutical industry should continue. The survey confirms public opinion: the relationship should continue but terms of the relationship may need to be rewritten to better reflect the complexities introduced by society. New societal pressures that force a redefinition of the relationship include the advent of technology transfer via the Bayh-Dole Act, increased financial pressures on physicians and institutions from Medicare reform and the public's cry for greater transparency on the part of pharmaceutical companies. The emerging relationship between big pharma and academia must evolve into one of mutual trust, respect and shared scientific and fiscal goals.

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Statement of the Problem

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Conflict of Interest

It takes only a quick glance at today's news channels or yesterday's paper to reveal an explosion in the number of articles and editorials about reported conflicts of interest. Conflicts generally arise when professional judgment conflicts with personal interests (or when differing professional judgments conflict). Most, if not all professionals face potential conflicts of interest during their careers. Attorneys face potential conflicts when they advise clients on whether to pursue legal action. Doctors face conflicts of interest when they order procedures that will benefit them financially or when they direct a patient to return for a follow-up appointment that will net yet another fee-for-service. Stock analysts face a conflict when they audit the same firms to which they are supposed to provide consulting services. Society as a whole has become keenly aware of the number and severity of conflicts of interest, in particular those that affect their financial welfare. Enron and WorldCom are two examples of highly publicized cases of conflict of interest that had a significant impact on the financial and legislative landscape of our country.

In the business world, solutions to the rise in cases of conflict of interest have included the Sarbanes-Oxley Act (U.S. Congress 2002) which limits the ability of accounting firms to provide both auditing and consulting services to the same clients. In the world of medicine, professional regulatory bodies issued strong advice about appropriate relationships and the regulation of the potential conflict of interest that can exist within these relationships. In 2002, three leading professional organizations – the American Medical Association, (American Medical Association, 2006), the American College of Physicians,(Coyle,2002), and the Accreditation Council for continuing Medical Education, (Accreditation Council for

Continuing Medical Education, 2006), issued or revamped guidelines regarding physicians' interactions with drug companies. In July 2002, acting through its trade association, the Pharmaceutical Research and Manufacturers of America, the industry adopted a broad code of conduct for its constituencies (Pharmaceutical Research and Manufacturers of America, 2006). In April 2003, the Office of the Inspector General of the Department of Health and Human Services released guidelines with which manufacturers were urged to comply to guard against the risk of liability, (Pharmaceutical Research and Manufacturers of America, 2006).

Potential Conflicts of Interest between Physicians and the Pharmaceutical Industry In no other industry does potential conflict of interest take on more drama and raise more concern than when the profession of medicine and the pharmaceutical industry are involved. As stated by David Blumenthal (Blumenthal, 2006, p. 1885), "When a great profession and the forces of capitalism interact, drama is likely to result. This has certainly has been the case where the profession of medicine and the pharmaceutical industry are concerned. On display in the relationship between doctors and drug companies are the grandeur and weakness of the medical profession – its noble aspirations and its continuing inability to fulfill them." Blumenthal goes on to say that as long as the professional relationship between physicians and the pharmaceutical industry is legal, all parties involved will continually face the temptation to test the limits of the personal, professional, governmental and industry codes that govern their conduct.

Potential conflicts of interest between medical providers and the manufacturers of the medicines they use to treat diseased patients obviously effects not only the health and welfare of patients but has far reaching consequences on the financial burden inflicted on our

nation's struggling medical care system. The potential of financial conflicts of interest between pharmaceutical manufacturers and physicians also casts doubt over the physician's commitment to serve the interest of the patient and maintain patient trust that is central to the physician-patient relationship. The troublesome financial dilemma between the medical professional and money is not a new one. In 1847 the *Boston Medical and Surgical Journal* (the predecessor to the *New England Journal of Medicine*) ran the following commentary:

That it is a profession in which an opportunity is presented for exercising the natural philanthropic yearnings of the human heart, chastened and heightened by a profound sense of Christian duty towards suffering humanity, must be admitted; but to pretend that a man takes upon himself the ceaseless labors of a medical practitioner for no other earthly motive than to prescribe drugs, as the greatest earthly blessings, is positively ridiculous, besides being untrue. Such a physician would fain make it appear that his charities were in proportion to the weight and measure of his doses. The fact is simply this, that the practitioner of medicine has a stomach to be filled, a body to be clothed, and in most cases a family to maintain – and a variety of relations which he bears to the whole community, renders it positively necessary that he should conform to the usages of civilized society. To do so there must be an adequate income from some source to meet the expense of being part and parcel of the general population. (Boston Medical and Surgical Journal, 1847).

If conflicts of interest arise in every industry and financial conflicts, particularly in the medical profession, have existed for centuries, why the recent heightened sense of urgency? It is possible, on any given day, to listen to the media and discover yet another news story or article discussing conflicts of interest in physicians' relationships with the pharmaceutical

industry. Three recent developments have focused attention of the issue of the relationship between the drug companies and physicians. One is the surge in spending on prescription drugs, which totaled \$162.4 billion in 2002 after years of double-digit percentage increases (Levit, 2004). A second is the publicity surrounding a number of prominent legal cases in which drug manufacturers have been convicted of crimes related to their marketing of drugs to physicians or have made payments in the settlement of civil suits for similar non-criminal violations. (Peterson, 2002). A third is an increasing recognition by both pharmaceutical companies and physicians that, in certain respects, the relationships between drug companies and doctors have become embarrassing to both parties and need to change (Darves, 2003). *An Historical Perspective on the Problem*

It has traditionally been true that when you desire perspective on the present a glance at the past is most prudent. The same is true for the present state of the relationship between the pharmaceutical industry and the medical industry. The enactment of Medicare in the mid-1960s signaled a profound change in payment for medical care. Until 1965 the average physician in practice earned about twice as much as the income of the average gainfully employed worker, but by the 1990s (despite managed care's restrictions) the figure had climbed to a multiple greater than five. Salaries and wages rose for most workers between 1995 and 1999, but not for physicians. Physicians and academic medical centers began to look for additional forms of income. Medicine, and in particular academic medicine, was transformed when the number of researchers trained by National Institute of Health funding increased the number of academic researchers. The National Institute of Health increased the number of physicians in research fellowships; many were trained in academic medical centers began to contry. Growth in the number of researchers occurred as the

pharmaceutical and medical-device industries poured large amounts of money into the coffers of clinical departments for help in designing and implementing research on their products. New drugs, new diagnostic tools and new therapeutic devices came into being at an unprecedented pace, (Kassirer, 2005). In 1980, Congress enacted a series of laws designed to speed the translation of tax-supported basic research into useful new products – a process sometimes referred to as "technology transfer". The most important of these laws is known as the Bayh-Dole Act. Bayh-Dole enabled universities and small businesses to patent discoveries emanating from research sponsored by the National Institute of Health and then to grant exclusive licenses to drug companies, (Angell, 2004). Securing industry support is now the accepted norm on medical school campuses. Institutions encourage young researchers to seek out industry supporters to fund their research and pay their salaries (Kassirer, 2005).

As physician salaries fell and industry participation in the technology transfer process accelerated, our nation began to experience unprecedented cost restructuring of its medical system. The addition of a drug benefit to our overburdened Medicare system lit a match under the smoldering embers of an explosive situation and finger-pointing commenced. *Academic Medical Centers*

Academic medical centers (AMC) lie at the heart of the debate. The rest of the medical community looks to medical centers, their medical schools and affiliated hospitals for influential advice and support. Research shows that behaviors established during medical training programs persist into practice, (McCormick, 2001). Academic institutions are charged with the responsibility of educating clinicians, conveying information, skills and attitudes to medical students, residents and house staff and keeping the practicing physician's

knowledge base and skill sets current. Much of this education involves the use and testing of medications and thus the subsequent interaction with industry. It is this interaction which is the source of this discussion.

Literature Review

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New Theories

A clearer focus on the issues that surround the debate regarding interactions between pharmaceutical companies and physicians would best be served by looking at the flurry of literature that has sprung from publishers hands during the last five years. An exhaustive review of the issue was authored by Dr. Jerome Kassirer. In his book entitled, "On the Take, How Medicine's Complicity with Big Business Can Endanger Your Health" (2005). Kassirer (2005) looks at what he calls "the impossible-to-resolve dilemma" between a doctor's professional role and his or her personal responsibilities. He contends that the pharmaceutical industry's efforts to influence physicians must give us serious pause. He points out that as industry's marketing efforts increase so do the potential conflicts that arise within the relationship between physicians and industry. "Most physicians who are close to industry swear that they are not and could not be influenced by financial conflict of interest, vet this posture ignores what we know about human nature and the powerful influence of money" (Kassirer, p. xvi). He describes a myriad of promotional efforts and items that are made readily available to physicians; these include pens, note pads, reprints, books, trips, lectures, continuing medical education, medical meetings, consultative services, meals, financial grants and the off-label promotion of drugs. In fact, according to Kassirer, the industry spends approximately 21 billion dollars a year promoting and marketing its products. (Kassirer, 2005). He points out that all of the promotion and promotional items lure physicians into unconsciously making biased decisions regarding medicines that do not always place the patient's interests first. He proposes that it would be best for physicians to divest themselves of all relations with industry, but he admits that this may not be feasible or practical (p. 193). He concedes that a complete divestiture of the relationship could be

constructive scientific collaboration between physicians and industry" (p. 193). Kassirer admits he has no magic solution to the potential conflicts that exist in the relationship but recommends that at the very least all professional relationships with industry must be characterized by honesty, accountability, transparency, and openness. In the year prior to the publication of On the Take, another author, Marcia Angell, MD, released her commentary on the relationship between physicians and the pharmaceutical industry. Angell's book, entitled, "The Truth about the Drug Companies, How They Dece Us and What to Do about It" (Angell, 2004) claims that the pharmaceutical industry has straved far from its original high purpose of discovering and producing useful new drugs.

industry. Angell's book, entitled, "The Truth about the Drug Companies, How They Deceive Us and What to Do about It" (Angell, 2004) claims that the pharmaceutical industry has straved far from its original high purpose of discovering and producing useful new drugs. She describes the pharmaceutical industry as primarily a "marketing machine designed to sell drugs of dubious benefit, using its wealth and power to co-opt every institution that might stand in its way, including the U.S. Congress, the Food and Drug Administration, academic medical centers, and the medical profession itself" (Angell, 2004). For two decades Angell was Editor-In-Chief at the New England Journal of Medicine and writes that she witnessed firsthand the influence of the drug companies in many aspects of medicine. She watched as the companies exerted a level of control over the way research was conducted and reported that she says was troubling and bias-producing. She also claims to have witnessed the demise of physicians who maintained a "thread-bare but genteel" lifestyle and began to search for and find commercial opportunities in medicine. She claims that as drug company profits skyrocketed during the 1980s and 1990s, do did the companies political clout. According to Angell the relationship between providers and industry must change. In chapters four and five she suggests that companies produce too many me-too drugs and too

counterproductive especially in situations where the relationship involves a "creative and

few innovative ones. In chapter 11 she states that the FDA is too much in the thrall of the industry it regulates. In chapters six and nine she concludes that drug companies have too much control over clinical research on their own products. Angell is also has strong opinions regarding patents and other exclusive marketing rights that she says are undesirably long and too elastic and gives thorough examples of this in chapter ten. In chapter eight she says that drug companies have too much influence over medical education about their products and in chapters one, three and seven gives important information about research and development, marketing, and pricing that she believes is kept secret. She gives evidence in chapters one and 12 that drug prices are too high and too variable. She recommends a shift away from Me-Too to innovative drugs, a strengthening of the FDA, the creation of an institute to oversee clinical testing of drugs, a curb on marketing rights, removing drug companies from medical education, reasonable and uniform pricing and more financial transparency from the companies.

Angell also authored an editorial in the May 18, 2000 issue of The New England Journal of Medicine in which she discussed the extent to which academic medicine had become intertwined with the pharmaceutical and biotechnology industries. She elaborated on the benefits and the risks of the alliance. She stated that although most medical schools have guidelines to regulate financial ties between their faculty members and industry, the rules are generally quite relaxed and are likely to become even more so (Angell, 2000). While conceding that there may be some merit to the claim for basic research, she suggests that in most clinical research, including clinical trials, the technology is essentially already developed. She warns that academic medical institutions are growing increasingly dependent upon industry and offered several suggestions to remedy the situation. She suggests that

financial ties should be prohibited altogether, including equity interest and many of the writing and speaking engagements. Rules regarding conflicts of commitment should be enforced and hospitals should forbid drug company representatives from coming into the hospital. She concludes by saying that academic medicine depends more than ever on the public's trust and goodwill and if the public begins to perceive that medical centers and physicians are gaining inappropriately they will lose the public trust and confidence. In response to the charge for more evaluation and regulation, The American College of Surgeons, the American Society of Internal Medicine, the American Board of Internal Medicine and the European Federation of Internal Medicine wrote and published The Charter on Medical Professionalism in the February 2002 issue of the Annals of Internal Medicine (Sox, 2002). The charter consists of a brief introduction and rationale, three principles, and 10 commitments. The Charter is based on the following premise: Changes in health care delivery systems in countries throughout the industrialized world threaten the values of professionalism. It also states that conditions of medical practice are tempting physicians to abandon their commitment to the primacy of patient welfare. The Charter charges physicians with the principle of primacy of patient welfare, patient autonomy and social justice. It calls physicians to commit to honesty with patients, professional competence, quality of care, appropriate relations with patients, access to care, just distribution of finite resources, scientific knowledge, trust by managing conflicts of interest and commitment to professional responsibilities. In summary, the charter calls physicians to seek to confront the challenges inherent in the increasing dependence on market forces that seek to transform health care. Without directly addressing the potential conflicts of interest between pharmaceutical companies and physicians, it is clear that the Charter was written as

an over-riding call to physicians to examine conflicts that could compromise their first commitment, the patient.

In his discussion on the interactions between clinical or academic medicine and the pharmaceutical industry, Michael Jibson, Ph.D. points out that the realities of the relationship are complex (Jibson, 2006). According to Jibson, (2006), physicians are not immune to marketing tactics and the potential conflicts of interest they present. He also writes that there is a clear body of information that substantiates the notion that their prescribing habits are influenced by pharmaceutical company marketing even when they do not believe it is occurring. Unlike many other authors, Jibson suggests that all interaction with industry is not inherently corrupt or corrupting to any who have contact with company representatives. He states that total separation of physicians from industry is not only implausible and unwise but "fails to acknowledge the importance of industry contributions to our knowledge base" (Jibson, 2006, p.37), and does not distinguish among the various types of interactions that occur between physicians and industry. Jibson states, "in the modern world, neither clinical medicine and industry nor academic medicine and industry can survive independent of one another. Through a process of social evolution and policy design, each has a unique and crucial role to play in the advancement and delivery of health care," (Jibson, 2006, p.38). Recognition of this interdependency is essential to any discussion of the respective roles of these endeavors and to any resolution of the conflicts that arise between them (Jibson, 2006). Jibson shares the views of all other authors reviewed for this paper. He concludes that despite the enormity of the numbers involved in theses efforts, medical care inevitably culminates in a unique interaction between physician and a patient. The physician is charged with alleviating suffering and administering necessary medication to meet that end. Industry

is ultimately charged with a fiduciary obligation to their shareholders. Both entities converge on one point, and according to Jibson, it is on this point – the development and distribution of effective medications – that the ultimate conflict of goals and ethical standards collide. Jibson makes six recommendations that are designed to improve the process of more well defined, ethical interactions. First, there must be clear distinctions between educational and promotional programs. Second, institutions and organizations should be active in establishing promulgating, and enforcing clear and consistent policies regulating educational activities. Third, training programs must maintain control over all educational activities. Fourth, disclosure of financial arrangements should be clear, candid and complete. Fifth, training programs should include formal didactic and supervisory instruction on physician interactions with industry. Finally, there is not substitute for constant attention to personal integrity and professional rigor. Jibson concludes by saving, "The medical profession and pharmaceutical industry constitute essential components of modern medical care. Although they have fundamental differences in goals and ethical standards, the interests of the two groups overlap in significant areas and their collaboration benefits all concerned" (Jibson, 2006, p. 39).

The Director of Scientific Education and Public Communication at the Broad Institute of MIT and Harvard, Fintan Steele, wrote in a 2005 Commentary in *Cell*, "The bench and the clinic are no longer sustainable as disparate areas of study, although many practitioners of one or the other have yet to fully appreciate that or figure out how to merge the two enterprises" (Steele, 2005, p.972). Steele concludes that Pharma is convinced they are in the business of human health but it serves two masters; shareholders and scientific research and discovery. According to Steele, shareholders have little patience for unrealized dividends

and short returns. "A firm commitment to rigorous and necessary scientific research as the basis of future drug development may necessarily mean the loss of many current shareholders and the uncertainty regarding the arrival of more far-sighted investors" (Steele. 2006, p.972). Steele predicts that big pharma will ultimately have to downsize their stock performance expectations and reorganize by developing designer drugs aimed at specific disease states that will fill unmet medical needs in smaller, less lucrative markets. According to Steele this will require a complete restructuring of the industry led by individuals that understand disease mechanisms that mean smaller, better-focused clinical trails. He also suggests that pharmaceutical companies retool their marketing and sales groups. The new marketing and sales groups should be retooled into a true educational operation. How this would impact the need for reforms in the relationship between industry and medicine is unknown at this time. Would these changes eliminate or reduce the friction that active marketing seems to have generated within academic medical centers? Retooling marketing and sales forces means rethinking the entire rewards system (with its unforgiving emphasis on sales quotas) with the goal of providing a real understanding of how these drugs work, who should receive them, and how this should be determined. "Pharma is already hearing the footsteps of academia, which is rushing to fill the growing void in pharma's pipeline of drugs in the early stages of discovery and even in development. Pharma may be yielding some of this ground but, according to Steele, would do better to become an active partner with academia" (Steele, 2006.p. 973). If pharma is going to not only survive but thrive, Steele says it will have to "quickly respond to market forces, the expectations of shareholders and produce the kind of transparency and scientific excellence that the public demands" (Steele, 2006, p. 973).

Methodology

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Study Objective

The objective of this study was to measure attitudes and beliefs of surgery residents regarding interactions with pharmaceutical representatives during their training. More specifically, the intention of the study was to assess whether residents believed that physicians should be allowed to interact with industry representatives, whether the interactions were of value to the residents, whether policies should be maintained or amended regarding interactions and whether research funding for academic research should be allowed to continue. Resident responses to the questionnaire are calculated as a whole to determine the general beliefs and opinions of the entire group of residents plus responses for the first and second, plus third and fourth year residents were tabulated to determine whether opinions change during the residency program.

Student Survey Instrument

The 2-page anonymous questionnaire was developed based on literature review and prior consultation with medical staff at the institution. The survey was reviewed and consent was obtained from attending surgical staff before students were asked to complete the survey. Surveys were collected between February 8th and February 22nd, 2006. The overall response rate was 34/40 (85%). Each survey began with a short introduction that discussed the purpose and design of the survey, who would receive copies of the anonymous results, and instructions for completing the survey. The surveys were distributed on three occasions during regularly scheduled resident education programs and collected by the administrative assistant in the department.

Study Design, Setting and Participants

The survey (see Appendix A)) asked 40 Surgery Residents from a prominent West Coast Academic Medical Center 19 questions regarding their interactions with drug industry representatives. The surveys were answered anonymously and completed by each physician during a regularly scheduled residency training seminar. The residency year for each respondent was noted to determine if opinions changed during the course of their four year program. The survey contained six possible answers to each of the nine questions. The six possible responses were; Strongly Agree, Agree, Neutral, Disagree, Strongly Disagree or Not Observed.

The first nine questions were designed to determine attitudes regarding personal interactions with pharmaceutical representatives. Questions 10 and 11 were designed to determine resident's beliefs regarding departmental policy with regards to interactions with industry representatives. Questions 12 through 16 were to determine beliefs regarding regulations imposed on interactions with industry representatives and questions 17 through 19 were to determine beliefs regarding appropriate sources or research funding.

Main Outcomes Measures

Overall responses to the 19-question survey were calculated as a total of all responses regardless of residency year to determine surgical resident's attitudes regarding interactions with pharmaceutical representatives (see Tables 1-19). A subset analysis of responses to each of the 19 questions was performed to determine how opinions changed during residency training. First and second year residents (n=18) were assessed independently from third (n=6) and fourth year residents (n=10), (see Tables 20-38).

Sample Selection

The General Surgery Residency is a five-year clinical, didactic, and investigative program. Physicians participating in this high-profile residency program were chosen to participate in this survey because the length of their educational experience and broad range of academic and clinical expertise made them ideal respondents. The surgical residency program gives each physician numerous opportunities over their five-year program to interact with a wide variety of pharmaceutical representatives, academic and industry-based research staff, colleagues and patients. The overall intensity of the surgical resident's commitment to their academic program and clinical expertise presented the opportunity to gain valuable insights into the opinions and beliefs that were guided and molded during their surgical training. In addition, the institution has maintained a relatively open policy towards interactions with the pharmaceutical industry, thus providing residents the opportunity to form opinions and beliefs based on actual exposure to the companies and individuals that represent the pharmaceutical industry. Data Analysis

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The following tables are a compilation of the data collected from the survey. The tables present ratios and a percent of total responses for each question. A more detailed textual and graphical analysis of the data is presented later in this section. It should be noted that total responses to some of the questions vary slightly because in some situations not all questions were answered.

Table 1: Interactions with pharmaceutical representatives; details

| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
|-------------------|-------------------|-------------|-----------|-----------|----------------------|-----------------|--------------------|
| R1 & R2 | 3/18 (17%) | 11/18 (61%) | 2/18(11%) | 2/18(11%) | 0 | 0 | 18 |
| R3 | 1/6(17%) | 4/6(66%) | 1/6(17%) | 0 | 0 | 0 | 6 |
| R4 | 5/10(50%) | 4/10(40%) | 1/10(10%) | 0 | 0 | 0 | 10 |
| Overall | 9/34(26%) | 19/34(56%) | 4/34(12%) | 2/34(6%) | 0 | 0 | 34 |

Table 2: Interactions with pharmaceutical representatives; source of information

| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
|-------------------|-------------------|-------------|------------|----------|----------------------|-----------------|--------------------|
| R1 & R2 | 2/18 (11%) | 10/18 (55%) | 5/18(28%) | 1/18(6%) | 0 | 0 | 18 |
| R3 | 0 | 3/6(50%) | 3/6(17%) | 0 | 0 | 0 | 6 |
| R4 | 1/10(10%) | 7/10(70%) | 2/10(20%) | 0 | 0 | 0 | 10 |
| Overall | 3/34(9%) | 20/34(59%) | 10/34(29%) | 1/34(3%) | 0 | 0 | 34 |

| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
|-------------------|-------------------|------------|------------|-----------|----------------------|-----------------|--------------------|
| R1 & R2 | 1/18 (5%) | 5/18 (28%) | 10/18(56%) | 0 | 2/18 | 0 | 18 |
| | | | | | (11%) | | |
| R3 | 1/6(17%) | 2/6(33%) | 2/6(33%) | 1/6(17%) | 0 | 0 | 6 |
| R4 | 2/10(20%) | 4/10(40%) | 2/10(20%) | 2/10(20%) | 0 | 0 | 10 |
| Overall | 4/34(26%) | 11/34(32%) | 14/34(41%) | 3/34(9%) | 0 | 0 | 34 |

 Table 3: Interactions with pharmaceutical representatives; educational information

 Table 4: Interactions with pharmaceutical representatives; support

| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
|-------------------|-------------------|------------|-----------|----------|----------------------|-----------------|--------------------|
| R1 & R2 | 5/18 (28%) | 9/18 (50%) | 2/18(11%) | 1/18(5%) | 0 | 0 | 18 |
| R3 | 1/6(17%) | 3/6(50%) | 2/6(33%) | 0 | 0 | 0 | 6 |
| R4 | 6/10(60%) | 4/10(40%) | 0 | 0 | 0 | 0 | 10 |
| Overall | 12/34(35%) | 16/34(47%) | 4/34(12%) | 1/34(3%) | 0 | 0 | 34 |

 Table 5: Interactions with pharmaceutical representatives; conduct

| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
|-------------------|-------------------|-------------|---------|----------|----------------------|-----------------|--------------------|
| R1 & R2 | 8/18 (44%) | 10/18 (56%) | 0 | 0 | 0 | 0 | 18 |
| R3 | 1/6(17%) | 5/6(83%) | 0 | 0 | 0 | 0 | 6 |
| R4 | 8/10(80%) | 2/10(20%) | 0 | 0 | 0 | 0 | 10 |
| Overall | 17/34(50%) | 17/34(50%) | 0 | 0 | 0 | 0 | 34 |

| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
|-------------------|-------------------|------------|-------------|------------|----------------------|-----------------|--------------------|
| R1 & R2 | 1/18 (55%) | 9/18 (50%) | 6/18(33.5%) | 1/18(5.5%) | 0 | 0 | 18 |
| R3 | 0 | 2/6(33%) | 3/6(50%) | 1/6(17%) | 0 | 0 | 6 |
| R4 | 3/10(30%) | 6/10(60%) | 1/10(10%) | 0 | 0 | 0 | 10 |
| Overall | 4/34(12%) | 17/34(50%) | 10/34(29%) | 2/34(6%) | 0 | 1/34(3%) | 34 |

 Table 6: Interaction with pharmaceutical representatives; industry sponsored talks

 Table 7: Interaction with pharmaceutical representatives; sales items and journal articles

| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
|-------------------|-------------------|------------|------------|-----------|----------------------|-----------------|--------------------|
| R1 & R2 | 1/18 (5%) | 5/18 (28%) | 9/18(50%) | 3/18(17%) | 0 | 0 | 18 |
| R3 | 0 | 2/6(33%) | 3/6(50%) | 1/6(17%) | 0 | 0 | 6 |
| R4 | 3/10(30%) | 3/10(30%) | 4/10(40%) | 0 | 0 | 0 | 10 |
| Overall | 4/34(12%) | 10/34(29%) | 16/34(47%) | 4/34(12%) | 0 | 0 | 34 |

 Table 8: Interactions with pharmaceutical representatives; influence on prescriptive

practices

| ~ | I feel that in practices durin | | | try represen | itatives have | e not negativ | ely influenced my |
|-------------------|-----------------------------------|------------|-----------|--------------|----------------------|-----------------|--------------------|
| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
| R1 & R2 | 5/18 (28%) | 9/18 (50%) | 3/18(17%) | 1/18(5%) | 0 | 0 | 18 |
| R3 | 0 | 4/6(66%) | 2/6(33%) | 0 | 0 | 0 | 6 |
| R4 | 7/10(70%) | 2/10(20%) | 1/10(10% | 0 | 0 | 0 | 10 |
| Overall | 12/34(35%) | 15/34(44%) | 6/34(18%) | 1/34(3%) | 0 | 0 | 34 |

| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
|-------------------|-------------------|------------|-----------|----------|----------------------|-----------------|--------------------|
| R1 & R2 | 3/18 (17%) | 9/18 (50%) | 4/18(22%) | 1/18(5%) | 1/18(5%) | 0 | 18 |
| R3 | 0 | 3/6(50%) | 3/6(50%) | 0 | 0 | 0 | 6 |
| R4 | 6/10(60%) | 4/10(40%) | 0 | 0 | 0 | 0 | 10 |
| Overall | 9/34(26%) | 16/34(47%) | 7/34(21%) | 1/34(3%) | 1/34(3%) | 0 | 34 |

 Table 9: Interaction with pharmaceutical representatives; continued interaction

 Table 10: Departmental Policy; maintain current policies

| Residency Year | Strongly Agree | Agree | Neutral | Disagre e | Strongly Disagree | Not Observed | Total Responses |
|-------------------|-------------------|------------|-----------|--------------|----------------------|-----------------|--------------------|
| R1 & R2 | 5/18 (28%) | 9/18 (50%) | 2/18(11%) | 0 | 1/18(5.5%) | 1/18(5.5%) | 18 |
| R3 | 0 | 6/6(100%) | 0 | 0 | 0 | 0 | 6 |
| R4 | 4/10(40%) | 4/10(40%) | 2/10(20%) | 0 | 0 | 0 | 10 |
| Overall | 9/34(26%) | 19/34(56%) | 4/34(12%) | 0 | 1/34(3%) | 1/34(3%) | 34 |

 Table 11: Departmental Policy; benefit to the Department of Surgery

| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
|-------------------|-------------------|------------|-----------|-----------|----------------------|-----------------|--------------------|
| R1 & R2 | 5/18 (28%) | 9/18 (50%) | 1/18(5%) | 2/18(11%) | 0 | 1/18(5%) | 18 |
| R3 | 1/6(17%) | 3/6(50%) | 2/6(33%) | 0 | 0 | 0 | 6 |
| R4 | 5/10(50%) | 4/10(40%) | 1/10(10% | 0 | 0 | 0 | 10 |
| Overall | 11/34(32%) | 16/34(47%) | 4/34(12%) | 2/34(6%) | 0 | 1/34(3%) | 34 |

| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
|-------------------|-------------------|-----------|------------|-----------|----------------------|-----------------|--------------------|
| R1 & R2 | 3/18 (17%) | 3/18 | 9/18(50%) | 2/18(11%) | 0 | 1/18(5%) | 18 |
| | | (17%) | | | | | |
| R3 | 0 | 0 | 5/6(83%) | 1/6(17%) | 0 | 0 | 6 |
| R4 | 4/10(40%) | 2/10(20%) | 3/10(30%) | 0 | 0 | 1/10(10%) | 10 |
| Overall | 7/34(20%) | 5/34(15%) | 17/34(50%) | 3/34(9%) | 0 | 2/34(6%) | 34 |

 Table 12: Regulation; local and national regulation are adequate

 Table 13: Regulation; policies mandated only at local level

Question 13. Policies relating to interactions with the pharmaceutical industry should be mandated only at the institutional level.

| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
|-------------------|-------------------|------------|-----------|------------|----------------------|-----------------|--------------------|
| R1 & R2 | 2/18 (11%) | 6/18 (33%) | 4/18(22%) | 5/18(28%) | 1/18(6%) | 0 | 18 |
| R3 | 0 | 2/6(33%) | 0 | 4/6(67%) | 0 | 0 | 6 |
| R4 | 1/10(10%) | 3/10(30%) | 3/10(30%) | 3/10(30%) | 0 | 0 | 10 |
| Overall | 3/34(9%) | 11/34(32%) | 7/34(21%) | 12/34(21%) | 1/34(3%) | 0 | 34 |

 Table 14: Regulation; policies mandated at the federal level

| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
|-------------------|-------------------|------------|-----------|-----------|----------------------|-----------------|--------------------|
| R1 & R2 | 1/17 (6%) | 7/17 (41%) | 4/17(23%) | 1/17(6%) | 3/17(18%) | 1/17(6%) | 17 |
| R3 | 0 | 5/6(83%) | 0 | 1/6(17%) | 0 | 0 | 6 |
| R4 | 1/10(10%) | 1/10(10%) | 5/10(50%) | 2/10(20%) | 1/10(10%) | 0 | 10 |
| Overall | 2/33(6%) | 13/33(40%) | 9/33(27%) | 4/33(12%) | 4/33(12%) | 1/33(3%) | 33 |

| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
|-------------------|-------------------|------------|-----------|------------|----------------------|-----------------|--------------------|
| R1 & R2 | 3/18 (17%) | 3/18 (17%) | 4/18(22%) | 6/18(33%) | 2/18(11%) | 0 | 18 |
| R3 | 0 | 1/6(17%) | 1/6(17%) | 4/6(66%) | 0 | 0 | 6 |
| R4 | 1/10(10%) | 2/10(20%) | 2/10(20%) | 5/10(50%) | 0 | 0 | 10 |
| Overall | 4/34(12%) | 6/34(18%) | 7/34(20%) | 15/34(44%) | 2/34(6%) | 0 | 34 |

Table 15: Regulation; policies determined only by personal moral and ethical code

Table 16: Regulation; policies mandated by voluntary participation in pharmaceutical

regulatory agency

Question 16. Policies related to interactions with industry should be independently managed by industry voluntarily participating in organizations like the Pharmaceutical Research and Manufacturers of America (PhRMA). (PhRMA members voluntarily adhere to codes designed to regulate interactions with healthcare professionals.)

| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
|-------------------|-------------------|------------|------------|------------|----------------------|-----------------|--------------------|
| R1 & R2 | 1/18 (6%) | 4/18 (22%) | 6/18(33%) | 7/18(39%) | 0 | 0 | 18 |
| R3 | 0 | 1/6(17%) | 3/6(50%) | 2/6(33%) | 0 | 0 | 6 |
| R4 | 1/9(11%) | 1/9(11%) | 5/9(56%) | 2/9(22%) | 0 | 0 | 9 |
| Overall | 2/33(6%) | 6/33(18%) | 14/33(43%) | 11/33(33%) | 0 | 0 | 33 |

 Table 17: Research; companies should provide grants

Question 17. Pharmaceutical companies should continue to provide grants to investigators to conduct clinical or non-clinical research.

| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
|-------------------|-------------------|-------------|-----------|----------|----------------------|-----------------|--------------------|
| R1 & R2 | 7/18 (39%) | 10/18 (56%) | 1/18(5%) | 0 | 0 | 0 | 18 |
| R3 | 1/6(17%) | 3/6(50%) | 2/6(34%) | 0 | 0 | 0 | 6 |
| R4 | 3/9(33%) | 5/9(56%) | 1/9(11%) | 0 | 0 | 0 | 9 |
| Overall | 11/33(33%) | 18/33(55%) | 4/33(12%) | 0 | 0 | 0 | 33 |

 Table 18: Research; grants should come only from non-industry sources

| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
|-------------------|-------------------|-------|-----------|------------|----------------------|-----------------|--------------------|
| R1 & R2 | 1/18 (5.5%) | 0 | 4/18(22%) | 12/18(67%) | 1/18(5.5%) | 0 | 18 |
| R3 | 0 | 0 | 3/6(50%) | 3/6(50%) | 0 | 0 | 6 |
| R4 | 0 | 0 | 0 | 7/9(78%) | 1/9(11%) | 1/9(11%) | 9 |
| Overall | 1/33(3%) | 0 | 7/33(21%) | 22/33(67%) | 2/33(6%) | 1/33(3%) | 33 |

Table 19: Research; collaboration with industry expands clinical and scientific knowledge.

| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
|-------------------|-------------------|-------------|-----------|----------|----------------------|-----------------|--------------------|
| R1 & R2 | 5/18 (28%) | 11/18 (61%) | 2/18(11%) | 0 | 0 | 0 | 18 |
| R3 | 0 | 6/6(100%) | 0 | 0 | 0 | 0 | 6 |
| R4 | 4/9(44%) | 5/9(56%) | 0 | 0 | 0 | 0 | 9 |
| Overall | 9/33(27%) | 22/33(67%) | 2/33(6%) | 0 | 0 | 0 | 33 |

Interactions with Sales Representatives

Figures 1.1 and 1.2 give student responses to the statement, "Pharmaceutical representatives should be allowed to detail and interact with physicians at this institution". Overall responses regarding attitudes associated with interactions with pharmaceutical industry representatives were, 9/34 (26%) strongly agreed and 19/34 (56%) agreed that pharmaceutical representatives should be allowed to detail and interact with physicians. A minority of students 4/34 (12%) had a neutral response and 2/34 (6%) disagreed. Physician's opinions are not in agreement with opinions stated by Angell (2004) and Kassirer (2005) but are more closely aligned with Steele (2005) and Jibson (2006) that support the value and continuance of the relationship.

Figure 1.1: Representatives Should be Allowed to Detail and Interact

Question 1. Pharmaceutical representatives should be allowed to detail and interact with physicians at this institution.

| Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Observations |
|-------------------|-------|---------|----------|----------------------|-----------------|-----------------------|
| 9 | 19 | 4 | 2 | 0 | 0 | 34 |

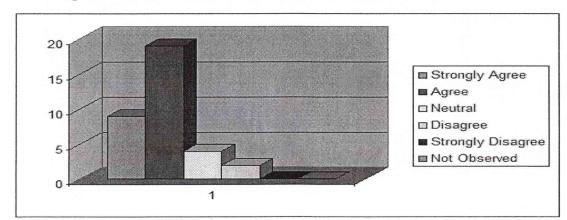


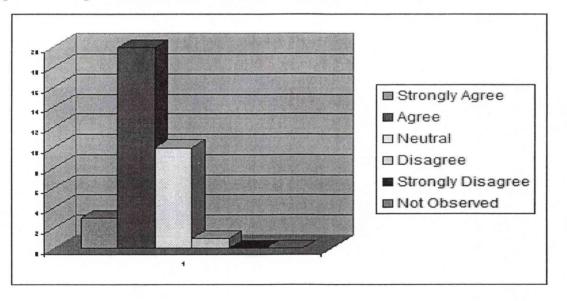
Figure 1.2: Representatives Should be Allowed to Detail and Interact

Figures 2.1 and 2.2 provide responses to the statement, "Representatives generally provide valuable information regarding their products." The majority of students felt that representatives generally provide valuable information, useful resources, and valuable support for departmental programs. As in question 1, these responses suggest that residents do not agree with assumptions made by Angell (2004) or Kassirer (2005).

Figure 2.1: Representatives Provide Valuable Product Information

| Question 2. R | epresentatives | generally | provide valua | ble informatio | n regarding the | eir products. |
|-------------------|----------------|-----------|---------------|----------------------|-----------------|-----------------------|
| Results: | | | | | | |
| Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Observations |
| 3 | 20 | 10 | 1 | 0 | 0 | 34 |

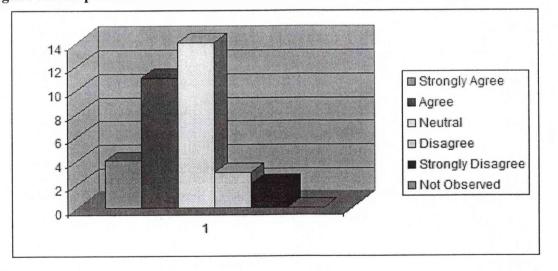




Residents were asked for their opinions regarding educational information and salesassociated literature that discusses pharmaceutical products and the diseases associated with the drugs. Figures 3.1 and 3.2 give the responses from surgical residents to this statement. A large number of physicians remained neutral on the issue (41%). Most (58%) agreed that the information and sales literature was valuable. These opinions run contrary to the opinions and observations of Angell (2004) and Kassirer (2005).

Figure 3.1: Representatives Provide Valuable Educational Information

| Question 3. F disease states | | | | ble education | al information i | related to the |
|---------------------------------|-------|---------|----------|----------------------|------------------|-----------------------|
| Results: | | | ~ | | - | - 1 |
| Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Observations |
| 4 | 11 | 14 | 3 | 2 | 0 | 34 |



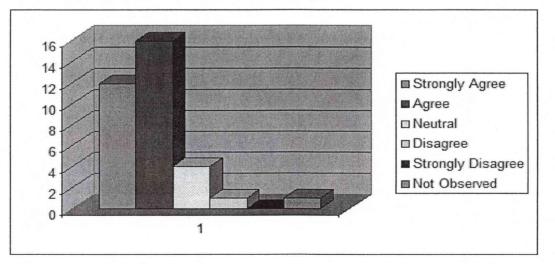
| Figure 3.2: Representative | s Provide | Valuable Educationa | l Information |
|----------------------------|-----------|---------------------|---------------|
|----------------------------|-----------|---------------------|---------------|

Most residents, (82%), agreed that representatives provide valuable support for departmental programs, see Figures 4.1 and 4.2. Unfortunately, this question did not address the sources of support that residents considered valuable, but it can be assumed, due to the author's familiarity with the department, that means of support include meals, books, research grants and funding for departmental programs. Angell (2000) and McCormick (2001) suggested that all forms of meals, books and funding result in an inappropriate alliance between medicine and industry and compromise medicine's academic and clinical objectivity and independence. Apparently, at some level, these residents do not share the opinions of Angell and McCormick.

| Figure 4.1: Represent | tatives Provide | Valuable Support |
|-----------------------|-----------------|------------------|
|-----------------------|-----------------|------------------|

| Question 4. R | epresentatives | provide val | uable suppor | t for departme | ental programs. | |
|-------------------|----------------|-------------|--------------|----------------------|-----------------|-----------------------|
| Results: | | | | | | |
| Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Observations |
| 12 | 16 | 4 | 1 | 0 | 1 | 34 |

Figure 4.2: Representatives Provide Valuable Support

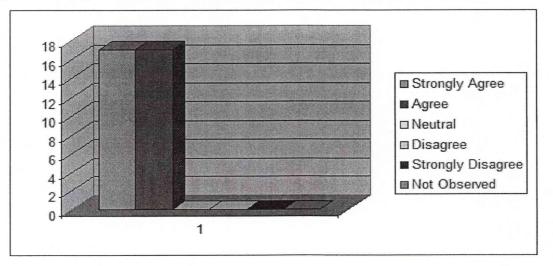


All residents (100%) felt that representatives conducted themselves in a professional, appropriate manner, see Figures 5.1 and 5.2. Though professional conduct was not addressed in the literature as a consideration in the relationship between medicine and industry it was included in the survey to determine if inappropriate behaviors had been observed in the academic medical center. Inappropriate or unprofessional behaviors on the part of one or two representatives can "color" the responses to the industry as a whole. According to responses, representatives of industry have generally conducted themselves in a professional manner.

Figure 5.1: Representatives Conduct Themselves in a Professional Manner

| Question 5. R | Representatives | generally o | conduct them | selves in a pro | ofessional, app | propriate manner. |
|-------------------|-----------------|-------------|--------------|----------------------|-----------------|-----------------------|
| Results: | | | | | | |
| Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Observations |
| 17 | 17 | 0 | 0 | 0 | 0 | 34 |





According to the results of Question 6, the majority (62%) of all surgery residents either strongly agreed or agreed that industry sponsored talks were generally educational and well balanced. A small number of all residents disagreed (6%) and 29% remained neutral. Kassirer (2005) and Angell (2004) claim that industry sponsored talks are not educational but purely promotional. The surgery residents seem to disagree with Kassirer and Angell or remained neutral, probably due to a lack of experience with the educational venues.

Figure 6.1: Industry sponsored talks are educational.

| Question 6 | . Industry spo | nsored talks | have general | lly been educ | ational and we | ell balanced. |
|-------------------|----------------|--------------|--------------|----------------------|-----------------|-----------------------|
| Results: | | | | | | |
| Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Observations |
| 4 | 17 | 10 | 2 | 0 | 1 | 34 |

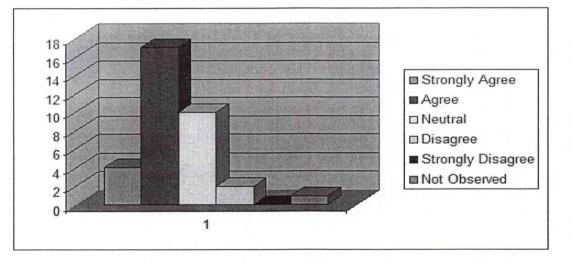


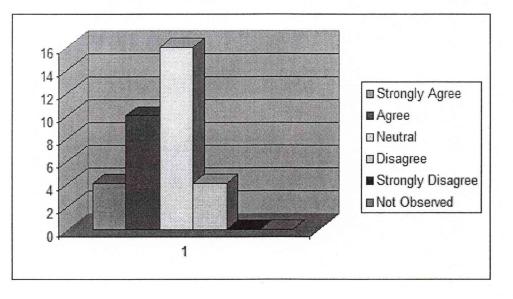
Figure 6.2: Industry sponsored talks are educational.

Answers to question 7 reveal either ambivalence or disinterest in the issue related to information in the form of sales items and journal articles. The answer sought to assess the value that residents placed on the information used by companies to discuss their products. According to all 34 residents surveyed, 41% found the information useful and 47% remained neutral on the issue. Strong opinions for or against the items were not expressed.

Figure 7.1: Sales Items and Journal Articles are Well Balanced and Useful

| Question 7. / well balanced | | | | | mal articles a | are generally |
|--------------------------------|-------|---------|----------|----------------------|-----------------|-----------------------|
| Results: | | | | | | |
| Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Observations |
| 4 | 10 | 16 | 4 | 0 | 0 | 34 |





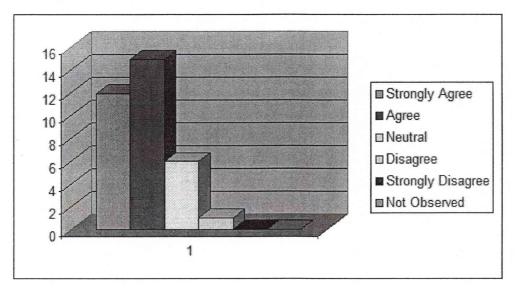
Most residents (79%) felt their prescriptive habits or decisions had not been negatively influenced by pharmaceutical representatives. A few residents remained neutral (18%) and one individual (3%) disagreed. Whether pharmaceutical influence on prescribing habits is subliminal (Wazana, 2000) or overt, surgery residents in this survey felt their decisions were not inappropriately influenced by industry representatives.

Figure 8.1: Interactions with Representatives Has Not Negatively Influenced

Prescriptive Practices

| Question 8. / influenced my | | | | | entatives ha | ve not negatively |
|--------------------------------|-------|---------|----------|-------------------|-----------------|-----------------------|
| Results: | | | | | | |
| Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Observations |
| 12 | 15 | 6 | 1 | 0 | 0 | 34 |

Figure 8.2: Interactions with Representatives Has Not Negatively Influenced



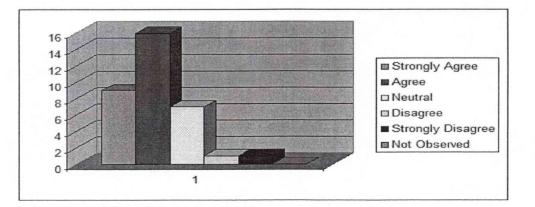
Prescriptive Practices

When asked whether residents will continue to interact with industry after graduation, the majority of physicians said yes (73%). A small number of residents remained undecided, or neutral (21%) and two physicians (6%) said no, they would not interact with industry after graduation. There may be a correlation between the percentage of residents that agreed that industry should be allowed to interact with physicians at the academic medical center (Question 1) and the percentage of residents (73%) that plan to continue to interact with industry after graduation. A correlation between behaviors learned during medical training and physician behavior following training have been presented in the literature (Jibson, 2006) and studies show that behaviors adopted during medical training determine physician behavior after the completion of residency programs. Whether there is a direct correlation between these two findings should be studied.

Figure 9.1: Will Continue to Interact with Industry

| | | | ny residency pr putical industry. | | ntinue to interac | ct with |
|-------------------|-------|---------|--------------------------------------|----------------------|-------------------|-----------------------|
| Results: | | | | | | |
| Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Observations |
| 9 | 16 | 7 | 1 | 1 | 0 | 34 |

Figure 9.2: Will Continue to Interact with Industry



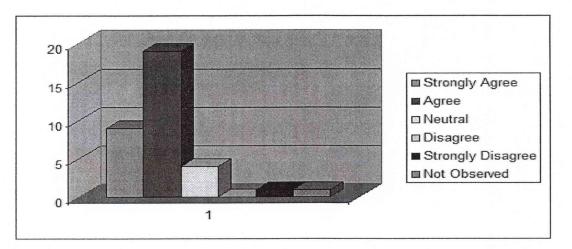
Departmental Policy

Overall responses to questions regarding departmental policy showed that 9/34 (26%) strongly agreed that the Department of Surgery should maintain their current policies regarding interactions with pharmaceutical companies and 19/34 (56%) agreed. Again, a minority of students 4/34 (12%) remained neutral on the same question while 1/34 (3%) strongly disagreed and 1/34 (3%) chose a response of not observed. Studdert points out that "The amount of regulatory, self-regulatory, and prosecutorial activity that is currently focused on conflicts of interest in the interaction between physicians and pharmaceutical companies is remarkable", (Studdert, 2004, p. 1898). Responses to this question indicate that residents would prefer self-regulation over national or federal regulation. This is consistent with the medical profession's historical determination to remain self regulated.

Figure 10.1: Maintain Current Policies

| Question 10. interactions w | | | | uld maintain | their current | t policies regarding |
|--------------------------------|-------|---------|----------|----------------------|-----------------|-----------------------|
| Results: | | | | | | |
| Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Observations |
| 9 | 19 | 4 | 0 | 1 | 1 | 34 |



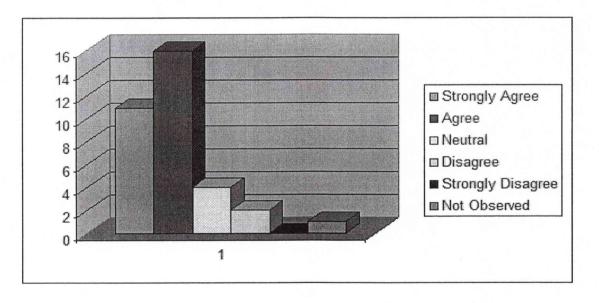


Residents were overwhelmingly positive regarding their interactions with pharmaceutical representatives. When asked the question whether the Department of Surgery benefited from their professional interactions with individuals in the pharmaceutical industry (question 11) 79% of residents either strongly agreed or agreed, 12% were neutral, 6% disagreed and 3% abstained.

Figure 11.1: Surgery Department has benefited from interaction with industry.

| Question 11. interactions wit | | | | | from their pro | fessional |
|----------------------------------|-------|---------|----------|----------------------|-----------------|-----------------------|
| Results: | | | | | | |
| Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Observations |
| 11 | 16 | 4 | 2 | 0 | 1 | 34 |

Figure 11.2: Surgery Department has benefited from interaction with industry.



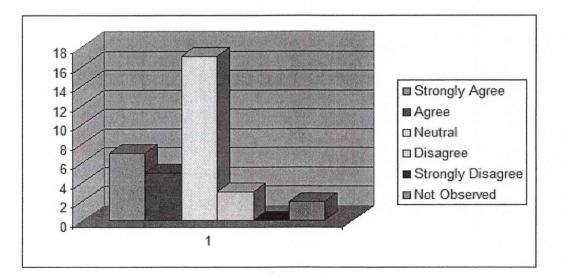
Regulation

Of the five questions regarding regulation of the relationship between the Surgery Department and the pharmaceutical industry the majority of students remained neutral, 17/34 (50%) on the question whether current regulations imposed on the pharmaceutical industry at local and national levels are adequate. A smaller proportion of total student responses showed strong agreement or agreement 12/34 (35%) with the same question. A small number of students disagreed, 3/34 (9%) with current regulatory policy and a few, 2/34 (6%) chose not observed as a response.

Figure 12.1: Current Regulations are Adequate

| Question ' levels are a | | regulations | imposed on the | e pharmaceutic | al industry at loc | al and national |
|----------------------------|-------|-------------|----------------|----------------------|--------------------|-----------------------|
| Results: | | 1 | | | | |
| Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Observations |
| 7 | 5 | 17 | 3 | 0 | 2 | 34 |

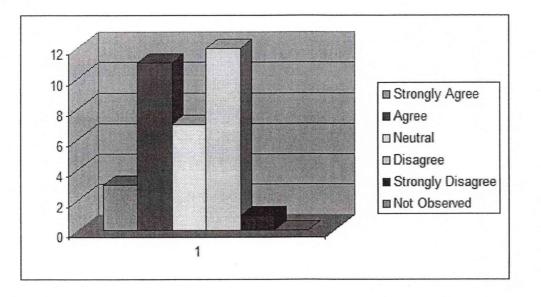
Figure 12.2: Current Regulations are Adequate



A great deal of ambivalence was observed in the overall physician responses to policyrelated questions. When asked whether policies relating to interactions with the pharmaceutical industry should be mandated only at the institutional level, the majority of physicians (41%) said they felt policies should be mandated at the institutional level, but 21% were neutral and 24% disagreed. There apparently exists a wide variety of opinion or experience related to the party that should be responsible for setting policy.

Figure 13.1: Policies Should be Mandated at the Institutional Level

| Question 13. P be mandated on | | | | /ith the phar | rmaceutical i | ndustry should |
|----------------------------------|-------|---------|----------|----------------------|-----------------|-----------------------|
| Results: | | | | | | |
| Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Observations |
| 3 | 11 | 7 | 12 | 1 | 0 | 34 |

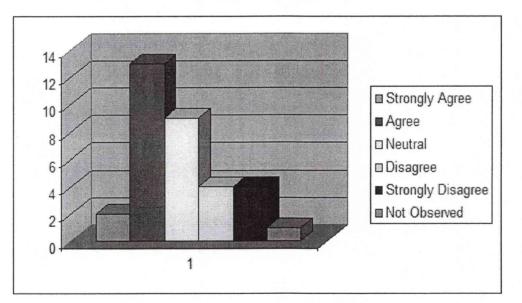


Physicians responded in much the same manner when asked if policies should be mandated at a federal level. The majority (46%) said yes, 27% remained neutral and 24% said no. Physicians appear to be uncertain about who should mandated policy.

Figure 14.1: Policies Should be Mandated at the Federal Level

| Question 14. | Policies relate | d to interac | tions with ind | lustry should l | be mandated a | at the federal level. |
|-------------------|-----------------|--------------|----------------|----------------------|-----------------|-----------------------|
| Results: | | | | | | |
| Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Observations |
| 2 | 13 | 9 | 4 | 4 | 1 | 33 |



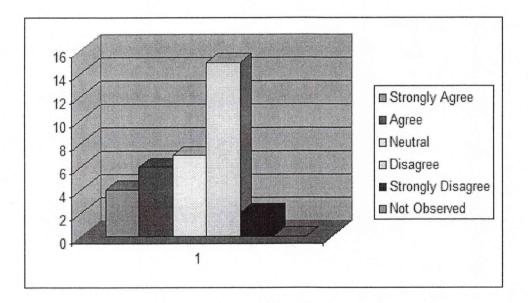


When asked whether policy decisions should be left up to the physician's personal code of ethics the majority of students said no (50%), 30% said yes and 20% remained neutral on the question.

Figure 15.1: Policies Should be Determined by Personal Moral Code

| Question 15. personal, ethic | | | | ustry should | only be detern | nined by the |
|---------------------------------|-------|---------|----------|----------------------|-----------------|-----------------------|
| Results: | | | | | | |
| Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Observations |
| 4 | 6 | 7 | 15 | 2 | 0 | 34 |



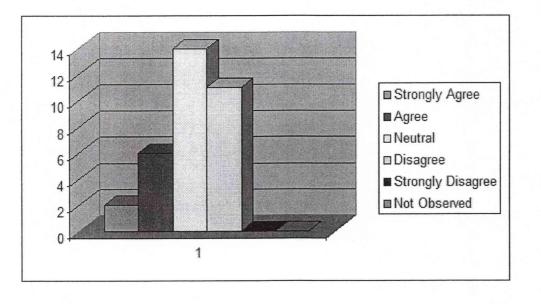


The final question related to policies produced the largest number of neutral responses of any question posed to residents. It is apparent that many residents are not aware of the Pharmaceutical Manufacturers of America (PhRMA) organization referred to in the question, or they have not had the opportunity to research the many regulatory options available.

Figure 16.1: Policies Determined by Voluntary Regulatory Agencies

| industry volunt | arily participati of America (P | ng in organ hRMA). (P | izations like t hRMA memb | the Pharmace | eutical Resear | ntly managed by ch and des designed to |
|-------------------|------------------------------------|--------------------------|------------------------------|----------------------|-----------------|--|
| Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Observations |
| 2 | 6 | 14 | 11 | 0 | 0 | 33 |

Figure 16.2: Policies Determined by Voluntary Regulatory Agencies



38

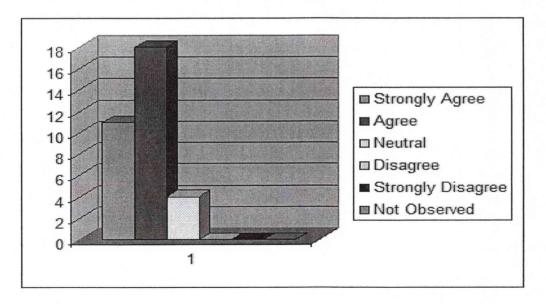
Research

The most definitive answers across all questions asked in the survey were in regards to research funding. When all students (regardless of residency year) were asked if pharmaceutical companies should continue to provide grants to investigators to conduct clinical or non-clinical research, 11/33 (33%) strongly agreed and 18/33 (55%) agreed. A small number of students, 4/33 (12%) remained neutral and no one disagreed or strongly disagreed.

Figure 17.1: Companies Should Continue to Provide Grants

| Question 17. investigators | | | | | to provide g | rants to |
|----------------------------|-------|---------|----------|----------------------|-----------------|-----------------------|
| Results: | | | | | | |
| Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Observations |
| 11 | 18 | 4 | 0 | 0 | 0 | 33 |

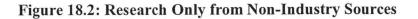


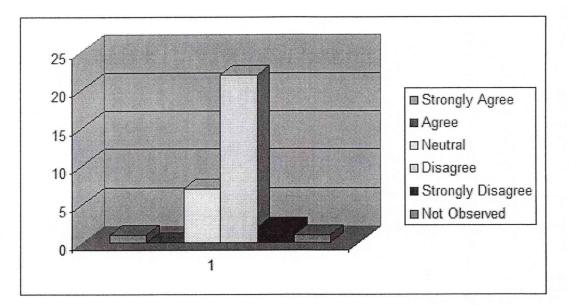


When all responses were tallied, the majority, 24/33 (73%) of students, regardless of residency year, disagreed with the statement that research funding should only come from non-industry sources. The majority of all residents believed that research funding should continue to come from industry sources.

Figure 18.1: Research Only from Non-Industry Sources

| Question 18. R | esearch f | unding sh | ould only be | e provided fi | rom non-indu | istry sources. | |
|----------------|-----------|-----------|--------------|---------------|--------------|----------------|----|
| Results: | | | | | | | |
| Strongly | Agree | Neutral | Disagree | Strongly | Not | Total | |
| Agree | | | | Disagree | Observed | Observations | |
| 1 | 0 | 7 | 22 | 2 | 1 | | 33 |



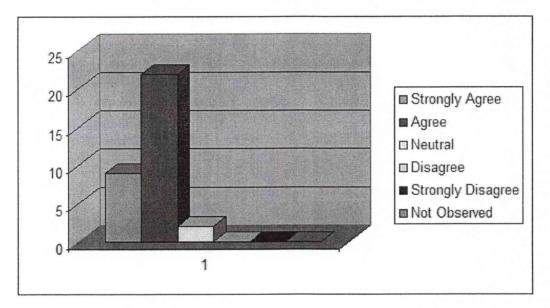


A large majority, 31/33 (94%) of all residents felt that research conducted in conjunction with the pharmaceutical industry generally plays a productive role in expanding clinical and scientific knowledge.

Figure 19.1: Research with Industry Expands Clinical and Scientific Knowledge

| | | | d in conjunctior cal and scienti | | maceutical indus | stry generally plays |
|-------------------|-------|---------|-------------------------------------|----------------------|------------------|-----------------------|
| Results: | | | | | | |
| Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Observations |
| 9 | 22 | 2 | 0 | 0 | 0 | 33 |

Figure 19.2: Research with Industry Expands Clinical and Scientific Knowledge



Resident Opinions Change Over the Course of Their Training

Survey data suggests that surgery resident attitudes regarding interactions with industry change during their four year residency. The data that follows is a subset analysis of the opinion survey discussed above. To determine how resident attitudes changed over the course of their training, the resident's educational year was noted on their survey and survey results for each of the 19 questions were recalculated to reflect responses based upon residency year. First and second year resident responses were combined and reported in the data as R1s & R2s. Third year resident responses were reported in the data as R3s and fourth year resident responses were reported as R4s.

A clear majority, 9/10 (90%) of all fourth year residents either agreed or strongly agreed that pharmaceutical representatives should be allowed to detail and interact with physicians at their institution. Only one student, 1/10 (10%) remained neutral and no one either disagreed or strongly disagreed. A smaller number of first and second year residents, 14/18 (78%) agreed or strongly agreed to the same question. Of the third year residents, 5/6 (83%) either agreed or strongly agreed that representatives should be allowed to detail and interact with physicians. All fourth year residents 10/10 (100%) responded favorably to eight of the nine questions related to interactions with industry.

During the course of this subset analysis it will become clear that resident attitudes do change over the course of their training. Responses to some questions, such as question number one show that attitudes and opinions shift only slightly, but answers to a majority of the 19 questions seem to indicate that resident's opinions shift *in favor* of interaction with industry over the course of their training. Explanations for the shift in attitude were not addressed in this survey. An explanation, that would be supported by the currently available literature

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would suggest the change in attitudes are the result of the increased awareness of the convergence of interests between academic medicine and industry as it relates to research interests that become a key component of the clinical academician's career.

Figure 20.1: Representatives Should be Allowed to Detail and Interact

Question 1. Pharmaceutical representatives should be allowed to detail and interact with physicians at this institution. **Results:** Strongly Agree Neutral Disagree Strongly Not Total Residency Observed Disagree Responses Year Agree 2 2 0 18 1 (R1/R2) 3 11 0 0

1

1

0

0

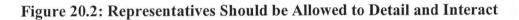
0

0

0

6

10



4

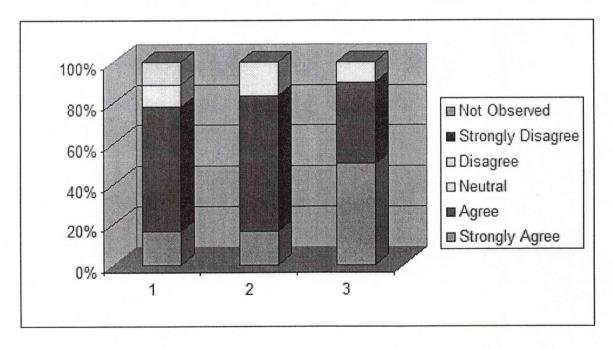
4

2 (R3)

3 (R4)

1

5

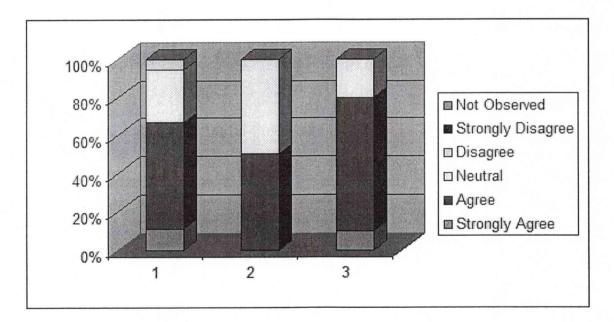


Responses to question two indicate a slight increase in favorable responses regarding the usefulness or value of information related to company products. Favorable opinions on the question for R1 & R2 vs. R3 and R4 residents were 66%, 50% and 80% respectively.



| Question 2. Re | presentative | s genera | ally provid | e valuable ir | nformation r | egarding the | ir products. |
|-------------------|-------------------|----------|-------------|---------------|----------------------|-----------------|--------------------|
| Results: | | | | | | | |
| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
| 1 (R1/R2) | 2 | 10 | 5 | 1 | 0 | 0 | 18 |
| 2 (R3) | 0 | 3 | 3 | 0 | 0 | 0 | 6 |
| 3 (R4) | 1 | 7 | 2 | 0 | 0 | 0 | 10 |



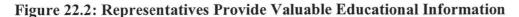


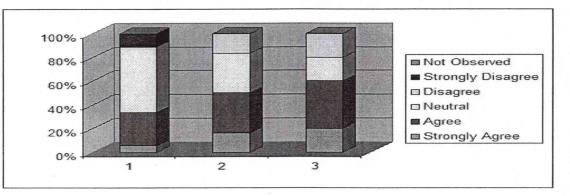
Responses to question 3 were similar to the first two questions and indicate that the longer residents are in their program the more valuable they believe educational materials become. Opinions of R1 & R2 vs. R3s and R4s were 33%, 50% and 60% respectively. The only negative response relating to interactions with industry was from 2/10 (20%) of fourth year residents that said they did not believe that representatives provided valuable educational information related to the disease states associated with their products.

An explanation for the shift in favorable opinion regarding the acceptability or worth of industry interaction from first to fourth year residents is not addressed in this survey but should be studied further. The potential importance of this observation and the impact it will have on clinical practice and collaboration between medicine and industry can only be elucidated by further controlled studies but will be woven into concluding comments later in this paper.

Figure 22.1: Representatives Provide Valuable Educational Information

| Question 3. <i>R</i> to the disease s | | | | | e educationa | al informatio | on related |
|--|-------------------|-------|---------|----------|----------------------|-----------------|--------------------|
| Results: | | | | | | | |
| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
| 1 (R1/R2) | 1 | 5 | 10 | 0 | 2 | 0 | 18 |
| 2 (R3) | 1 | 2 | 2 | 1 | 0 | 0 | 6 |
| 3 (R4) | 2 | 4 | 2 | 2 | 0 | 0 | 10 |



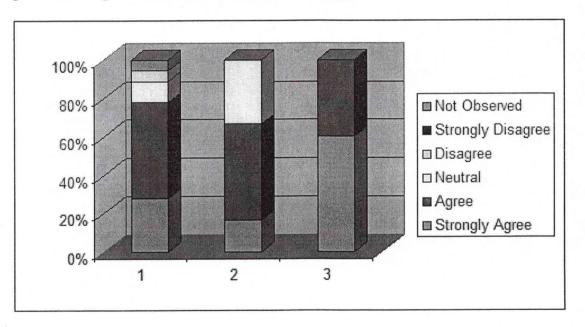


Responses to question four indicate that the longer residents are in their surgery program the more valuable they consider support from industry for departmental programs. All (100%) R4s agreed on the value of support, versus 78% and 67% of the R1s/R2s and R3s.

| Figure 23.1: Representatives | Provide Va | luable Support |
|------------------------------|------------|----------------|
|------------------------------|------------|----------------|

| Question 4. Re | presentative | s provide | e valuable | support for | department | al programs | |
|-------------------|-------------------|-----------|------------|-------------|-------------------|-----------------|--------------------|
| Results: | | | | | | | |
| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
| 1 (R1/R2) | 5 | 9 | 2 | 1 | 0 | 1 | 18 |
| 2 (R3) | 1 | 3 | 2 | 0 | 0 | 0 | 6 |
| 3 (R4) | 6 | 4 | 0 | 0 | 0 | 0 | 10 |

Figure 23.2: Representatives Provide Valuable Support

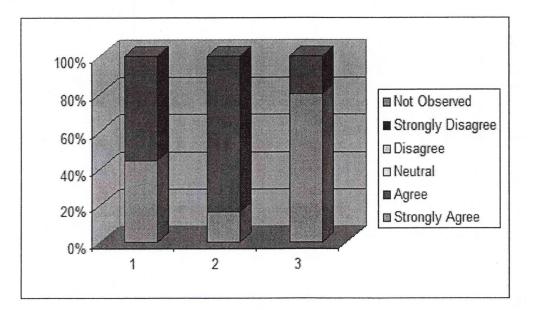


Everyone, regardless of residency year believed that industry representatives conduct themselves in a professional manner. It is important to note that this question regarding conduct was included in the survey to determine if residents had been exposed to aggressive or inappropriate sales behaviors. In the financially competitive world of pharmaceutical sales it is not uncommon to encounter sales representatives that can be "pushy or obnoxious". Encounters with representatives "acting badly" could negatively influence responses regarding *all* industry representatives.

Figure 24.1: Representatives Conduct Themselves in a Professional Manner

| Question 5. Re manner. | presentative | s genera | ally condu | ct themselve | es in a profe | ssional, app | oropriate |
|---------------------------|-------------------|----------|------------|--------------|----------------------|-----------------|--------------------|
| Results: | | | | | | | |
| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
| 1 (R1,R2) | 8 | 10 | 0 | 0 | 0 | 0 | 18 |
| 2 (R3) | 1 | 5 | 0 | 0 | 0 | 0 | 6 |
| 3 (R4) | 8 | 2 | 0 | 0 | 0 | 0 | 10 |

Figure 24.2: Representatives Conduct Themselves in a Professional Manner

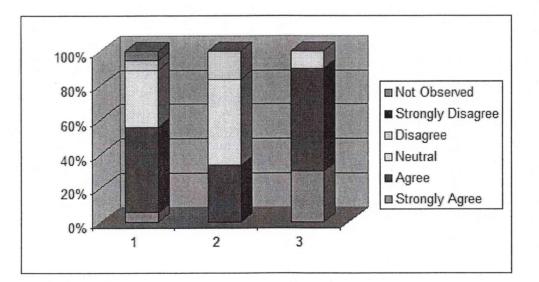


Over the course of their surgical residency opinions shifted slightly, indicating that residents felt industry-sponsored talks or educational programs were generally well balanced. Again, the largest proportion of favorable responses came from fourth year residents (90%). This may indicate that these individuals have had more opportunity to attend talks or that their opinions have changed due to increased exposure to the educational programs. Of the R1/R2s and R3s responses 55% and 33% agreed on the educational value and balance of the programs.

Figure 25.1: Industry Talks are Educational and Well Balanced

| Question 6. Inc | lustry talks h | ave beel | n educatio | onal and ger | nerally well b | balanced. | |
|-------------------|-------------------|----------|------------|--------------|----------------------|-----------------|--------------------|
| Results: | | | | | | | |
| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
| 1 (R1,R2) | 1 | 9 | 6 | 1 | 0 | 1 | 18 |
| 2 (R3) | 0 | 2 | 3 | 1 | 0 | 0 | 6 |
| 3 (R4) | 3 | 6 | 1 | 0 | 0 | 0 | 10 |

Figure 25.2: Industry Talks are Educational and Well Balanced



A larger proportion of fourth year residents felt that information in the form of sales items and journal articles were generally well balanced and useful sources of information. It is uncertain why attitudes changed, particularly in the fourth year of residency. To objectively answer this question would require further study. Whereas 33% of the first, second and third year residents found sales items and journal articles helpful, a clear majority (60%) of all fourth year residents found the items helpful.

Figure 26.1: Sales Items are Generally Useful Sources of Information

| Question 7. Info balanced and us | | | | ems and jou | ırnal articles | are general | ly well |
|-------------------------------------|-------------------|-------|---------|-------------|----------------------|-----------------|--------------------|
| Results: | | | | | | | |
| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
| 1 (R1/R2) | 1 | 5 | 9 | 3 | 0 | 0 | 18 |
| 2 (R3) | 0 | 2 | 3 | 1 | 0 | 0 | 6 |
| 3 (R4) | 3 | 3 | 4 | 0 | 0 | 0 | 10 |

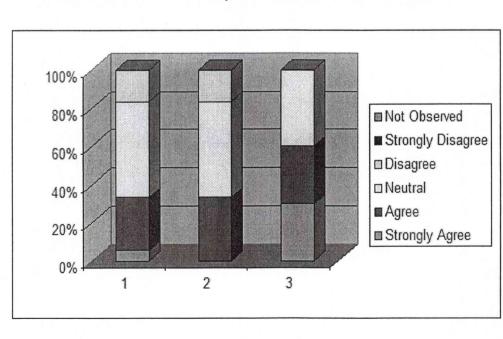


Figure 26.2: Sales Items are Generally Useful Sources of Information

The survey also attempted to determine whether residents believed their prescriptive practices were negatively influenced by industry during the course of their education. The majority of fourth year residents (90%) said they did not believe that industry negatively influenced their prescriptive practices during their four years of residency versus 78% of first and second year students and 66% of third year students. Again, opinions appear to have changed over the course of their training.

Figure 27.1: Interactions Have Not Negatively Influenced Prescribing Habits

| Question 8. I feinfluenced my pr | | | | | sentatives ha | ave not nega | atively |
|----------------------------------|-------------------|-------|---------|----------|----------------------|-----------------|--------------------|
| Results: | | | | | | | |
| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
| 1 (R1/R2) | 5 | 9 | 3 | 1 | 0 | 0 | 18 |
| 2 (R3) | 0 | 4 | 2 | 0 | 0 | 0 | 6 |
| 3 (R4) | 7 | 2 | 1 | 0 | 0 | 0 | 10 |

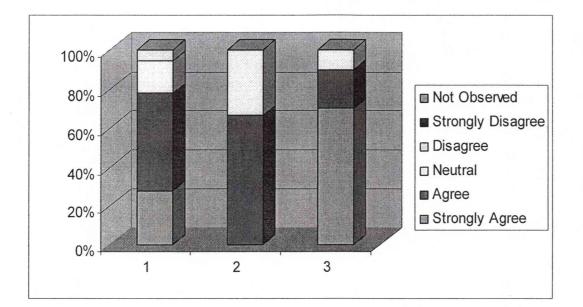


Figure 27.2: Interactions Have Not Negatively Influenced Prescribing Habits

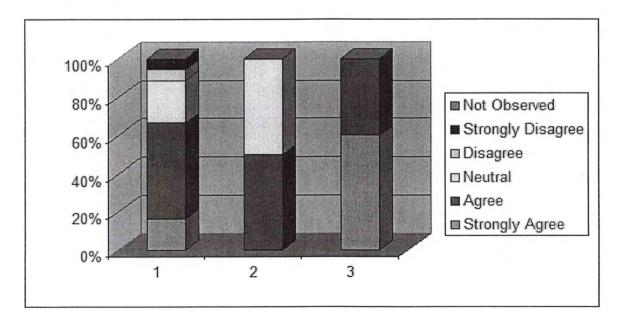
50

The percentage of favorable opinions related to interactions with industry representatives increased with each year of residency. Fourth year residents were twice as likely to allow industry representatives to detail their drugs and interact with physicians than were their first, second or third year counterparts. All, 10/10 (100%) fourth year residents stated they would continue to interact with industry at the conclusion of their residency program versus 12/18 (67%) of first and second year residents and 3/6 (50%) of third year residents.

Figure 28.1: Will Continue to Interact with Representatives

| Question 9. Upon representatives fro | | | | gram I will co | ntinue to inte | ract with | |
|---|-------------------|-------|---------|----------------|----------------------|-----------------|--------------------|
| Results: | | | | | | | |
| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
| 1 (R1/R2) | 3 | 9 | 4 | 1 | 1 | 0 | 18 |
| 2 (R3) | 0 | 3 | 3 | 0 | 0 | 0 | 6 |
| 3 (R4) | 6 | 4 | 0 | 0 | 0 | 0 | 10 |





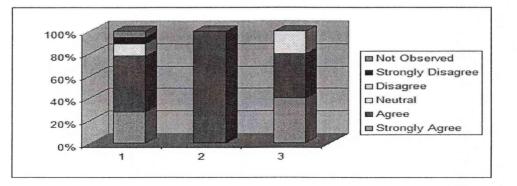
Departmental Policy and Regulation

Only a few major medical centers in the nation have policies that regulate student interactions with industry. Neither the medical center nor the Department of Surgery that participated in this study has policies that guide or speak to interactions with industry. This medical school and other major medical centers like it have allowed individual departments to develop, implement and manage policies that relate only to members of each applicable department. The Surgery Department at the institution surveyed has continued an open, collaborative relationship with industry that has allowed for industry support of educational conferences. Responses to the seven survey questions related to policy and regulation indicate that the majority, 28/34 (82%) of students (regardless of residency year) believe the Department of Surgery should maintain their current policies regarding interactions with pharmaceutical companies. The majority of first, second, third and fourth year residents agreed on this point.

| Figure 29.1: The Department Should Maintai | 1 Current Policies |
|--|--------------------|
|--|--------------------|

| Question 10. The interactions with | | | | uld maintai | n their curre | nt policies r | egarding |
|------------------------------------|-------------------|-------|---------|-------------|----------------------|-----------------|--------------------|
| Results: Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
| 1 (R1R2) | 5 | 9 | 2 | 0 | 1 | 1 | 18 |
| 2 (R3) | 0 | 6 | 0 | 0 | 0 | 0 | 6 |
| 3 (R4) | 4 | 4 | 2 | 0 | 0 | 0 | 10 |

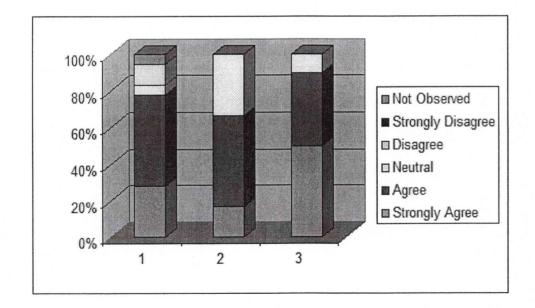
Figure 29.2: The Department Should Maintain Current Policies



When residents were asked whether they believed the Department of Surgery had generally benefited from their professional interaction with individuals in the pharmaceutical industry the majority (90%) of fourth year residents said yes. Again, a shift in opinion was observed during the fourth year of residency. Only 78% of first and second year residents said yes and 67% of third year residents responded favorably.

Figure 30.1: The Department has Benefited from Interactions with Industry.

| Question 11. The interactions with | | | | | | n their profe | ssional |
|------------------------------------|-------------------|-------|---------|----------|----------------------|-----------------|--------------------|
| Results: | | | | | | | |
| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
| 1 (R1/R2) | 5 | 9 | 1 | 2 | 0 | 1 | 18 |
| 2 (R3) | 1 | 3 | 2 | 0 | 0 | 0 | 6 |
| 3 (R4) | 5 | 4 | 1 | 0 | 0 | 0 | 10 |



| Figure 30.2: The Department has Benefited from Interacti | ons with Industry. |
|--|--------------------|
|--|--------------------|

When asked whether current regulations imposed on the pharmaceutical industry at local and national levels are adequate, 60% of fourth year residents said yes. Only 34% of the first and second year residents agreed and no one (0%) of third year residents agreed that regulations were adequate. A large number of individuals in each of the classes remained neutral (or had no opinion) on the matter, indicating either a lack of information or interest in the subject. Again, a shift in opinion seems to have occurred during the fourth year of residency.

Figure 31.1: Current Regulations are Adequate

| Question 12. C national levels an | | | posed on | the pharma | ceutical ind | ustry at loca | l and |
|--------------------------------------|-------------------|-------|----------|------------|----------------------|-----------------|--------------------|
| Results: | | | | | | | |
| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
| 1 (R1/R2) | 3 | 3 | 9 | 2 | 0 | 1 | 18 |
| 2 (R3) | 0 | 0 | 5 | 1 | 0 | 0 | 6 |
| 3 (R4) | 4 | 2 | 3 | 0 | 0 | 1 | 10 |

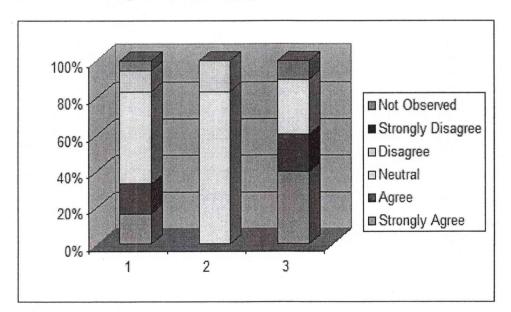


Figure 31.2: Current Regulations are Adequate

54

Resident responses varied when asked if policies related to interactions with the pharmaceutical industry should be mandated only at the institutional level. Forty percent of the fourth year residents said yes, 30% remained neutral and 30% said no. The majority (67%) of third year residents said no, 44% of first and second year residents said yes. It is unclear why opinions were so variable and what factors affect physician's choices. Physicians may be unclear regarding who bears the greatest responsibility for setting policy.

Figure 32.1: Policies Should be Mandated Only at the Institution

| Question 13. P mandated only a | | | | vith the pha | rmaceutical | industry sho | ould be |
|-----------------------------------|-------------------|-------|---------|--------------|----------------------|-----------------|--------------------|
| Results: | | | | | | | |
| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
| 1 (R1/R2) | 2 | 6 | 4 | 5 | 1 | 0 | 18 |
| 2 (R3) | 0 | 2 | 0 | 4 | 0 | 0 | 6 |
| 3 (R4) | 1 | 3 | 3 | 3 | 0 | 0 | 10 |

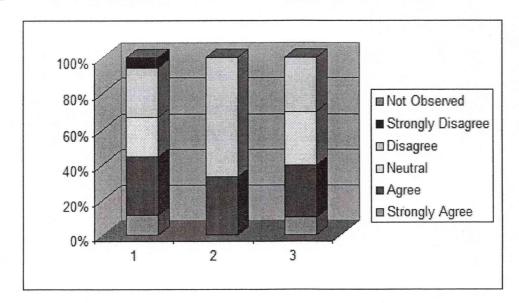


Figure 32.2: Policies Should be Mandated Only at the Institution

There was a great deal of disagreement among first and second, third and fourth year residents in relation to federal regulation of policies related to interactions with industry (Question 14). A clear majority, (83%) of third year residents agreed that policies should be mandated at a federal level, but only 20% of the fourth year residents agreed or strongly agreed that policies should be made on a federal level.

Figure 33.1: Policies Should be Mandated at the Federal Level

| Question 14. P federal level. | olicies relate | d to inte | ractions w | vith industry | should be n | nandated at | the | | | |
|----------------------------------|-------------------|-----------|------------|---------------|----------------------|-----------------|--------------------|--|--|--|
| Results: | Results: | | | | | | | | | |
| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses | | | |
| 1 (R1/R2) | 1 | 7 | 4 | 1 | 3 | 1 | 17 | | | |
| 2 (R3) | 0 | 5 | 0 | 1 | 0 | 0 | 6 | | | |
| 3 (R4) | 1 | 1 | 5 | 2 | 1 | 0 | 10 | | | |

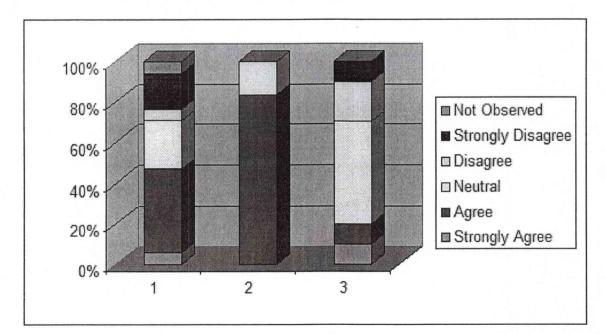
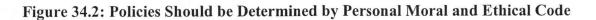


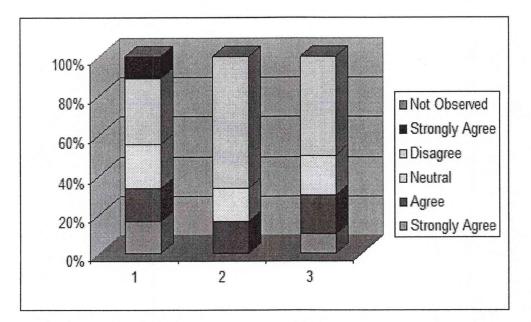
Figure 33.2: Policies Should be Mandated at the Federal Level

The majority of third and fourth year residents (66% and 50% respectively) did not believe that policies related to interactions with industry should only be determined by the personal, ethical and moral code of each physician. Forty-four percent of first and second year residents agreed. To understand the reasons behind their answers will require further study but it could be assumed that residents believe policies should exist that supersede the ethical code that may or may not exist in themselves or their colleagues.

Figure 34.1: Policies Should be Determined by Personal Moral and Ethical Code

| Question 15. Peppersonal, ethical | | | | | should only | be determir | ned by the |
|-----------------------------------|-------------------|-------|---------|----------|----------------------|-----------------|--------------------|
| Results: | | | | | | | |
| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
| 1 (R1/R2) | 3 | 3 | 4 | 6 | 2 | 0 | 18 |
| 2 (R3) | 0 | 1 | 1 | 4 | 0 | 0 | 6 |
| 3 (R4) | 1 | 2 | 2 | 5 | 0 | 0 | 10 |





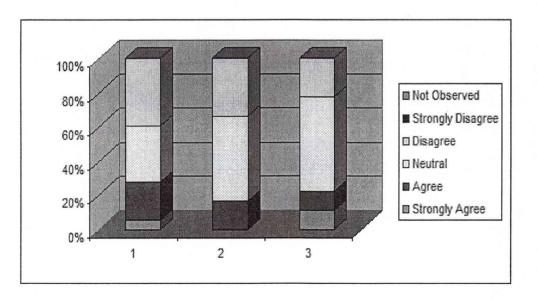
The reason for this discrepancy may be due to the small sample size for the third year class or due to the fact that fourth year residents are more likely to have completed a year of research and thus have a different perspective on the relationship with industry. Comments related to this issue are purely supposition and should be studied further but will be discussed at more length at the conclusion of this document.

Opinions regarding regulation by voluntary participation in a professional association varied. In general, the majority of residents remained neutral on the question, indicating either a lack of opinion or a lack of familiarity with the regulatory agency.

Figure 35.1: Policies Should be Managed by Voluntary Regulatory Agencies

| Question 16. <i>P</i> <i>industry voluntar</i> <i>Manufacturers of</i> <i>regulate interaction</i> | ily participat f America (P | ing in org hRMA). | ganization (PhRMA | s like the Pl members v | harmaceutic | al Research | and |
|--|--------------------------------|----------------------|----------------------|----------------------------|----------------------|-----------------|--------------------|
| Results: | | | | | | | |
| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
| 1 (R1/R2) | 1 | 4 | 6 | 7 | 0 | 0 | 18 |
| 2 (R3) | 0 | 1 | 3 | 2 | 0 | 0 | 6 |
| 3 (R4) | 1 | 1 | 5 | 2 | 0 | 0 | 9 |

Figure 35.2: Policies Should be Managed by Voluntary Regulatory Agencies



Research

The last three survey questions were related to resident beliefs regarding funding for research investigators and whether funding should continue to come from industry or should only come from non-industry sources. When asked whether pharmaceutical companies should continue to provide grants to investigators to conduct clinical or non-clinical research the majority of physicians from each class said yes (95%, 67% and 89% respectively). Opinions on this question did not vary significantly during the course of training. This majority of opinion may exist during all classes because surgery residents understand at the beginning of their course of study they will be involved in research work at some time during their surgical training.

| Question 17. Plato conduct clinica | | | | uld continue | to provide g | grants to inv | estigators |
|------------------------------------|-------------------|-------|---------|--------------|----------------------|-----------------|--------------------|
| Results: | | | | | | | |
| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
| 1 (R1/R2) | 7 | 10 | 1 | 0 | 0 | 0 | 18 |
| 2 (R3) | 1 | 3 | 2 | 0 | 0 | 0 | 6 |
| 3 (R4) | 3 | 5 | 1 | 0 | 0 | 0 | 9 |

Figure 36.1: Companies Should Continue to Provide Grants

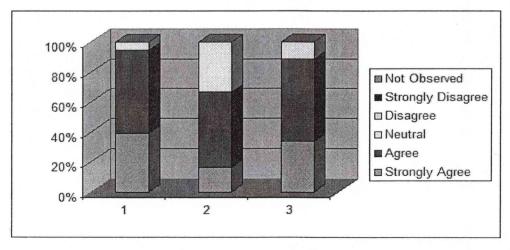
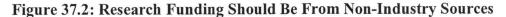


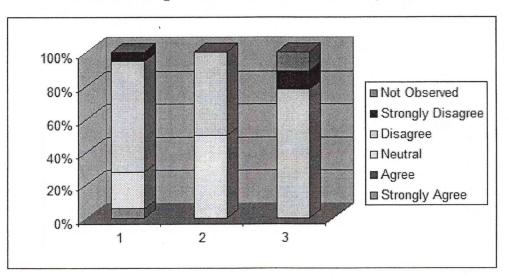
Figure 36.2: Companies Should Continue to Provide Grants

Responses to the question that asked whether research funding should only be provided from non-industry sources indicated that the majority (89%) of all fourth year residents were in favor of industry funding. A smaller proportion of first/second and third year residents (72% and 50% respectively) indicated that they would be in favor of industry-funded research. A shift in opinion in favor of industry-sponsored research during the fourth year of residency may indicate that residents have an increased interest in funding due to their advanced research interests or they may have had more experience collaborating with industry in their fourth year or residency.

Figure 37.1: Research Funding Should Be From Non-Industry Sources

| Question 18. R | esearch fund | ding sho | uld only b | e provided f | rom non-ind | lustry source | es. | | | |
|-------------------|-------------------|----------|------------|--------------|----------------------|-----------------|--------------------|--|--|--|
| Results: | | | | | | | | | | |
| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses | | | |
| 1 (R1/R2) | 1 | 0 | 4 | 12 | 1 | 0 | 18 | | | |
| 2 (R3) | 0 | 0 | 3 | 3 | 0 | 0 | 6 | | | |
| 3 (R4) | 0 | 0 | 0 | 7 | 1 | 1 | 9 | | | |



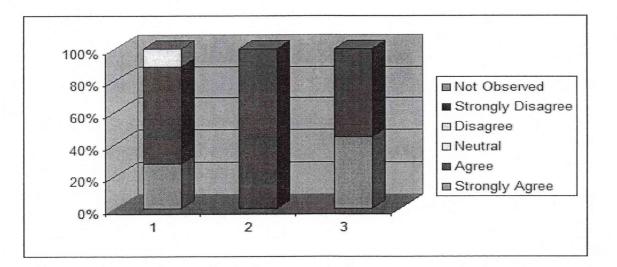


The last question (question 19) was designed to determine if residents had favorable opinions regarding research conducted in conjunction with industry.

Figure 38.1: Research with Industry Expands Clinical and Scientific Knowledge

| Question 19. <i>R</i> plays a productiv | esearch cor /e role in exp | nducted i banding | in conjunc clinical ar | tion with the | e pharmace knowledge. | utical indust | ry generally |
|--|-------------------------------|----------------------|---------------------------|---------------|--------------------------|-----------------|--------------------|
| Results: | | | | | | | |
| Residency Year | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Not Observed | Total Responses |
| 1 (R1R2) | 5 | 11 | 2 | 0 | 0 | 0 | 18 |
| 2 (R3) | 0 | 6 | 0 | 0 | 0 | 0 | 6 |
| 3 (R4) | 4 | 5 | 0 | 0 | 0 | 0 | 9 |

Figure 38.1: Research with Industry Expands Clinical and Scientific Knowledge



Limitations of the Survey

There are certain limitations to this study that should be considered. Although the students that responded to this survey and comprise the resident staff at the institution surveyed are originally from cultural, ethnic and geographically diverse populations their opinions can generally be assumed to have been formed within the same institution. To diversify the responses and thus control for institutional bias it would be most prudent to select students

from several institutions around the United States. The actual number of students representing each resident class was limited and can be responsible for disproportionately skewing the response percentages. The total number of student respondents from the third year class was six and the fourth year class was nine or ten, respective of the question. Surveying a larger number of students from other academic medical institutions would have produced more statistically significant outcome scores. Another variable that weighs heavily upon student responses is the actual or perceived attitudes of the attending physicians and professors at the institution. It is interesting to note that a similar survey was conducted within the same institution but in a different department and though the questions were not identical the survey sought to obtain information similar to information on this survey. Overall, resident responses in the other department were vastly different. The majority of residents in the other departments were opposed to any interaction with industry and found no value in the relationship. It is also interesting to note that attitudes of the attending physicians and professor associated with the other survey mirror the responses of the residents. Whether resident responses mirror those of their department heads and professors is yet to be determined and would be worthy of analysis. As mentioned earlier most surgical attending staff and professors associated with residents in this survey have condoned and maintained an open relationship with industry.

It should also be noted that although residents have had numerous opportunities to meet and collaborate with industry representatives during their tenure as surgical residents, they may not have had the opportunity to read and discuss issues related to industry regulation and interaction. Most surgical residency programs are intense clinical and academic programs that require more than 80 hours per week of the residents time. It is reasonable to assume

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that any "spare" time afforded each resident is not spent reading the latest articles on industry interaction and federal regulation. This may have left residents more vulnerable to absorbing or adopting beliefs and attitudes that mirror those of close colleagues or professors. This also is supposition and can only be supported by further research.

Conclusions and Recommendations

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This study sought to shed light on the current attitudes and beliefs held by surgery residents at one major academic medical institution regarding the value and regulation of interactions with the pharmaceutical industry. It also sought to determine whether those attitudes adopted in the first and second years of surgical residency were likely to change over the course of the third and fourth years of residency training.

It is clear from the data collected during the course of this survey that some fundamental beliefs are held by all surgical residents, regardless of their residency year. The majority of residents in this study believe that pharmaceutical representatives should be allowed to continue to detail and interact with physicians at their institution. The majority of all residents also believe that representatives provide valuable educational support for their departmental programs and activities and are in favor of continuing support and interaction at this level. A majority of students felt that current departmental policy regarding interactions with industry should continue, but many were unsure or neutral about written local, regional or federal policies regarding interactions with industry. This may stem from lack of familiarity with local or national policies and the current body of literature that has analyzed interactions with industry at other academic medical institutions.

Physician Attitudes Changed During Residency

Finally, analysis determined that attitudes regarding research funding shifted slightly over the course of the four years of surgical residency. Most residents, regardless of residency year agreed that funding from pharmaceutical companies was of value but when asked whether they believed that research conducted in conjunction with the pharmaceutical industry generally plays a productive role in expanding clinical and scientific knowledge, 100% of the fourth year residents either strongly agreed or agreed, versus 89% of the first and second year

students. It is safe to assume that exposure to clinical research studies may have had an impact on this change in attitude and belief.

This study has demonstrated that of all surgical residents surveyed, the overall attitude toward interactions with pharmaceutical representatives was positive and indicated that students were in favor of allowing industry reps to detail their drugs or products and continue to interact with physicians. This attitude continued during the fourth year of residency for all students surveyed. The physicians who participated in this study also agreed they would continue to meet with industry representatives beyond their training. These attitudes seem to be in keeping with the restructuring our society is experiencing relative to the newly held partnership between industry and academia.

By 1998 the number of patents produced by universities increased twenty-fold, and businesses were spun off by faculty at an increasing rate (Coyle, 2002). As discussed earlier in this document, the Bayh-Dole Act made it possible for academic institutions to successfully transfer technology, net profits and leave the production of products to manufacturing partners. At present, more than 100 universities and medical schools have invested in new companies to promote discoveries of their staff and more than 150 institutions have technology-transfer offices. The relationship between industry and academia is changing and as evidenced in the surgery department survey, at least this portion of the academic world is not willing to discard the relationship and wishes to continue to interact. But, as evidenced by the surgical student's positions on policies related to restrictions on those interactions, the landscape and the rules that govern the vital relationship should undergo some change.

Rewriting Terms of the Relationship

There is a lot at stake in the evolving and highly visible relationship between industry and medicine and as Steele points out, "Physicians do not exist in isolation; rather they are subject to changes in the culture and to the norms of society. And the norms of society, with respect to conflict of interest, have changed remarkably. In government, in the media, in the judicial system, in the securities business – to mention only a few – conflict of interest has become problematic, and despite occasional public outcries against blatant examples, serious conflicts are often tolerated" (Steele, 2005, p. 972). In the minds of some authors and observers, collaboration with industry is synonymous with conflict of interest. It is the contention of this author that though some conflicts of interest are apparent and the potential for numerable conflicts of interest between medicine and industry exist, particularly with the advent of increased collaboration due to provisions in the Bayh-Dole Act, conflicts are not inevitable.

Acceleration in technology transfer has also made conflict of interest possible but not inevitable. Changes in the relationship between industry and academic medicine do not signal the inevitable downfall of the medical profession as we know it. Though it is true that the relationship between medicine and industry has changed dramatically, those changes may not be due to the blatant greed of all academicians, clinicians and industry executives. It may not mean, as one author suggests, that "Putting business strategies on a high pedestal encouraged many in medicine to ignore a long-held principle that the patient comes first, and a permissive attitude outside of medicine toward financial conflicts of interest undoubtedly led many to think that such arrangements were also acceptable inside the walls of health care" (Steele, 2005, p. 973). Rather, the changes, as put forth in the introduction of this

document are the consequence of runaway health care costs, falling physician income, increased financial demands on academic medical centers and pharmaceutical companies and an increased emphasis on research at academic medical centers.

The Pharmaceutical Industry

The role of the pharmaceutical industry is also changing. Pharmaceutical executives are going to have to grapple with the demands and long held academic norms that fundamentally guide the research upon which they so heavily rely. "An increase in our understanding of disease mechanisms should lead to new therapeutic interventions, but only if these efforts are led by scientific research that is open, collaborative, focused and determined" (Jibson, 2006, p.37). Pharmaceutical companies are going to have to struggle with empty "pipelines"; those empty late phase clinical trials that promised but did not deliver marketable products. Drug companies are also going to have to do a better job at juggling investor expectations. As the age of blockbuster drugs wanes, investor expectations will have to adjust to pipelines filled with molecules designed to meet unmet medical needs in smaller markets. Another major adjustment in the relationship between industry and medicine is the need for more transparency on the part of pharmaceutical companies. Disclosing materials, methods and formulas is common practice in academia but not so in the world of competitive practices guarded by longer than necessary patent protection. As Sox suggests, "Pharma may be vielding some of this ground but would do better to become an active partner with academia. This means not just licensing discoveries made at universities and research institutes but actively participating in the research under academic "rules". More than just "splitting tasks" based on respective traditional strengths, this strategy would allow academia and pharma to inform each other throughout the research and drug development process. Working together,

academia and pharma will build "trust, mutual scientific respect, and concomitant scientific goals" (Sox, 2002, p. 244).

In light of the potential for conflict of interest in all occupations, the research training that has become an accepted and essential part of all academic medical centers, the changing structure of our legal technology transfer capabilities and the increasing complexity of scientific research and the collaborative relationships between industry and medicine it is absolutely ludicrous and distracting to focus undue attention only on the activities of pharmaceutical sales representatives and the physicians that listen to their "details". Those that wish to provide appropriate, intelligent leadership should rather focus on the larger picture; the need to retool but maintain the important relationship between medicine, in particular academic medicine, the emphasis on research funding and subsequent technology transfer and the role that each clinician, researcher and industry as a whole brings to the mix, it would be most appropriate to refocus discussion and dialogue on structural changes within our society.

It's a new era for academia and the pharmaceutical industry. We should not be quick to point accusatory fingers at the changes and label them bad, inappropriate or corrupt but should be quick to view change as an inevitable consequence of human discovery. As a society we should continue to seek ways to adapt to the changes in the world of medicine and finance rather than continue to make attempts to return to the way things have always been done. This survey should act as a reminder that today's students are the physician leaders of tomorrow. Resident opinion, as stated in this survey, indicate that physicians wish to continue to collaborate and interact on a professional level, but are asking for new ways to

define and regulate the relationship that holds the potential for a brighter, more productive, profitable future for patients, academic institutions and the world of pharmaceutical discovery.

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Appendix A

INTERACTION WITH PHARMACEUTICAL INDUSTRY

A SURVEY FOR THE UNIVERSITY OF WASHINGTON MEDICAL CENTER, DEPARTMENT OF SURGERY RESIDENCY PROGRAM JANUARY, 2006

Purpose

The purpose of this survey is to assess current attitudes and opinions regarding professional interactions with representatives of the pharmaceutical industry. All responses will be confidential. The Department of Surgery at the University of Washington will receive a copy of the results of the survey. Providing candid feedback is an important component of this survey. Your thoughtful, honest, and accurate feedback is greatly appreciated. Your responses should be based on actual interactions and/or opinions formed during your residency.

Instructions

Please include examples and other useful information. Please be candid in your responses.

| | Pharmaceutical Industry Survey | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | N/A or Not | Observed |
|-----|--|-------------------|-------|---------|----------|----------------------|------------|----------|
| Int | eractions with Sales Representatives | | | | | | | |
| 1. | Pharmaceutical representatives should be allowed to detail and interact with physicians at this institution. | | | | | | | |
| 2. | Representatives generally provide valuable information regarding their products. | | | | | | | |
| 3. | Representatives generally provide valuable educational information related to the disease states associated with their products. | | | | | | | |
| 4. | Representatives provide valuable support for departmental programs. | | | | | | | |
| 5. | Representatives generally conduct themselves in a professional, appropriate manner. | | | | | | | |
| 6. | Industry sponsored talks have generally been educational and well balanced. | | | | | | | |
| 7. | Information in the form of sales items and journal articles are generally well balanced and useful sources of information. | | | | | | | |
| 8. | I feel that my interactions with industry representatives have <i>not</i> negatively influenced my prescriptive practices during my residency. | | | | | | | |
| 9. | Upon completion of my residency program I will continue to interact with representatives from the pharmaceutical industry. | | | | | | | |
| | Comments and examples: | | | | | | | |

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| Research | | | | |
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| 17. Pharmaceutical companies should continue to provide grants to investigators to conduct clinical or non-clinical research. | | | | |
| Research funding should only be provided from non-industry sources. | | | | |
| 19. Research conducted in conjunction with the pharmaceutical industry generally plays a productive role in expanding clinical and scientific knowledge. | | | | |

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To enhance their effectiveness, pharmaceutical companies should start ...

To enhance their effectiveness, pharmaceutical companies should stop ...

To sustain their effectiveness, pharmaceutical companies should continue ...

Additional comments or suggestions: