The Influence of Pharmaceutical Company Sponsored Educational
Programs, Promotions and Gifts on the Self-Reported Prescribing Beliefs and
Practices of Certified Nurse Practitioners in Three States

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DEDICATION

This project is dedicated to the two men in my life who always believe I can do anything; my husband “Mr. Bear” and my father Derek Muncey. Without the two of you, I could never have achieved my goal. And for mum, who would have been so proud.
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ABSTRACT
The Influence of Pharmaceutical Company Sponsored Educational Programs, Promotions and Gifts on the Self-Reported Prescribing Beliefs and Practices of Certified Nurse Practitioners in Three States
Elizabeth Muncey Blunt
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The influence of pharmaceutical industry sponsored education, promotions and gifts on the prescribing practices of physicians and medical students has been well documented in the literature (Avorn et al., 1982; Curcura, 1999; Gonul et al., 2001; Stolberg & Gerth, 2000; Wazana, 2000). Nurse practitioners also prescribe pharmaceutical products for their patients. However, the effect of corporate promotions on the prescribing practices of nurse practitioners has not been assessed. This quantitative, descriptive study investigated the relationship between pharmaceutical company sponsored educational programs, promotions and gifts and the self-reported prescribing beliefs and practices of certified nurse practitioners.

This study utilized a survey type questionnaire to ascertain the self-reported prescribing beliefs and practices of NPs after encountering pharmaceutical company sponsored educational programs, sales visits, promotional products, or gifts. A survey was developed, piloted, and sent to nationally certified nurse practitioners in three states. A 56% response rate was obtained.

Data demonstrate that nurse practitioners practice is influenced by their interactions with pharmaceutical companies (p< 0.05) yet, like their physician counterparts, some NPs do not recognize the influence pharmaceutical companies have on their prescribing practice. NPs value pharmaceutical interactions and recognize the
benefits accrued including: increased access to medications for patients, education opportunities for NPs, educational resources for patients and potentially, increasing opportunities for NP-pharmaceutical company cooperation in education and research. However, the practicing nurse practitioner needs to be able to recognize and acknowledge the influence of pharmaceutical company promotions in order to utilize the information appropriately. Nurse practitioners need to become critical users of pharmaceutical company services. They need to be aware and understand the influence pharmaceutical companies may exert on their prescribing practices. Professional nursing organizations need to develop position statements on NP-pharmaceutical company interaction, and educators need to integrate pharmaceutical marketing and influence issues into the curriculum.
CHAPTER 1: INTRODUCTION

Introduction

Pharmaceutical companies spend more than $15 billion dollars each year in the promotion and marketing of their products (National Institute for Health Care Management, 2001; IMS Health, 2002). Estimates are that 5 to 8 billion dollars annually goes to sales representatives to promote their products (Greene, 2000; Wolfe, 2002). United States (U.S.) drug spending increased 17.1% to $154.5 billion dollars in 2001. One-quarter of this increase was due to a shift to the use of more expensive drugs (National Institute for Health Care Management, 2002). By 2003, U.S. prescription drug sales had risen to $216.4 billion, up by 11.5% from the previous year (IMS Health, 2004). Meanwhile, global sales of generic drugs are expected to grow by more than 20 percent annually to reach an estimated $80 billion by 2008 (IMS Insights, 2004). The proportion of the gross domestic product (GDP) spent on healthcare varies around the world from a low of 7.4% in the UK to a high of 14.7% in the U.S. (IMS Health, 2004). This high GDP is reflective of the billions of dollars spent each year on pharmaceutical and other healthcare products.

Pharmaceutical companies vie for the favor of healthcare providers in order to increase sales of their company’s product. They use a number of tactics including providing educational programs, sales visits to practice sites, free drug samples and gifts to providers (Murray, 2002; Wazana, 2000; Wolf, 1998). They also market directly to patients through the media and the popular press using print advertisements and television commercials. These direct-to-consumer advertising methods are another attempt to influence the prescriber by having the patient request specific pharmaceutical
products they have seen advertised through a variety of media or recommended by family or friends. (Calfee, 2001; Chin, 2001; Wang, Ausiello & Stafford, 1999). Since 1995, research and development staff the U.S. brand name drug companies have decreased by 2%, while marketing staff have increased by 59%. Currently, 22% of pharmaceutical staff are employed in research and development, while 39% are in marketing (Socolar & Sager, 2001).

The influence of pharmaceutical company sponsored educational programs and gifts on the prescribing practices of medical doctors (MD’s), medical students, and residents has been well documented in the literature (Avorn, Chen & Hartley, 1982; Curcera, 1999; Gonul, Carter, Petrova, & Srinivasan, 2001; Stolberg & Gerth, 2000; Wazana, 2000). Nurse Practitioners (NPs) also serve as prescribing providers to a large variety of patient populations, and prescribe pharmaceutical products for their patients. NPs also are recipients of pharmaceutical company sponsored education, sales visits, promotions and gifts (Scott-Levin, 2000a). Greene (2000) reported that pharmaceutical sales representatives had begun to target NPs and Physician’s Assistants for informational sales visits. While NP’s decision making process for the selection of medications for their patients has been found to be similar to those of MDs, studies have shown differences in prescribing patterns including an increased use of non-pharmacologic treatment modalities, selection of lower priced prescription alternatives and an increased use of educational materials by NPs (Mahoney, 1994; Munroe, Pohl, Gardner, & Bell, 1982; Wright & Neill, 2001). Although there is much data in the literature about MD prescribing beliefs and practices, the results of the MD studies cannot be assumed to be reflective of NP practice. Despite this, to date there has only
been one published study addressing the influence of pharmaceutical company sponsored education programs, sales visits, promotions or gifts on NP prescribing beliefs and practices. The NP study (Kessenich, 1999) was a qualitative design with a very small NP population. After the initial investigation, no further research was conducted (C.R. Kessenich, personal communication, February 18, 2002). The purpose of this study is to investigate the relationship between pharmaceutical company sponsored education, promotions and gifts and the self reported prescribing beliefs and practices of certified NPs.

Physicians and Pharmaceutical Company Influence

Several studies have found that medical students and residents significantly underestimate the influence pharmaceutical company sponsored education has on their prescribing practices (Steinman, Shlipak & McPhee, 2001; Wazana, 2000; Waud, 1992). These findings have raised the issue of the ethics surrounding the influence pharmaceutical company educational programs and gifts have on physician’s prescribing practices (Avorn, et al., 1982; Curcara, 1999; Gonul et al., 2001; Wazana, 2000). The American College of Physicians is so concerned about this influence that they issued two Position Statements, one in 1990 and one in 2002 (appendix A), on physician-pharmaceutical company interaction, educational programs, and gifts (Coyle, 2002a; 2002b). The American Medical Association (AMA) has also issued ethical guidelines for gifts to physicians from industry, first in 1991 and updated in July 2002 (AMA, 1991; 1995-2002), [appendix B]. Concurrent with the development of the second set of American College of Physicians guidelines, the Pharmaceutical Research and Manufacturers of America (PhRMA) developed and approved a new Code of Interactions
with Healthcare Professionals (PhRMA, 2002a), [Appendix C]. The Code is a set of voluntary guidelines for pharmaceutical representatives and others involved in marketing pharmaceuticals. The guidelines address the interaction of pharmaceutical representatives and health care professionals, including the following categories: (a) general interaction, (b) entertainment, (c) continuing education, (d) consultants, and (e) educational and healthcare practice-related items. The Code, July 1, 2002, placed clear parameters on acceptable and unacceptable interaction between the pharmaceutical sales representative and the health care provider (PhRMA, 2002b).

Nurse Practitioners and Pharmaceutical Companies

Today, there are over 102,000 nurse practitioners working in urban, rural, and suburban communities providing care to a variety of patient populations from primary care to specialty practice (National Center for Workforce Analysis, 2004; National Sample Survey of Registered Nurses, 2001). Nurse practitioners in all 50 states and the District of Columbia have some level of prescriptive authority, with 26 states allowing nurse practitioners to prescribe independently (Greene, 1999; Scott-Levin, 2000b). According to a Scott-Levin survey (2000a), in 1999 nurse practitioners wrote 29 million prescriptions. That number was 55% from 1998 and up 75% over the last five years (Greene, 2000). This increase in the number of prescriptions written by NPs is attributed to two major factors. First, there are increasing numbers of NP in practice each year (McGiven, 1993; National Center for Workforce Analysis, 2004; Spratley, Johnson, Sochalski, Fritz, Spenser, 2001; Scott-Levin, 2000b) and second; more states are granting NPs the right to prescribe under their own name rather than the name of their collaborating physician (Pearson, 2002). Whatever the causes of the increase in NPs
prescribing, the result remains the same; more NPs are writing prescriptions each year. Despite this increase, there is a dearth of published studies that address the influence of pharmaceutical company education, sales visits and promotions on NP prescribing beliefs or practices.

Purpose of the Study

This study seeks to answer the question does the receipt of pharmaceutical company sponsored education, sales visits, promotional products and gifts influence the prescribing beliefs and practices of NPs? The logical follow-up to this question is if NPs prescribing beliefs and practices are influenced, what are the implications for NP educators and curricula, practicing NPs, and for nursing professional organizations? Additional questions include; 1) does the geographic location of the NPs practice (urban, suburban or rural) influence the number of self-reported interactions with pharmaceutical company programs, promotions and gifts?, 2) do NPs change or modify their prescribing after pharmaceutical company interaction?, 3) do NPs recognize the influence pharmaceutical company interactions have on their prescribing practice and how does that relate to their perception of the influence? 4) what is the importance of sample availability to the NPs practice? 5) Do NPs believe it is appropriate to accept sample drugs for their patients?, 6) how useful do NPs believe pharmaceutical company information is to their practice? 7) Do NPs believe pharmaceutical company information is unbiased?, 8) Do NPs believe pharmaceutical companies play an important role in patient and NP education?, 9) Would NPs continue to see pharmaceutical company representatives if they provided items or information the NP viewed as useful to their practice?, and 10) are NPs behaviors congruent with their beliefs about accepting
pharmaceutical company promotions, products and gifts?, and finally, 11) what, if any, influence does direct-to consumer marketing have on NPs prescribing practice?

Persuasion Theory (Bar-On & Parker, 2000; Reardon, 1981; Story, 1997) will be used as the framework for this study.

Stakeholder Groups

This study will provide important information for three groups involved in nursing practice issues. First, information related to the effect of NP-pharmaceutical company interaction will be important to faculty who teach NP students about critical decision making related to prescribing medications. If NPs are influenced by pharmaceutical company interactions in a similar manner as physicians and medical students, the issue of influence can then be addressed in the NP curriculum. This will begin to prepare NP students to critically assess the information they receive from pharmaceutical sources while in training and allow them to begin making their prescriptive decisions accordingly. This has clear implications for NP education at both the preparatory and post-graduate continuing education levels.

Second, this information may be important to NPs who currently practice and interact with pharmaceutical companies. If the findings indicate that NPs, like MDs, are influenced by pharmaceutical company marketing techniques, this potential influence on practice will be important to identify in order to make appropriate judgments about the information and gifts they receive from the pharmaceutical companies. The third stakeholder group will be professional nursing organizations and State Boards of Nursing. These organizations develop and disseminate standards of care, professional guidelines and scopes of practice, therefore the findings of this study will be important to
all groups of stakeholders. If NPs are influenced by pharmaceutical company
interactions in a similar manner as physicians and medical students, nursing professional
organizations may choose to develop guidelines related to NP-pharmaceutical company
interactions.
CHAPTER 2: REVIEW OF THE LITERATURE

Introduction

This chapter will present a review of the literature on the historical development of the NP role, compare the roles of the NP and the physician, identify several persuasion theories and models, and review the literature on the influence of pharmaceutical company sponsored education, promotions and gifts on physician prescribing practices. The chapter will also review the single article in the literature about pharmaceutical company influence and NP prescribing practices, address the direct-to-consumer marketing issue and finally, identify existing professional guidelines related to pharmaceutical company interaction with physicians, NPs and other healthcare providers.

Historical Development of the Nurse Practitioner Role

The early 1960’s saw a period of social upheaval and change in the United States that paved the way for the growth of the NP role (Hickey, Ouimette, & Venegoni, 2000; Marchione & Garland, 1980; McGivern, 1993; Thompson, Kershbaumer & Krisman-Scott, 2001). John F. Kennedy was president, civil rights were becoming a topic of discussion throughout the nation, social welfare movements were growing, and the needs of many underserved communities were beginning to be recognized (Kane et al., 1989; Sheehy & McCarthy, 1998). Lack of even basic healthcare services in rural and urban underserved communities pointed to a lack of primary care providers especially in the pediatric and family care arenas (Marchione & Garland, 1980). An inadequate distribution of available physicians, identification of women and children as underserved populations, and escalating healthcare costs led to a 1963 Surgeon General report recommending that nurses be educated to provide primary care in collaboration with
physicians (Elder & Bullough, 1990; Hickey et al., 2000; Thompson et al., 2001). This report, in conjunction with the desire of nurses to achieve professional autonomy, led to the development of the nurse practitioner role (Marchione & Garland, 1980).

The first reported nurse practitioner training program was established at the University of Colorado in 1965 by Loretta Ford, Ph.D., a nurse educator, and Henry Silver, M.D., a pediatrician (Ford & Silver, 1967; Hickey et al., 2000; Larson, 1996; Marchione & Garland, 1980; Thompson et al., 2001). Dr. Ford identified a medically underserved pediatric population in rural Colorado. At the time, registered nurses and nurse midwives were providing women’s healthcare independently, without a physician, in these same communities. Dr. Ford believed that baccalaureate prepared nurses with advanced practice and skills training could provide primary care services to pediatric populations in these underserved areas (Ford & Silver, 1967). Working with Dr. Silver in 1965, she established the first nurse practitioner program. This program was 24-months in length and was designed to train post-baccalaureate nurses to provide pediatric primary care in rural Colorado (Ford & Silver, 1967; Hickey et al., 2000; Thompson et al., 2001; Marchione & Garland, 1980). Ford and Silvers’ NP program was based on a nursing model, which focused on the promotion of health, and growth and development in children as well as the prevention of disease and disability (Ford, 1982, 1986). Their model “afforded the nurse an opportunity to assess autonomously, innovate and work collaboratively with physicians and families in providing care” (Sheehy & McCarthy, 1998, p. 32). Over the next twenty years, the NP role continued to flourish in a society that expressed concern for affordable, accessible primary care for all (Marchione, 1980; Sheehy & McCarthy, 1998). This environment permitted a growing nurse practitioner
community to autonomously serve not only children but also adults, the elderly and families (Hickey et al., 2000; McGiven, 1993).

The number of nurses prepared as NPs over the last fifteen years has grown from approximately 23,500 NPs in 1988 (McGiven, 1993) to an estimated 53,753 in 1996, to over 102,829 in March 2000 (Spratley, Johnson, Sochalski, Fritz, Spenser, 2001). However, it was not until the 1980’s that one saw the nurse practitioner role begin to expand beyond the primary care setting (Hickey et al., 2000). Increasing patient acuity (the complexity of illness and intensity of nursing care required by the patient), shortened length of hospital stays, fragmentation of care and the intricacy of healthcare systems led the way for the development of the acute care nurse practitioner role. Acute care NPs function primarily in hospitals or acute care centers or but may also be found in comprehensive management clinics for the chronically ill, practicing with specialty physician groups such as orthopedists, urologists and cardiologists as well as collaborating with their primary care nurse practitioner counterparts on management of complex patients (Hickey et al., 2000; National Center for Workforce Analysis, 2001; Thompson et al., 2001). This role has expanded the scope of NP practice beyond primary care and into acute care hospitals, long-term care facilities and a variety of other patient care arenas. This increase in the scope of NPs practice, and consequently the prescribing function has caught the attention of pharmaceutical companies who have begun to specifically target NPs with their educational programs, promotional products and gifts (Greene, 2000).

There were over 102,000 NPs in the United States in 2000. This is an increase of 44.8% between March 1996 and March 2000. An estimated 76,650 (74%) of these
NPs have national certification. The majority (62%) have completed a Masters degree program, compared with 46% who were Masters prepared in 1996 (Spratley, Johnson, Sochalski, Fritz, Spenser, 2001).

Currently, NP entry-into-practice education requirements vary from state to state and NPs come from a variety of educational backgrounds including certificate, Masters or Post-masters level preparation. For example, an NP may have a Master of Science in Nursing (MSN), which he or she obtained in a Nursing Administration track. While prepared as an administrator, the nurse may decide to return to direct patient care and then to enter a nurse practitioner program. Depending on where the nurse lives, there may not be a Master’s level NP program in their area while, perhaps, there is a certificate NP program available close by. At that time, they may choose to complete a certificate NP program, thus have an MSN in Nursing Administration but be NP prepared at the certificate level. Still other NPs programs were completed at the MSN level. These discrepancies will begin to decline over the next few years as many states are now requiring NP entry-into-practice at the MSN level. NP certifying bodies also have moved to the MSN for entry into practice, or will be doing so by 2007 (NCC, 2003).

NPs work in a variety of geographic settings from urban to rural, working in independent practices, small office groups and for large hospitals and medical centers. They serve a variety of patient populations, from newborn to geriatric, and care for their patients in offices, hospitals, nursing and geriatric centers, private homes, public clinics and clinical trials practices (Pearson, 2002). Today NPs may be certified in the care of families, children, acute care or hospitalized patients, geriatrics, women’s health care, family or adult psychiatric mental health care, neonatal care, and adult primary care.
(American Nurses Credentialing Center, 2002a; National Certification Corporation, 2002a). Some NPs are certified in more than one specialty area. Forty-one states require that NPs be both licensed in the state of practice and certified by a national certifying body in order to practice. There are four U.S. organizations, which offer certifying exams for Nurse Practitioners. These are the American Nurses Credentialing Center (ANCC), American Academy of Nurse Practitioners (AANP), National Certification Board of Pediatric Nurse Practitioners and Nurses (NCBPNP/N), and the National Certification Corporation (NCC). ANCC offers certifying exams for a variety of NP specialties. AANP offers only Family and Adult NP certification exams. NCC offers only Women’s Health Care NP and Neonatal NP certification which neither ANCC nor AANP offer. NCBPNP/N offers only pediatric NP certification.

These certifying bodies administer certification examinations that measure entry-into-practice NP competencies. Each certifying exam content is specific to the role for which the NP is requesting certification. The largest of the certifying organizations is ANCC with 58,000 advanced practice nurses certified under their auspices (ANCC, 2002a). ANCC administers NP certifying exams in the following areas: Family, Adult Primary Care, Adult Acute Care, Pediatrics, Psychiatric Mental Health, Pediatric Acute Care, and Geriatrics (ANCC, 2002b). AANP offers Family and Adult NP certification and has available an Academy membership list which includes NPs and other certified nurses. NCC is the only certifier of Women’s Health Care and Neonatal NPs in the United States. By the end of 2001, NCC had certified 10,707 NPs (NCC, 2002a). The National Certification Board of Pediatric Nurse Practitioners and Nurses (NCBPNP/N)
certifies Pediatric Nurse Practitioners (CPNP). Since 1977 the NCBPNP/N has certified more than 8000 CPNPs (NCBPNP/N, 2002).

ANCC and NCC are the two largest certifiers of NPs in the United States with a combined population of approximately 72,500 certified Nurse Practitioners. Of note, the combined number of 72,500 NPs identified as being certified by ANCC and NCC is significantly less than the estimated 102,000 NPs currently licensed in the U.S. There are several possible reasons for this discrepancy; (1) some states do not require NP certification in order to be licensed or to practice in the state, one such example is Florida, which requires state licensure but does not require national certification in order to practice; (2) NPs who became certified in the past may have let their certification lapse because of retirement or death, (3) some NPs choose to be certified by more than one certifying body; for example ANCC and AANP, (4) NPs certified by AANP and NCBPN/N are not included in the combined ANCC and NCC numbers, (5) some NPs are certified in more than one specialty area, for example Adult Primary Care and Women’s Health care. Some or all of these factors may affect the reported number of certified NPs.

NP licensure is regulated by the states. In most states, re-licensure occurs every two years following initial license issuance. Some states require continuing education credits for re-licensure. Other states simply renew the license with payment of a renewal fee. National re-certification must occur every five years (7 years for CPNPs who are certified by NCBPNP/NP0). Re-certification requires both a documented clinical practice component of 1000 hours (NCC) or 1500 (ANCC) hours in five years (or an average of 3.7 to 5.5 hours per week) plus a minimum of 75 hours (NCC) to 125 hours
(ANCC) of continuing education credits within the same five-year period (ANCC, 2002b; NCC, 2002b). NCBPNP/N has slightly different recertification regulations, requiring re-certification every 7 years. CPNPs certified by NCBPNP/N may recertify by one of five options, several of which do not require a clinical practice component (NCBPNP/N, 2002).

NPs and Prescriptive Authority

Nurse practitioners in all 50 states and the District of Columbia have some level of prescriptive authority, with 26 states allowing nurse practitioners to prescribe independently (Greene, 1999; Scott-Levin, 2000b). According to a Scott-Levin survey, in 1999 nurse practitioners wrote 29 million prescriptions. That number is up 55% from 1998 and up 75% over the last five years (Scott-Levin, 2000a). During the first quarter of 2000, NPs reported writing an average of 68 prescriptions per week (Scott-Levin, 2002b). During the same quarter, 10% of all pharmaceutical sales calls went to NPs and Physicians Assistants (PAs), an estimated 1.2 million calls in the quarter. Of that total, NPs accounted for 728,000 and PAs for 501,000 of the sales calls (Scott-Levin, 2000b). Despite the documented number of sales calls to NPs, there has been only one small published study that addressed the influence of pharmaceutical company education, sales visits and promotions on NP prescribing beliefs or practices (Kessenich & Westbrook, 1999).

Nurse Practitioners and Physicians: Role Comparison

Over the last thirty years, many studies have been conducted comparing physician and nurse practitioner roles, specifically outcomes and effectiveness across a wide array of issues including patient management, length of visit, decision-making,
prescribing practices and patient satisfaction (Bryant & Graham, 2002; Pulcini & Vampola, 2000; Mundinger et al., 2000; Sox, 2000; Wright & Neill, 2001). Many have found the quality of care provided by NP’s to be equal that of MD’s, especially in the management of primary care populations (Brown & Grimes, 1995; DeNoon, 2002; Spitzer, Sackett & Sibley, 1974; U.S. Congress, 1986).

Patient satisfaction with their health care is one of many indicators of quality health care (Bryant & Graham, 2002). A number of studies have addressed satisfaction of patients cared for by NPs in a variety of settings (Brown & Grimes, 1995; Bryant & Graham, 2002; Perry, 1995). Other studies have compared the levels of patient satisfaction of patients managed by MDs verses those managed by NPs (DeNoon, 2002; Pinkerton & Bush, 2000). Patient satisfaction of those cared for by NPs in independent practice has also been found to be positive at nurse-managed clinics across the United States (Bagwell, 1987; Haq, 1993; Pulliam, 1991).

Using a large-scale randomized design in the same clinical practice group, Mundinger, et al. (2000) conducted the first study comparing the practice outcomes of physician and NP providers with comparable patient populations. This study found no significant difference in overall patient outcomes between the patients cared for by NP’s and those cared for by physicians. The study concluded “In an ambulatory care situation in which patients were randomly assigned to either nurse practitioners or physicians, and where nurse practitioners had the same authority, responsibilities, productivity and administrative requirements, and patient population as primary care physicians, patients' outcomes were comparable” (Mundinger, et al, 2000, pg. 65).
The advent of Nurse Managed Health Centers (NMHC) in the U.S. has also generated much data on the efficacy of the NP in managing primary care patient populations. NMHC are primary care facilities, most often found in urban or rural underserved communities. These centers provide care to high concentrations of minority or disadvantaged populations who have historically experienced woefully inadequate access to health care services (Anderko & Uscaín, 2001; Edwards, Kaplan, Barnett & Logan, 1998; Helvie, 1999). The centers are usually established with federal funding and NPs, nurse educators and other non-physicians provide healthcare to the population. Research has shown that primary care patients who receive health care at these centers are at least as satisfied with their medical care as those cared for by physicians in primary care settings, have less emergency department visits, require less hospitalizations, are managed more cost effectively and have equal health outcomes as those cared for by physicians (Erikson, 2000; Mundinger et al., 2000; Safriet, 1992). A study by Erikson (2000) showed that both Pediatric NPs (PNPs) and Family NPs (FNPs) prescribed lower cost antibiotics than physicians in three clinical practice sites over a 2-year period. Patient outcome data was similar for all patients regardless of whether their primary care provider was a physician or an NP (Erikson, 2000).

A study by Safriet (1992) reviewed over 20 years of research in NP patient management. The study reported that NPs provided care at a lower cost than physicians, prescribed fewer drugs, used less expensive tests and selected lower cost treatment options than physicians, while providing a comparable level of care. The study concluded that NPs provide cost effective care and recommended that barriers to NP practice, such as prescriptive authority limitations, be eliminated. The study further
concluded that there are advantages to joint physician-NP practice. These occur not because the NPs cost less to hire, but rather that the NPs tend to select treatment options that are less costly than, but as effective as, the treatment plans implemented by physicians (Safriet, 1992).

Horrocks, Anderson, & Salisbury (2002) performed a Meta analysis of the literature on NP patient satisfaction and outcomes in the United Kingdom (UK). Their findings are similar to U.S. data that patient satisfaction and outcomes are comparable for patients receiving care in primary care settings. Their review demonstrated that NPs tend to provide longer consultations with their patients and carry out more investigations than MDs. Additionally, no differences were found in return visits, referrals or prescriptions written. They note in their discussion:

Nurse Practitioners can provide care that leads to increased patient satisfaction and similar health outcomes when compared with care from a doctor. Nurse practitioners seemed to provide a quality of care that is at least as good, and in some ways better, than doctors (Horrocks et al., 2002, pg. 821).

They conclude that increasing the availability of NPs in primary care in the UK is likely to lead to high levels of patient satisfaction and a high quality of care.

Another large UK study by Sakr, et al. (n=700) looked at the care provided to emergency department patients presenting with minor injuries. The study showed the care provided by the NPs was clinically equal in outcomes to the care provided by junior doctors. Further, the NPs were identified as documenting more complete medical histories. Fewer patients seen by the NPs required unscheduled follow-up visits. There were no significant differences between the adequacy of physical examination, adequacy
of treatment or request for x-rays, between the NP and MD groups (Sakr, Angus, Perrin, Nixon, Nicholl, Wardrope, 1999).

Studies of Acute Care NPs (ACNPs) have shown similar results when their practice was evaluated. Dahle, Smith, Ingersol & Wilson (1998) found ACNPs management of uncomplicated, hospitalized, congestive heart failure patients to be more cost effective than physician management. This was evidenced by a significant decrease in total hospital costs, a trend towards decreased length of stay and no significant difference in the 30-day readmission rates of the patients (Dahle et al., 1998). Overall, patient satisfaction with the care provided by NP’s has been found to be equal to that of physicians in similar settings and practice populations (Mundinger et al., 2000; Rhee & Dermyer, 1995).

Lambling, Adams, Fox, and Divine investigated geriatric patient management in a 2004 study. This study used a convenience sample of 100 geriatric patients and 17 care providers (5 NPs and 12 MDs) and compared the care delivered in an inpatient geriatric unit. Their results show that NPs deliver effective care to hospitalized geriatric patients. “Overall, the NPs met expectations, sometimes surpassing their counterparts in selected areas, such as identifying the need for and initiating physical and occupational therapy consultation, nutrition consultation, and advanced directive discussion” (Lambling, Adams, Fox, & Divine, 2004).

Despite these findings, the American Medical Association continues to oppose independent NP practice, although it suggests that MDs work in close collaboration with NPs. Yank Coble, president-elect of the AMA in 2002, stated that most primary care patients are not very sick and that with adequate rest, 98% of them would get better
without medical intervention. He believes NPs do not have the scientific background to keep up with the rapidly changing world of medicine and expressed concern that NPs will miss subtle or complex illnesses in their patients (DeNoon, 2002). He is countered by Lucy Marion, PhD, president of the National Organization of Nurse Practitioner Faculties (NONPF) who states:

Not every doctor is trained to treat every kind of medical issue that is out there…Doctors who work with us realize there is a whole domain of practice in which nurse practitioners are highly qualified and need no supervision to perform (DeNoon, 2002, p. 2).

Given the similarity in care provided by NPs and MDs, influences on their practice, and outcomes for their patients, it is possible that NPs are influenced in a similar manner as MDs when exposed to pharmaceutical company influence.

Persuasion Theory

Persuasion affects everyone, every day (Aylesworth & Goodstein, 1999; Dillard & Peck, 2000; Jacobs, 1995). Every time we look at a television commercial, negotiate a meeting time with a business associate or try to convince a friend to stop smoking, we are engaging in persuasion. Pharmaceutical companies use these same techniques in an attempt to influence healthcare providers’ prescriptive decisions. Advertising in medical journals, educational visits to practice sites, sample medications for distribution to patients, and gifts to healthcare providers, are all intended to influence the MD or NPs choice of prescription drugs.

Persuasion is closely linked to emotion and whether we recognize it or not, persuasion is based on an emotional response to the situation in which we find ourselves
Persuasion also involves cognition (Bar-On & Parker, 2000). It is the interaction of emotion and cognition that may lead to a change of attitude or belief (O’Donnell & Kable, 1982).

Many people confuse the term persuasion with similar terms such as communication, coercion or propaganda. However, there are significant differences in the words. Communication is defined as an information exchange between two individuals by a system of symbols, signs or behaviors, an exchange of information (Websters, 1985). Propaganda is defined as dissemination or promotion of popular ideas; information or rumor. Coercion is defined as enforcing or bring about by force (Jowett & O’Donnell, 1999). Persuasion does not include aspects of force, coercion or rumor. Rather, it is a complex, continuing, interactive process in which sender and receiver are linked by symbols, verbal and non-verbal, through which the persuader attempts to influence the listener to adopt a change in a given attitude or behavior because the listener has had his or her perceptions enlarged or changed (Jowett & O’Donnell, 1999; O’Donnell & Kable, 1982). Persuasion necessitates that an individual change attitude, beliefs or behavior voluntarily because they have experienced a specific, mind changing interaction. Most often, this change of mind is related to the individuals’ own needs, wants or desires. These changes can come about instantaneously or they may take days, months or years (Storey, 1997).

There are four specific elements of persuasion: both a sender and receiver of information are required, the exchange is interactive or dynamic, the change in behavior or belief must be voluntary and there is some amount of time required for this transaction to occur (Bettinghaus, 1980).
There are many theories about how persuasion occurs. Most rely on a model of interpersonal communication to influence another individual. One theory relies on identifying how to resist persuasion (Nabi, 1999; O’Donnell & Kable, 1982; Storey, 1997).

**Early Studies in Persuasion Theory**

**Yale Studies**

Research into the nature of persuasion began at Yale University in the mid 1940’s and early 1950’s (Reardon, 1981). During and after World War II Carl Hovland and associates were concerned with influencing the morale of soldiers on the battlefield and changing the attitudes of civilians towards the war effort. They believed “that attitude is an implicit approach or avoidance response to some object. As such, it is an emotional reaction (Reardon, 1981, pg.65). The Yale group focused on belief as the change agent of attitude and they defined beliefs as the cognitive or knowledge component of attitude (Bettinghaus, 1980). Much of the work of the Yale Group focused on stimulus-response, source credibility, personality traits and susceptibility to persuasion as well as extensive work on fear as a persuader (Bettinghaus, 1980; Jowett & O’Donnell, 1999; Reardon, 1981). The Yale Group established the relationship between emotion and cognition as the intrinsic elements of change in beliefs or attitudes, one definition of persuasion.

**Cognitive Dissonance**

Festinger’s Theory of Cognitive Dissonance asserts that persuasion occurs when an individual learns new information or experiences a new event which is different from their ingrained set of ideas and beliefs (Bettinghaus, 1980; Reardon, 1981; Storey, 1997). Festinger proposes, as do many other social theorists, that change and growth occur only
when the individual is in a state of conflict. Humans are always striving for a sense of equilibrium or homeostasis and new information causes tension or disequilibrium. This results in the individual seeking to change in order to reestablish homeostasis (Festinger, 1968).

According to Festinger (1968) people seek to reduce dissonance in one of four ways; revoking their decision, increasing the attractiveness of the alternative, decreasing the attractiveness of the unchosen alternative, or creating cognitive overlap between the items in question (Storey, 1997). Others hypothesize that we attempt to resolve dissonance in one of three ways; the individual may change, in this case, be persuaded; they may lash out and fight the new information in the hope of reestablishing their own reality or they may flee and simply avoid the conflict of information by removing themselves from the environment (O’Donnell & Kable, 1982; Bettinghaus, 1980). An example of attempted resolution of cognitive dissonance is found in the current attitudes towards smoking cigarettes. We have information that smoking is harmful (information), we do not want to die (fear) but we want to smoke (dissonance between the known information that smoking is harmful and our desire to smoke). In order to resolve the dissonance we can try to refute the scientific data (revoke the information), choose to stop smoking (creative cognitive overlap), smoke only reduced tar cigarettes (increasing the attractiveness of the alternative), or stop smoking and say, “I didn’t really like smoking anyway” (increasing the attractiveness of the alternative). All these approaches attempt to resolve the conflict and return the individual to homeostasis.
**Exposure Learning Theory**

Zajonc’s Exposure Learning Theory asserts that the more frequently individuals are exposed to an idea or concept, the more likely they are to adopt that belief (Bettinghaus, 1980). In other words, increased exposure leads to increased familiarity, which leads to increased acceptance. There is comfort in familiarity and like Festinger’s Cognitive Dissonance Theory; Exposure Learning Theory focuses on the need of the individual to feel comfortable, or familiar with an idea or concept. Zajonc also found that frequent exposure actually reinforced low positive or negative beliefs. Therefore, beliefs about an idea or concept were slightly negative prior to exposure, rather than convincing the individual to change their belief to the positive, frequent exposure reinforced negative attitude, thereby persuading a shift to the negative realm.

**Diffusion of Innovations Theory**

Coleman’s Diffusion of Innovations Theory (1968) looks at the influence and persuasion inherent in peer networks. His late 1960’s work identified the impact of mass interpersonal communication networks (peer networks) on individual members attitudes and beliefs. His research identified the strength of peer network communication when he discovered that a group of physicians continued to use less than appropriate prescribing practices even after receiving hard data and scientific reports identifying specific antibiotics as the best treatment for a disease entity (Bettinghaus, 1980; Coleman, Katz, Menzel, 1968). Coleman theorized that the influence of peer opinion and experience outweighed the impact of scientific data for this group. Peer persuasion was more
influential than medical journal articles. He acknowledged that peer influence networks might take years to have an impact but that the impact, when achieved, could be significant.

*Elaboration Likelihood Model*

Petty and Cacioppo clearly labeled emotion and cognition in their Elaboration Likelihood Model (ELM), one of the most frequently cited theories of persuasion (Jowett & O’Donnell, 1999; O’Donnell & Kable, 1982; Weiss, 2000). ELM addresses the individuals’ effort to process new information based on their motivation and ability to engage in message and issue-related thinking (Jowett & O’Donnell, 1999). ELM asserts that individuals use both cognitive abilities and emotional response to the information to interpret the data and make a decision. They describe motivation as 1) the individuals’ personal involvement or interest in the issue, 2) the ability to process persuasive arguments and attentional factors, and 3) the determination that there is sufficient time or inclination to focus on the issue. Petty and Cacioppo (1985) found that the less individuals are interested in the issue, the less attention they paid to the information presented and the less motivated they were to cognitively process the argument. When motivation for the issue was low, peripheral cues became more important (Jowett & O’Donnell, 1999). For example, in advertising, when an individual is not hungry (basic need) a hamburger commercial becomes essentially unimportant. Watchers then tend to notice the peripheral cues more, such as the attractiveness or credibility of the presenter, the background music or visual displays. When they are hungry, the food itself becomes the focus of interest. In this scenario, cognition and emotions interplay to focus attention on the area of most importance to the individual at the time of exposure.
Spiral of Silence Theory

This theory asserts community of peers as the most influential aspect of persuasion. A sense of belonging to a community is a basic human need (Maslow, 1969). Noelle-Neumann (1991) proposes that when individuals exhibit unacceptable behavior, ideas or beliefs the community of peers shuns them resulting in isolation and forcing the individual to resolve the need for belonging. Such a state of affairs causes individuals to reassess opinions, beliefs and attitudes. If they are persuaded to change their ways and conform to the peer group, they are accepted into the community. If they do not conform, they are isolated (Jowett & O’Donnell, 1999; Noelle-Neumann, 1991). Thus, individuals constantly reassess community and personal opinion and, based on cognitive assessment and emotional response to that assessment, make decisions to conform or be isolated.

Persuasion and Emotion

Emotion is a patterned collection of chemical and neural responses processed consciously or unconsciously (Weiss, 2000). The site of emotional response is the body and brain. Physiologic responses of emotion are experienced primarily through the viscera and the musculoskeletal system. The same emotional responses are also transmitted to the brain where specific areas such as the monoaminergic nuclei in the brainstem, the amygdala, ventro-medial prefrontal cortices and hypothalamus convert the information into cognitive responses (Bechara, Trane, & Damasio, 2000; Lane, 2000). The emotion is expressed physiologically as sweating palms, a pounding heart, flushed skin or an increased pulse and cognitively as a changes in foci of attention. Once the information reaches the brain and viscera, the brain focuses its attention on the stimulus
and begins its cognitive, decision-making. In this way the emotions are organizers, prioritizers and motivators of behavior (Lane, 2000; Machleit & Eroglu, 2000). Each individual has inherent adaptive functions that are based on personally relevant events. A person who fears heights may not be fazed by spiders. Each emotion also has a distinct goal or purpose for the individual. The purpose may be direction of cognitive processing, arousal, sustaining of action, or physical activity. We are all “hardwired” for fight or flight. It is inherent in every human. That fight or flight response is the joint product of situational cues and physiologic arousal. Our need to fight or flee is usually based on our needs, wants or desires and is why we spend so much time persuading.

**Persuasion and Culture**

Persuasion is a transactional event involving both cognition or thought and an emotional component. It is human nature to look to others to fulfill our needs and reinforce our perceptions and self-esteem. Individuals are forever trying to shape the world to meet our needs which requires persuading others to do what we want or need them to do. Persuasion theories have shown us that persuasion is response shaping, response reinforcing and response changing.

Persuasion is also culturally bound. Aaker and Williams (1998) have shown that ego-focused emotional appeals lead to more favorable attitude changes for members of an individualist culture, while non-egocentric appeals lead to more favorable attitude changes in collectivist cultures. Egocentric communities, such as the Western world of the United States and Western Europe, tend to focus on the needs of self. Collectivist cultures, such as the Eastern cultures of China and Japan, tend to repress the needs of self
in order to promote the betterment of the community. This research demonstrates the impact of cultural orientation on emotional appeals response.

_Persuasion Techniques_

Persuasion is a transaction involving verbal and non-verbal communication. Rush Limbaugh, a popular radio talk show host, has been identified by many as a persuasive speaker. Jacobs (1995) identifies some of the persuasion techniques used by Limbaugh and other successful marketers wishing to persuade the consumer to purchase a product or change their behavior. Persuasion techniques include:

- **Stories, anecdotes and metaphors.** Stories are used to persuade because they are familiar and comforting so the storyteller can control the ending and make the outcome what we want. Metaphors are also used to invoke universal meaning. “You’re throwing your money away”, “Don’t get burned on that deal”.

- **Double Bind.** The speaker provides the listener with two alternatives both of which lead to the result the persuader is trying to obtain. “Do you want to go shopping on Monday or Tuesday”? gives the listener a choice but both outcomes will have them going shopping. It is much harder to say no when choices are given. Double binds are most effective when using two positives.

- **Contingency.** The persuader links ideas or two choices together so the listener must accept or reject both together. “Perhaps you are not courageous enough to do what I asked”.

- **Rapport.** The speaker creates an affinity with the listener by establishing a bond or sameness. It instills a sense of confidence or togetherness. “My friends…”, “I know how you feel…”, I am an American, just like you”.
- **Authority.** The persuader utilizes rank or role to influence decisions. The authority does not have to be real to be effective. Assumptions of authority or people in authority roles such as health care providers or military leaders can be very persuasive. “This medicine will make you better”, “we can win this war”.

- **Humor.** Humor often bonds the listener to the speaker, especially if the brunt of the joke is the speaker her/himself.

- **Emotional words and language.** Certain words, phrases or descriptions can trigger positive or negative emotions in a group. These words or phrases may be culturally or often socio-economically bound. Words like patriotism, proud, winning, truth and excellence are all viewed as positive. Negative words in our culture include communism, enslave, liar, manipulate and tyranny.

**Persuasion Theory Summary**

Persuasion is a combination of cognitive processing and affective response. Persuasion occurs when someone pushes the “right buttons” in another individual to trigger the meshing of emotions and cognition. Some emotional responses, such as fight or flight, are instinctively inherent in us as humans. Others are learned. Emotional responses are cued by the situation in which individuals find themselves. The individuals’ responses, both physiologic and emotional, are based on prior experience and motivation. What terrifies one person will barely ruffle the hair of another. Pushing those emotional and cognitive buttons is persuasion. From large corporations, like the pharmaceutical companies who are trying to sell a product, to the charitable organization pulling at your heartstrings for a donation, to mothers “guilting” their children into
coming for dinner each is searching for the right combination of cognition and emotion that will make you do what they want. This is persuasion.

Buyer Behavior Marketing Model

Pharmaceutical companies market their products to health care providers, patients, and health care facilities in order to increase sales their products and strengthen sales revenues. There are many marketing models in the literature, which address the influences affecting how, and why individuals and organizations choose which products they will purchase (Aaker & Williams; 1998, Bar-On & Parker; 2000, Curcura, 1999; Gonul et al., 2001; Mintzes, 1998; Tutor2u, 2004; Wolfe, 2002). This study will focus on the buyer behavior-stimulus response model of marketing (Tutor2u, 2004).

The Buyer Behavior - Stimulus-Response Model (S-R) illustrates the many factors that go into marking choices and decisions by pharmaceutical companies and others who wish to sell a product or service. One can assume the purpose of most pharmaceutical company incentives such as samples and education programs is to influence or persuade healthcare providers to change prescribing behavior and prescribe a drug from the sponsor company’s array of products. Generally, S-R models assume that an incentive of some type, with appropriate modification for specific groups and populations, will result in a response that could be predicted by the marketer; that is, the marketer’s offer to take a health care provider to a high priced restaurant for dinner and an educational program about a new drug, or a new use for an existing drug, will result in the healthcare provider prescribing more of the pharmaceutical company’s product presented at the dinner. Figure 1 summarizes this well-developed and tested model of buyer behavior (tutor2u, 2004).
In this model, marketing questions and other factors enter the “black box” known as the customer and produce certain responses. The marketing personnel must try to decide how the customer thinks and emotionally responds to the event, represented in the chart by the black box. This could be termed both a cognitive and an emotional response to the event. The buyer characteristics will influence how they understand, interpret and perceive the stimuli. Then, a decision-making process occurs which ultimately determines what, if any, buying behavior is occurs.

The first stage of understanding buyer behavior is to focus on the factors that determine the buyer characteristics found in the black box area of figure 2 (tutor2u, 2004).
Once the buyer characteristics have been identified for the target population, marketing strategies appropriate to the specific buyer group can be developed and a marketing plan implemented.

Figure 2 – Buyer characteristics


The influence of pharmaceutical company sponsored education and gifts on the prescribing practices of MD’s, medical students and residents have been well
documented in the literature (Avorn et al., 1982; Curcura, 1999; Gonul et al., 2001; Stolberg & Gerth, 2000; Wazana, 2000). More than $11 billion dollars are spent each year by pharmaceutical companies in promotion and marketing of their products. It has been estimated that 5 to 8 billion dollars goes to sales representatives to promote their products (Greene, 2000). This is an estimated $8,000 to $13,000 per year spent on each physician in the United States (Gibbons et al., 1998; Greene, 2000; Wazana, 2000; Westfall, McCabe, & Nicholas, 1997). MD’s, medical students and residents have all admitted that attendance at educational conferences would be significantly less if promotional gifts and free meals were not included (Steiman, Shlipak & McPhee, 2001; Wazana, 2000).

A recent *New York Times* article (Harris, 2004) describes the current federal investigation of several large, multinational, pharmaceutical companies. The investigation involves companies such as Schering-Plough, Bristol-Myers Squibb, Johnson and Johnson, and Wyeth. Through a review of securities filings and interviews with physicians and pharmaceutical company executives, the government has identified inappropriate and illegal marketing tactics including direct monetary incentives and encouraging physicians to bill third party payers for drugs given to the physician free of charge.

The check for $10,000.00 arrived in the mail unsolicited. The doctor who received it from the drug maker Schering-Plough said it was made out to him personally in exchange for an attached “consulting” agreement that required nothing other than his commitment to prescribe the company’s medicines. Two other physicians said in separate interviews that they, too, received checks unbidden from Schering-Plough (Harris, 2004).
Other pharmaceutical companies have paid fines and/or pled guilty to criminal charges involving the marketing of their products in recent years. In 2003 Astra Zeneca paid $355 million in fines, TAP Pharmaceuticals paid $875 million in 2001, and in May 2004, Pfizer Pharmaceuticals agreed to pay $430 million in fines. All of these companies plead guilty to criminal charges of fraud for encouraging physicians to bill the federal government for drugs the company gave the physicians without cost. Prosecutors in Philadelphia are currently investigating whether or not Schering-Plough overcharged Medicaid for pharmaceuticals given to patients (Harris, 2004).

These issues have raised a question about the unethical influence such programs may have on physician’s prescribing practices (Avorn et al., 1982; Curcua, 1999; Gonul et al., 2001; Wazana, 2000, Wolfe, 2002). Several studies have found that medical students and residents significantly underestimate the influence pharmaceutical company sponsored education has on their prescribing practices (Steinman et al., 2001; Wazana, 2000; Waud, 1992). In a 1982 study (Avorn et al., 1982) 46% of physicians reported that pharmaceutical representatives were moderately to very important in influencing their prescribing habits. Steinman et al. (2000) reported that 61% of medical residents stated that industry promotions did not influence their own prescribing, however only 16% believed other physicians to be similarly uninfluenced. A 2002 ethics survey conducted by the journal *Medical Economics* found that 71% of physician respondents did not think that accepting gifts, trips or hospitality diminished their objectivity (Murray, 2002). Murray reports, “Indeed, many physicians found the suggestion [that they may be influenced] insulting” (Murray, 2002, pg. 119). Chew and colleagues (2000) found that
in the treatment of hypertension, over 90% of physicians would dispense a sample that
differed from their preferred drug choice if the sample was available in the office to
dispense to a patient. According to industry estimates, $7.2 billion dollars worth of free
pharmaceutical samples were distributed in 2000 (IMS Health, 2002). Westfall et al.
(1997) found that 96% of physicians and their staff had taken medication samples for
personal or family use during the preceding year. Only 2 of the 53 respondents reported
taking no sample medications in the previous year. The authors estimated the retail
worth of these drugs at nearly $10,000 in 1997 Westfall, et al. also point to the issue of
physicians in training learning to prescribe medications based on whatever samples are
available in the office rather than on what is the most effective medication indicated for
the patient’s problem. They state: “The use of whatever medication is available on the
sample shelf (usually the more expensive of several options) is contrary to the
development of good prescribing habits that will be necessary for success in practice”
(pg. 142).

Hodges (2002) examined interactions between pharmaceutical company
representatives and psychiatry residents and interns in seven Canadian teaching hospitals.
Results showed a correlation between the receipt of promotional items and a belief that
discussion with the pharmaceutical representatives did not influence physician
prescribing. The more gifts or promotional items the resident or intern had received, the
less likely he or she was to believe the pharmaceutical representative influenced his or
her prescribing (Hodges, 1995). A University of Chicago (1997) team studies
advertising directed towards medical students and the students’ attitude towards
pharmaceutical representatives. The study found that 90% of the students had received
one or more books from pharmaceutical representatives. The students believed the pharmaceutical representatives to be helpful and informative and also stated that they felt obligated to listen to the pharmaceutical company representatives informational sales pitch after they had received a free meal or a gift (Sandberg, Carlos, Sandberg & Roizen, 1997).

Bowman and Pearle (1988) studied the impact of commercial company funding of continuing medical education (CME) courses and found that “while the rates for prescribing some of the related drugs increased after the courses, overall the sponsoring drug companies products were favored” (pg.17). They further state that although physicians attending CME conferences should be aware of this potential influence, the final evaluation of drugs to be prescribed remains the responsibility of the physician prescriber (Bowman & Pearle, 1998). Lurie, Rich and Simpson (1990) found that 33% of medical residents reported that they had changed their prescribing practice based on information provided by pharmaceutical representatives. Studies have shown medical students thought it inappropriate to accept certain gifts, yet when asked about their own behavior, indicated that they had accepted those same items (Steinman, Shlipak & McPhee, 2001; Wazana, 2000). Wang et al. (1999) found that there was a significant increase in MD’s requests for specific drugs to be placed on their hospital’s drug formulary or pharmacy after attending an educational program sponsored by the parent pharmaceutical company. These requests for formulary and hospital pharmacy additions were despite a lack of clear scientific data supporting the advantage of the requested drug over the existing formulary product. Similar findings were reported by Wazana (2000) in a meta analysis of 29 articles found in the peer-reviewed literature related to the extent of,
and attitudes towards, the relationship between physicians and the pharmaceutical industry and its impact on the knowledge, attitudes and behaviors of physicians.

Wolf (1998) conducted a study in his allergy and asthma office practice in Nashville, Tennessee and found that the office practice received approximately $262,662.00 worth of pharmaceutical sample products in one year. The practice is comprised of only two health care providers, Wolf and one NP, who together practice in 3 offices sites for a total of only 10 days of patient office visits per week. Wolf itemized the classifications of drug samples received and the pharmaceutical companies who provided them. He commented, “There may not always be as large a pipeline of samples at our disposal. We need to avail ourselves of the opportunity and options at hand” (Wolf, 1998, pg. 1699). In a response to Dr. Wolf’s study, Westfall et al. (1998) challenge Wolfs’ belief that the availability of drug samples is a positive thing. “Wolf seems to support physicians’ partnerships with the pharmaceutical industry. We hope that a physicians’ partnership with his or her patients will always take precedence” (Westfall, McCabe & Nicholas, 1998, pg. 1699).

Haxby (1995) examined drug samples distributed by pharmaceutical companies to the Oregon Health Sciences family medical clinic over a 14-month period of time and found that the clinic received a total of 1,117 separate deliveries or visits, resulting in 331 different drug samples from 43 different pharmaceutical companies. Most of the clinic’s health care providers admitted they did not know what was actually delivered when they signed for samples. Many of the samples delivered were found to be drugs not stocked by the clinic’s pharmacy and not on formulary (not an approved drug) at the institution (Haxby, Rodriguez, Zenchnich, Schuff, & Tanigawa, 1995).
Studies have also looked at the reliability or accuracy of information provided by pharmaceutical company representatives through office visits and educational programming. Zeigler, Lew, & Singer (1995) surveyed 27 physicians who attended 13 conferences at which lunch was provided by a pharmaceutical company. Twelve pharmaceutical representatives from nine different drug companies gave presentations ranging from 30 seconds to 12 minutes in length, with an average length of 2.4 minutes. The authors concluded that pharmaceutical representatives statements about their products were inaccurate 11% of the time and that the inaccurate information directly contradicted information readily available to them. They also found that statements about the representatives’ drug products were more favorable than statements referring to their competitors’ drugs. Eighty five percent of the physicians in the study felt pharmaceutical representatives provided useful information while only 26% said they recalled false statements in the presentations. Thirty seven percent of the physicians said information from pharmaceutical representatives influenced the way they prescribe drugs (Ziegler, Lew, & Singer, 1995).

These findings have led to the development of several non-profit organizations focused on highlighting the physician-pharmaceutical company representative interaction and on any inappropriate marketing and promotional activities. Goodman, an internal medicine physician from New York founded one such organization, No Free Lunch. The organizations’ message is “Our quarrel is not with the pharmaceutical industry, but with pharmaceutical industry promotion. The time has come to eliminate its influence from our practices” (No Free Lunch, 2002a). The membership and supporters of No Free Lunch are listed as “physicians, pharmacists, dentists, nurses, physician assistants,
medical ethicists and others” (No Free Lunch, 2002a). The organization provides reference lists from key pharmaceutical-physician studies, a forum for concerned health care professionals and a downloadable slide presentation on the subject of pharmaceutical company influence, promotions and gifts. The site sells paraphernalia such as coffee mugs and tee shirts to raise money to continue the effort. The web site also contains a pledge that health care providers may take if they are committed to being free of pharmaceutical company influence. The pledge states:

I, _________________, am committed to practicing medicine in the best interest of my patients and on the basis of the best available evidence, rather than on the basis of advertising or promotion. I therefore pledge to accept no money, gifts, or hospitality from the pharmaceutical industry; to seek unbiased sources of information and not rely on information disseminated by drug companies; and to avoid conflicts of interest in my practice, teaching, and/or research (No Free Lunch, 2002b).

The Medical Lobby for Appropriate Marketing (MaLAM) was founded in 1983. MaLAM is an international non-profit organization for health professionals whose aim “is to defend health care from misleading and harmful marketing” (Healthy Skepticism, 2002). The organization goals are to provide a forum for (a) dialogue between health professionals and pharmaceutical companies, (b) support of high quality compassionate health care, (c) reliable drug information services, and (d) empowered health professionals who improve their critical appraisal skills (Healthy Skepticism, 2002). The
organization changed its name from MaLAM to Healthy Skepticism in 2001 when it
adjusted its focus from “misleading promotion in developing countries where the
consequences may be worse because of lack of regulatory controls and lack of
independent information” to “misleading promotion in any country” (Healthy Skepticism,
2002).

The literature has demonstrated that physicians are influenced by their
interactions with pharmaceutical companies and are frequently unaware of the extent of
the influence. As NPs practice in a manner similar to MDs, it may be that NPs are also
influenced by interaction with pharmaceutical companies and their marketing
promotions.

Nurse Practitioners Interactions with Pharmaceutical Company Representatives

In 1999, Kessenich and Westbrook reported the results of a small study in which
the researcher interviewed 6 NPs in the New England area about their interactions with
pharmaceutical company representatives and other factors that may have influenced their
prescribing practices. The NPs were asked about 1) acceptance of drug samples, 2)
dispensing free (sample) medications, 3) the perceived influence of the sample
medications on the NPs prescription choices, 4) drug information from pharmaceutical
company representatives, 5) sources of new drug information, 6) attendance at
pharmaceutical company sponsored events, 7) acceptance of gifts and 8) attention to
pharmaceutical company advertisements (Kessenich & Westbrook, 1999).

Of the sample population, 100% of the NPs had attended pharmaceutical
company sponsored educational programs and all (100%) had accepted free sample
medications for their patients. Four of the NPs (67%) had received written or verbal
communication about drug products during pharmaceutical company encounters such as office lunches. Four of the NPs (67%) believed the availability of sample medications might have influenced their prescribing choices. All 6 NPs had read drug advertisements in professional journals and 100% of the NPs believed that pharmaceutical companies influenced their prescribing behaviors, “even in a subliminal manner” (Kessenich & Westbrook, 1999, pg. 537).

It is difficult to compare the results of this study to studies involving MDs because of the small size of the sample. However, the issues addressed in the research questions are reflective of issues identified in the physician literature. The findings of this study were 1) NPs appear to have a realistic view of the influence marketing may have on their prescribing behavior and 2) pharmaceutical companies may have some influence on NPs prescribing behaviors and practices. The researchers concluded that further studies need to be undertaken to identify factors that may influence NPs prescriptive decisions (Kessenich & Westbrook, 1999).

Direct to Consumer Marketing.

A more recent method of pharmaceutical marketing is to target the patient consumer rather than the MD, NP, or PA. Since the early 1990’s, pharmaceutical companies have been advertising directly to the consumer (DTC) through television advertisements, mass market publications, billboards and gifts that entice the patient to ask about, and ask for, specific products when they see their healthcare provider (Manning & Masia, 2001). Many of the advertisements use familiar or famous people to pitch their products including Olympic gold medal ice skater Dorothy Hamil advertising for the arthritis medication Celebrex and Senator Bob Dole extolling the virtues of
Viagra. These advertisements tend to present the products as the best, newest or most effective product for the complaint. Many infer that if the patients’ healthcare provider is not prescribing this medication for them, they are not getting the best possible management of their illness or problem (Ingelfinger, 1972; Mintzes, 1998; Mixed Reaction to Consumer Advertising, 2003). These tactics compel the patient to ask the MD or NP about the drug, and sometimes, to directly request the advertised drug in place of, or in addition to, their current medications (Mintzes, 1998; Wolfe, 2002). Patient requests for specific products have been documented to affect the MD’s choice of prescription for the patient (Mixed Reaction to Consumer Advertising, 2003; Steinman et al., 2001). Wolfe notes “There is evidence that many drug advertisements are not balanced or accurate and duped gatekeepers may not adequately resist patients’ exhortations to write a prescription” (2002, p.525). These concerns are mirrored by a 2002 study published in the British Journal of Medicine which looked at U.S. and Canadian primary care practice sites to ascertain whether or not MDs were influenced by their patients’ requests for prescription drugs. The authors reported that patients requested prescription drugs in 12% of the visits. Of the requested prescription drugs, 42% were products advertised directly to consumers. After controlling for many of the variables in the study, the authors concluded that the patient’s request for a prescription medication significantly influenced the physicians’ choice of drugs prescribed. “In most cases physicians prescribed requested medications but were often ambivalent about the choice of treatment” (Mintzes, et al., 2002, pg. 279).

Several studies have looked at the accuracy of information provided by pharmaceutical sales representatives about their products. Westfall et al. (1998, pg.
state that physician prescription biases “are often generated by information supplied by pharmaceutical representatives and the sample medications they dispense, not necessarily on the best scientific evidence available in the medical literature”. Ziegler et al. (1995) found that a significant number of pharmaceutical representatives’ comments and claims were inaccurate.

Overall, promotional spending on prescription drugs rose to $15.7 billion in 2000, up from $13.9 billion in 1999 and only $9.2 billion in 1996 (National Institute for Health Care Management, 2001). An estimated two and one-half billion dollars were spent on direct-to-consumer advertising in 2000 up from $1.8 billion in 1999 and $791 million in 1996 (National Institute for Health Care Management, 2002). Increases in the sales of the 50 drugs most heavily advertised to consumers were responsible for almost half (47.8%) of the $20.8 billion increase in spending in 2000. (National Institute for Health Care Management, 2002). In 2000, Merck spent $161 million on advertising for Vioxx, a new drug for relief of arthritis pain. That is more than Anheuser-Busch spent advertising Budweiser beer ($146 million) or PepsiCo spent advertising its soft drink, Pepsi Cola ($125 million). The increase in Vioxx sales in 2000 accounted for 5.7% of the 1-year increase in drug spending in the U.S. (National Institute for Health Care Management, 2001).

A 2001 publication by Pfizer Pharmaceuticals addressed the issue of direct-to-consumer marketing and took a position that the trend is good for the patient (Manning & Masia, 2001). The authors stated that direct-to-consumer advertising empowers the consumer-patient by “encouraging them to explore and discuss with a physician health concerns that might otherwise have been ignored” (pg. 3). They disputed the claim that
direct-to-consumer advertising drives up the cost of healthcare saying “undiagnosed, untreated and under-treated diseases often get attention and appropriate treatment as a result of DTC ads” (pg. 2). Others have voiced similar beliefs, agreeing that patients who see “their” problem addressed in a television commercial, magazine advertisement or on a billboard are more likely to ask their healthcare provider about the condition and therefore receive earlier intervention for the problem (Calfee, 2001; Holmer, 1999). A recent FDA survey of 500 physicians reported that 37% said DTC advertising had affected their practice “somewhat positively”, while 27% said DTC advertising’s impact was negative (Mixed Reaction to Consumer Advertising, 2003, pg. 13). Manning and Keith (2001) stated that the increased advertising costs associated with DTC marketing are generally recovered by the increase in volume of sales, resulting in increased profits for the pharmaceutical company, not in an increased cost to the patient.

**Professional Guidelines: The Medical Community**

As early as 1990 the American College of Physicians voiced its concern about the influence of pharmaceutical company sponsored educational programs and gifts on physicians’ and medical students’ prescribing practices with the release of its position paper *Physicians and the Pharmaceutical Industry* (American College of Physicians, 1990; American Medical Association, 1991; Wazana, 2000). This position paper addressed the potential influence that pharmaceutical companies could have on physician prescribing practices. Despite the existence of the position statement for over a decade, and the American College of Physicians and American Medical Associations’ recommendation that it be discussed with all students and residents, studies showed that only 23% to 50% of residents knew the position statement existed. Additionally, only
62% of practicing physicians knew of at least one of the guidelines (Gibbons et al., 1998). This lack of knowledge about the influence that pharmaceutical company sponsored education has on the prescribing practices of medical students and residents has resulted in a recent American College of Physicians position statement released on March 5, 2002 (Coyle, 2002a; 2002b). This new statement reiterated the need for awareness of the implications of pharmaceutical company sponsored education and its influence on prescribing practices and recommended that all medical students, residents and physicians receive training on this issue (Coyle, 2002b). The 2002 position statement specifically addressed the responsibility of graduate and continuing medical education providers to ensure that unbiased educational content is provided and organizational policies are in place to identify acceptable and unacceptable interactions with the pharmaceutical industry both for medical students and for practicing physicians (Coyle, 2002a; 2002b). Other professional medical associations have similar guidelines concerning pharmaceutical sales representatives interactions with physicians. These associations include the American Medical Association, Canadian Medical Association, the Royal College of Physicians and Surgeons of Canada, the Academy of Medicine and the American College of Physicians (Wazana, 2000). Notwithstanding their stand on pharmaceutical company influence, the American Medical Association continues to generate $20 million annually by selling detailed personal and professional information on all doctors practicing in the United States to the pharmaceutical industry for use in the pharmaceutical company’s physician prescribing databases (Stolberg & Gerth, 2000).
Professional Guidelines: The Nursing Community

Despite the extensive literature addressing the influence of pharmaceutical company sponsored educational programs, promotions, and gifts on physician prescribing practices, to date, none of the fifty State Boards of Nursing, none of the myriad of professional nursing organizations, and only one NP professional organization have addressed this issue in their licensure, accreditation regulations, or professional guidelines. The American College of Nurse Practitioners (ACNP) has both a policy guideline regarding industry sponsorship at the ACNP annual clinical conference (ACNPa, 2004) and a policy statement on NPs and direct to consumer prescription/nonprescription drug advertising (ACNPb, 2004). The clinical conference guidelines state:

The ACNP recognizes industry as a partner by accepting sponsorship and support funding as one of its revenue sources for ACNP programs. The ACNP also recognizes the potential for commercial bias, perceived or otherwise, as well as members concerns about industry involvement.

We value the partnership the ACNP has established with Industry, however, ACNP will never compromise the Independence of its programs through relationships with its corporate partners. Appropriate guidelines and input from attendees are essential components of managing our relationship with industry if we are to maintain our integrity as an organization and the confidence of the medical profession (ACNPa, 2004).

The ACNP policy statement about NPs and direct to consumer marketing addresses the need for accurate and complete information disclosure to consumers. The statement incorporates the United States Food and Drug Administration's
"Guidance to the Industry - Consumer Directed Broadcast Advertisements"
document, which reminds pharmaceutical advertisers not to limit their promotions to physicians.

To this end, it is the position of ACNP and the more than 88,000 nurse practitioners in the United States (HRSA 2000) that patients and families must be given correct consumer information regarding the profession and the care delivery, which can be affected and expected by Americans. One area of consumer information is contained in pharmaceutical advertising of prescription and nonprescription (OTC) drugs and immunizing agents.

This has been addressed by the United States Food and Drug Administration's "Guidance to the Industry - Consumer Directed Broadcast Advertisements" (August 1999) which states: "FDA also reminds sponsors of prescription drug advertisements to be careful not to imply that only physicians can prescribe their products." It is enormously important that consumers be directed to all qualified health care professionals who are able to diagnose, treat and prescribe these agents. If the consumer is directed to only one group of licensed prescribers, in effect, consumers are misdirected and denied the correct and complete information by which they base their health care decisions (ACNP - Policy Statement: Nurse Practitioners and Direct to Consumer Prescription/Nonprescription Drug Advertising, 2004).

This recognition of the interaction between the pharmaceutical industry and the practicing NP is an important first step in the acknowledgment that pharmaceutical influence extends beyond the currently identified physician population.

In light of the dearth of information about NP-pharmaceutical company interaction, the purpose of this study is to answer the question, does the receipt of pharmaceutical company sponsored education, sales visits, promotional products and gifts influence the prescribing beliefs and practices of NPs?
CHAPTER 3: METHODOLOGY

Introduction

This quantitative correlational study used a survey type questionnaire designed to ascertain the self-reported prescribing beliefs and practices of NPs after encountering pharmaceutical company sponsored educational programs, sales visits, promotional products, or gifts.

Survey Tool

The study instrument (appendix D), a 22-question survey, was developed by the researcher from a review of the literature, review of the survey tool developed by Berger-Evans and colleagues, personal experiences and content expert review.

Bergman-Evans’ survey asked final clinical year physician, pharmacy and NP students about their knowledge of pharmaceutical company education programs and gifts, their faith in the pharmaceutical company representatives’ knowledge and information and how they selected which drugs to prescribe for their patients. Reliability and validity data were run for the Bergman-Evans survey (Bergman-Evans, 2002). Dr. Bergman-Evans and her colleagues gave permission for the adaptation of their survey for this study, if necessary.

The survey questionnaire from Bergman-Evans and colleagues was significantly modified in order to reduce the number of survey items and eliminate questions which were not applicable to this study. The questions eliminated included participant’s general knowledge of pharmaceutical spending and budgets and student knowledge about professional nursing organizations’ stance on pharmaceutical company – NP interactions. Some items were revised to be more appropriate for practicing NPs and additional items,
such as the NPs predominant patient practice population and whether the NP has ever accepted any of the listed promotional or gift items, were added. Additionally, the demographic information to be collected was expanded in order to more fully describe the respondent population. This refinement of the Bergman-Evans survey reduced the total number of survey items from 58 to 44, resulting in a 22 question Blunt survey. Furthermore, the Blunt Survey emerged as a very different tool than the Bergman-Evans’ as item construction and analysis proceed.

The survey was designed to collect demographic data related to the survey population including, number and type of pharmaceutical company-NP interactions, and issues related to direct-to-consumer marketing. Questions related to NPs personal practices and beliefs included: whether or not the NPs felt their prescribing practices were influenced by pharmaceutical company sponsored gifts such as pens, note pads, textbooks; promotions such as drug samples, or by education programs at conferences, dinners or in their practice site; whether the NP’s felt other NPs were influenced by these interactions; and whether or not NPs had ever changed their prescribing practices after a pharmaceutical company interaction such as an educational program, promotion or receipt of a gift. Respondents were then asked their reasons for changing their prescribing practice after the encounter, if they had made changes. Additionally, NPs were asked to rate the appropriateness of accepting pharmaceutical company promotional products or gifts, or attending a pharmaceutical company presentation at a conference, dinner or office luncheon. They were also asked what, if any, promotional products, educational programs or gifts they might have accepted and their beliefs about the
appropriateness of accepting such items. Respondents were also asked how important a patient request for a specific drug would be to their prescribing practice and how important sample drugs available in the office would be to their prescriptive decisions.

Next, NPs were asked several questions related to pharmaceutical company representative interactions. First, they were asked to rate the likelihood that they would see a pharmaceutical representative again if they received an item useful in their practice such as an educational monograph, product information, drug samples, note pads or pens, or educational materials. Second, they were asked to indicate strength of agreement or disagreement about statements related to the usefulness, accuracy, and importance of pharmaceutical company representative information. Finally the respondents were asked to rate the adequacy of information they received during their nurse practitioner education program regarding how a nurse practitioner should interact with pharmaceutical representatives so that they could make informed prescribing decisions.

Survey items were nominal or scaled. A panel of NP experts, NP educators and practicing NPs was used to test the survey for content validity. The final pilot survey (appendix E) was tested for reliability and external validity once Institutional Review Board (IRB) approval for the study was obtained. Cronbach's Alpha was run to determine test reliability. The questionnaire was revised based on the results of pilot testing.

Demographic data collection include (a) age, (b) sex, (c) race, (d) educational preparation: diploma, associate degree, bachelors degree, masters degree, PhD or EdD, (e) years of nursing experience, (f) years of NP experience, (g) number of encounters per
month with pharmaceutical companies through sales visits and educational programs, (h) whether the respondent has ever received drug samples, gifts, promotional products and (i) educational programs or information, (j) belief in the reliability of information provided by pharmaceutical companies, (k) self-assessment as to whether pharmaceutical company interaction affects their prescribing practice and (l) their perception of the prescribing practice of their peers.

Independent variables were defined as (a) number of encounters with pharmaceutical company representatives, (b) receipt of pharmaceutical samples, gifts or educational materials, (c) NP beliefs about the validity of information provided by pharmaceutical company representatives. Dependent variables were defined as (a) NPs self-reported change in prescribing practice and (b) NPs self-reported belief in the accuracy and usefulness of product information received through educational programs, promotions and gifts.

Pilot Data Analysis

The pilot survey was used to assess the internal reliability of the Blunt Nurse Practitioner Prescribing Survey tool. Two pilot tests were performed. The first pilot survey was sent to a total of 99 nurse practitioners in October 2003. The names selected were the first 23 names on the purchased ANNC national certification mailing list for New York, Pennsylvania and Florida (name numbers 1 – 23) and the first 10 names from each of the three states on the NCC mailing lists (name numbers 1 – 10). A total of 54 surveys were returned completed, with 47 usable surveys and 7 NPs stating that they had not prescribed medications or practiced within the last 5 years. The returned surveys
were reviewed by a statistician who identified several problems with the survey construction that would result in unusable survey data if the survey were implemented as constructed. After consultation with the statistician and revision of the survey, including changes in scaling and survey layout, a second pilot survey was mailed out in November 2003 to 51 nurse practitioners. The names selected were 12 names on the purchased ANCC national certification mailing lists for New York, Pennsylvania and Florida (name numbers 24-35) and 5 names from each of the three states on the NCC mailing lists (name numbers 11-16). A total of 19 surveys were returned with 14 surveys meeting inclusion criteria. The five surveys excluded were NPs who had not prescribed medications or practiced within the last 5 years. Cronbach Alpha, a correlation coefficient used to test the internal consistency of a survey tool, determined reliability of the survey.

Cronbach Alpha requires only one test administration (Creswell, 1994) and can be used for both binary-type and large-scale data (Creswell, 1994; Nunnally, 1978). It measures the squared correlation between observed scores and true scores or, in other words, it measures reliability in terms of the ratio of true score variance to observed score variance. “A reliable test should minimize the measurement error so the error is not highly correlated with the true score. On the other hand, the relationship between the true score and the observed score should be strong. Cronbach Alpha examines this relationship” (Using SAS for Item Analysis and Test Construction, 2004).

The Cronbach Alpha procedure returns two coefficients, raw and standardized.
The raw Cronbach Alpha is based on item correlation. The stronger the items are inter-related, the more likely the test is consistent. Standardization is based on item covariance. Variance is a measure of how a distribution of a single item or variable spreads out. Covariance is a measure of the distribution of the two variables. The higher the correlation coefficient, the higher the covariance. Standardization is a linear transformation. The higher the Alpha score, the more reliable the test. Although there is no universally agreed upon “correct” Alpha, a score of 0.70 and above is generally deemed an acceptable score for reliability (Nunnally, 1978). Additionally, a low Alpha score may not indicate a “poor” test. Survey items must be grouped in order to assess their reliability. Inappropriate grouping of items may result in poor Alpha results. Conversely, the test may measure several attributes or dimensions, rather than just one, which may also result in a lower Alpha score. Remedies to these issues include a factor analysis, which may allow combination of several factors into fewer factors, and dropping test items that affect overall consistency which, may also increase the Alpha and produce better internal consistency (Using SAS for Item Analysis and Test Construction, 2004).
Analysis of Results

The pilot survey consisted of 43 items, which were assigned to one of five groupings (table 1).

Table 1 - Pilot Survey Groups

<table>
<thead>
<tr>
<th>Group Number</th>
<th>Survey Grouping</th>
<th>Survey Items</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Beliefs about the appropriateness of pharmaceutical influence</td>
<td>5a, 5b, 5c, 5d, 5e, 5f, 5g, 5h, 5i, 5j, 5k</td>
</tr>
<tr>
<td>2</td>
<td>Beliefs about pharmaceutical influence on personal practice and Beliefs about the reliability and accuracy of pharmaceutical company product information</td>
<td>1, 2, 24, 25, 27, 28, 29, 30, 31, 32</td>
</tr>
<tr>
<td>3</td>
<td>Personal practices related to pharmaceutical interactions</td>
<td>3, 4, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 18, 20, 21, 22, 23, 26</td>
</tr>
<tr>
<td>4</td>
<td>Beliefs about pharmaceutical company influence on other nurse practitioners</td>
<td>17</td>
</tr>
<tr>
<td>5</td>
<td>Demographics</td>
<td>6, 19, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43</td>
</tr>
</tbody>
</table>

Group 1

Group 1, beliefs about the appropriateness of pharmaceutical influence, showed an Alpha of .7674 demonstrating internal consistency (table 2). Individual subscale reliabilities ranged from .7131 to .8107. No changes were made to this grouping.
Table 2 - Group 1: Beliefs About Appropriateness of Pharmaceutical Influence

<table>
<thead>
<tr>
<th>Item</th>
<th>Scale Mean if Item Deleted</th>
<th>Scale Variance if Item Deleted</th>
<th>Corrected item-Tot Correlation</th>
<th>Squared Multiple Correlation</th>
<th>Alpha if Item Deleted</th>
</tr>
</thead>
<tbody>
<tr>
<td>5a</td>
<td>19.6923</td>
<td>23.8974</td>
<td>.3043</td>
<td>.3918</td>
<td>.7665</td>
</tr>
<tr>
<td>5b</td>
<td>20.0000</td>
<td>24.3333</td>
<td>.4862</td>
<td>.8464</td>
<td>.7457</td>
</tr>
<tr>
<td>5c</td>
<td>20.0000</td>
<td>21.5000</td>
<td>.6967</td>
<td>.9455</td>
<td>.7131</td>
</tr>
<tr>
<td>5d</td>
<td>19.3846</td>
<td>20.4231</td>
<td>.5686</td>
<td>.7298</td>
<td>.7267</td>
</tr>
<tr>
<td>5e</td>
<td>19.9231</td>
<td>27.5769</td>
<td>-.0568</td>
<td>.8966</td>
<td>.8107</td>
</tr>
<tr>
<td>5f</td>
<td>20.0000</td>
<td>22.3333</td>
<td>.5831</td>
<td>.9315</td>
<td>.7285</td>
</tr>
<tr>
<td>5g</td>
<td>18.3846</td>
<td>20.7564</td>
<td>.6454</td>
<td>.8024</td>
<td>.7150</td>
</tr>
<tr>
<td>5h</td>
<td>19.6923</td>
<td>21.5641</td>
<td>.6405</td>
<td>.8424</td>
<td>.7190</td>
</tr>
<tr>
<td>5i</td>
<td>18.0000</td>
<td>23.0000</td>
<td>.4953</td>
<td>.9722</td>
<td>.7400</td>
</tr>
<tr>
<td>5j</td>
<td>18.0769</td>
<td>26.7436</td>
<td>.0759</td>
<td>.9603</td>
<td>.7863</td>
</tr>
</tbody>
</table>

Alpha = .7674

Group 2

Group 2, beliefs about pharmaceutical influence on personal practice, showed an Alpha of -.4140 and a standard deviation of -.2525 indicating problems in the item grouping. These findings indicate measurement of unrelated attributes or dimensions within the group. This group needed to be reorganized to increase the internal reliability.
The survey items were placed into two new groups, Run 1 and Run 2, to improve correlation of attributes.

Run 1

Run 1 (items 1 and 2) beliefs about pharmaceutical influence on personal practice, yielded an improved Alpha of .1111 (table 3). However, this is still an unacceptable Alpha level. To further improve Alpha, the items were regrouped again by separating items 1 and 2 placing them into two different groups. These final groups can be found in table 10.

Table 3 - Run 1: Beliefs About Pharmaceutical Influence on Personal Practice

<table>
<thead>
<tr>
<th>Item</th>
<th>Scale Mean if Item Deleted</th>
<th>Scale Variance if Item Deleted</th>
<th>Corrected Item-Total Correlation</th>
<th>Squared Multiple Correlation</th>
<th>Alpha if Item Deleted</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3.0714</td>
<td>.3791</td>
<td>.0629</td>
<td>.0040</td>
<td>.</td>
</tr>
<tr>
<td>2</td>
<td>.7857</td>
<td>.1813</td>
<td>.0629</td>
<td>.0040</td>
<td>.</td>
</tr>
</tbody>
</table>

Alpha = .1111

Run 2

Run 2a (items 24, 25, 27, 28, 29, 30, 31, 32) beliefs about the reliability and accuracy of pharmaceutical company product information, yielded an Alpha of .5397 (table 4).
Table 4 - Run 2a: Beliefs about Pharmaceutical Influence

<table>
<thead>
<tr>
<th>Item</th>
<th>Scale if Item Deleted</th>
<th>Scale if Item Deleted</th>
<th>Corrected Item-Total Correlation</th>
<th>Squared Multiple Correlation</th>
<th>Alpha if Item Deleted</th>
</tr>
</thead>
<tbody>
<tr>
<td>24</td>
<td>17.1429</td>
<td>3.8242</td>
<td>.1356</td>
<td>.6852</td>
<td>-.3654</td>
</tr>
<tr>
<td>25</td>
<td>16.7857</td>
<td>2.3352</td>
<td>.4592</td>
<td>.4227</td>
<td>-1.0816</td>
</tr>
<tr>
<td>27</td>
<td>16.7143</td>
<td>3.7582</td>
<td>.0155</td>
<td>.4303</td>
<td>-.3036</td>
</tr>
<tr>
<td>28</td>
<td>16.5000</td>
<td>3.6538</td>
<td>.1317</td>
<td>.2317</td>
<td>-.3965</td>
</tr>
<tr>
<td>29</td>
<td>17.0714</td>
<td>4.2253</td>
<td>-.1399</td>
<td>.5342</td>
<td>-.1426</td>
</tr>
<tr>
<td>30</td>
<td>15.5714</td>
<td>3.3407</td>
<td>.0123</td>
<td>.5025</td>
<td>-.3416</td>
</tr>
<tr>
<td>31</td>
<td>16.2143</td>
<td>5.4121</td>
<td>-.4484</td>
<td>.7020</td>
<td>.2203</td>
</tr>
<tr>
<td>32</td>
<td>15.5000</td>
<td>4.7308</td>
<td>-.3201</td>
<td>.3962</td>
<td>.1111</td>
</tr>
</tbody>
</table>

Alpha = -.2462

Reconfiguration of the items in this group had no impact on increasing Alpha to an acceptable level. Removing items 29, 30, 31, and 32 resulted in an improved Alpha for the remaining items. However, the Alpha of .5397 remains too low for internal consistency (table 5).
Table 5 - Run 2b: Beliefs about the Reliability and Accuracy of Pharmaceutical Company Product Information

<table>
<thead>
<tr>
<th>Item</th>
<th>Scale Mean if Item Deleted</th>
<th>Scale Variance if Item Deleted</th>
<th>Corrected Item-Total Correlation</th>
<th>Squared Multiple Correlation</th>
<th>Alpha if Item Deleted</th>
</tr>
</thead>
<tbody>
<tr>
<td>24</td>
<td>6.3571</td>
<td>2.2473</td>
<td>.4939</td>
<td>.2558</td>
<td>.3814</td>
</tr>
<tr>
<td>25</td>
<td>6.0000</td>
<td>1.6923</td>
<td>.3371</td>
<td>.1457</td>
<td>.4773</td>
</tr>
<tr>
<td>27</td>
<td>5.9286</td>
<td>2.0714</td>
<td>.2981</td>
<td>.1050</td>
<td>.4934</td>
</tr>
<tr>
<td>28</td>
<td>5.7143</td>
<td>2.3736</td>
<td>.2567</td>
<td>.1313</td>
<td>.5208</td>
</tr>
</tbody>
</table>

Alpha = .5397

Expert review thought the items to be too similar for respondents to be able to differentiate between the individual items. However, the focus of these items was thought to be integral to the study. Based on analysis, it was decided to collapse items 24, 25, 27, and 28 into two items related to NPs beliefs about the usefulness of the pharmaceutical representatives’ information. Items 29 – 32 were reassigned to new groups.

Group 3

Prior to running statistical analysis on Group 3, personal practices related to pharmaceutical interactions (items 3, 4, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 18, 20, 21, 22,
the grouping was reviewed. Based on this review and the advice of content experts, it was decided to subdivide Group 3 into several smaller groups to better isolate the issues related to prescribing. The original Group 3 was broken down and the items assigned to four new groups designated as Run1, Run 2, Run 3 and Run 4.

Run 1

Question 18, *receipt of promotional products and gifts* (items 18a, 18b, 18c, 18d, 18e, 18f, 18g, 18h, 18i, 18j, 18k), was a multi-factorial question with 11 possible answer groupings. Analysis of this group alone resulted in an Alpha of .7300 (table 6).

Table 6 - Run 1a: Receipt of Promotional Products and Gifts

<table>
<thead>
<tr>
<th>Item</th>
<th>Scale Mean if Item Deleted</th>
<th>Scale Variance if Item Deleted</th>
<th>Corrected Item-Tot Correlation</th>
<th>Squared Multiple Correlation</th>
<th>Alpha if Item Deleted</th>
</tr>
</thead>
<tbody>
<tr>
<td>18c</td>
<td>2.5000</td>
<td>2.2692</td>
<td>.4219</td>
<td>.</td>
<td>.7301</td>
</tr>
<tr>
<td>18d</td>
<td>3.1429</td>
<td>2.2857</td>
<td>.3073</td>
<td>.</td>
<td>.7327</td>
</tr>
<tr>
<td>18e</td>
<td>2.5000</td>
<td>2.2692</td>
<td>.4219</td>
<td>.</td>
<td>.7031</td>
</tr>
<tr>
<td>18f</td>
<td>2.5000</td>
<td>2.2692</td>
<td>.4219</td>
<td>.</td>
<td>.7031</td>
</tr>
<tr>
<td>18g</td>
<td>3.1429</td>
<td>1.9780</td>
<td>.5872</td>
<td>.</td>
<td>.6600</td>
</tr>
<tr>
<td>18h</td>
<td>3.1429</td>
<td>1.9780</td>
<td>.5872</td>
<td>.</td>
<td>.6600</td>
</tr>
<tr>
<td>18i</td>
<td>3.2143</td>
<td>2.3352</td>
<td>.3565</td>
<td>.</td>
<td>.7172</td>
</tr>
</tbody>
</table>

*** 18A has zero variance  *** 18B has zero variance  *** 18J has zero variance

Alpha = .7300

Note: Statistics based on inverse matrix for scale ALPHA are meaningless and printed as .
Based on item analysis, items 18d, conference registration fees, and 18i sample drugs for your personal use, were deleted from the question to further improve the Alpha as they did not appear to be integral to the run. This resulted in an improved Alpha of .7366 for the group (table 7).

Table 7 - Run 1b: Receipt of Promotional Products and Gifts

<table>
<thead>
<tr>
<th>Item</th>
<th>Scale Mean if Item Deleted</th>
<th>Scale Variance if Item Deleted</th>
<th>Corrected Item Total Correlation</th>
<th>Squared Multiple Correlation</th>
<th>Alpha if Item Deleted</th>
</tr>
</thead>
<tbody>
<tr>
<td>18c</td>
<td>2.1429</td>
<td>1.3626</td>
<td>.4148</td>
<td>.</td>
<td>.7204</td>
</tr>
<tr>
<td>18e</td>
<td>2.1429</td>
<td>1.3626</td>
<td>.4148</td>
<td>.</td>
<td>.7204</td>
</tr>
<tr>
<td>18f</td>
<td>2.1429</td>
<td>1.3626</td>
<td>.4148</td>
<td>.</td>
<td>.7204</td>
</tr>
<tr>
<td>18g</td>
<td>2.7857</td>
<td>1.1044</td>
<td>.6262</td>
<td>.</td>
<td>.6368</td>
</tr>
<tr>
<td>18h</td>
<td>2.7857</td>
<td>1.1044</td>
<td>.6262</td>
<td>.</td>
<td>.6368</td>
</tr>
</tbody>
</table>

*** 18A has zero variance
*** 18B has zero variance
*** 18J has zero variance

Alpha = .7366

Note: Statistics based on inverse matrix for scale ALPHA are meaningless and printed as .

Run 2

Next, items 3 and 4 were removed and placed in a group titled factors affecting prescription choices by NPs. This run yielded an Alpha of .0731 (table 8). A low Alpha
was anticipated for this grouping as it represents two specific issues, the importance of patients request for a specific drug and the availability of samples in the office, both of which may affect NPs prescribing decisions. At this time, it is not known how important these two factors are to the NPs prescriptive decisions and what other factors, such as geographic location, population type, and NP experience may also influence this issue. Content experts felt these two issues were an important part of the study and should remain as stated.

Table 8 - Run 2: Factors Affecting Prescription Choices by NPs

<table>
<thead>
<tr>
<th>Item-total Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scale Mean if Item Deleted</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>4</td>
</tr>
</tbody>
</table>

Alpha = .0731

Run 3

Item 7, I have changed or modified my prescribing practice after attending a pharmaceutical company sponsored educational program or presentation or after receiving promotional items, is a single item with a dichotomous response and could not
be tested for internal consistency using Cronbach Alpha. However, 55% of respondents indicated they have changed their prescribing practice after attending a pharmaceutical company sponsored event while 45% indicated they had not changed their prescribing practice after such an event. This item was retained.

Run 4

A final group was formed with the remaining items from the original Group 3 (items 8, 9, 10, 11, 12, 13, 14, 15, 16) and titled personal practices related to accepting pharmaceutical company gifts. This grouping yielded an Alpha of .5906 (table 9). Item 11, as effective and had more convenient dosing, yielded zero variance and was removed from the survey. Reconfiguration of the items in this group had no impact on increasing Alpha to an acceptable level. Again, a low Alpha was anticipated for this grouping as it represents reasons NPs change their practice after interaction during a pharmaceutical company sponsored event. As all NPs do not attend the same programs or events, nor do they receive the same pharmaceutical company information from the same representative, there may be a wide range of reasons NPs change their practice in relation to pharmaceutical company sponsored events. These items were felt by the experts to be an integral part of NPs prescriptive choice and may be the reason NPs choose to change medications for their patients, although it is not known at this time if this is related to pharmaceutical company influence.
Table 9 - Run 4: Personal Practices Related to Accepting Pharmaceutical Company Gifts

<table>
<thead>
<tr>
<th>Scale</th>
<th>Scale</th>
<th>Corrected</th>
<th>Squared</th>
<th>Alpha</th>
</tr>
</thead>
<tbody>
<tr>
<td>if Item</td>
<td>if Item</td>
<td>Item-Total</td>
<td>Multiple</td>
<td>if Item</td>
</tr>
<tr>
<td>Deleted</td>
<td>Deleted</td>
<td>Correlation</td>
<td>Correlation</td>
<td>Deleted</td>
</tr>
</tbody>
</table>

- Scale Mean: 4.8333, Variance: 3.2424, Correlation: -.3789, Alpha: .6869
- Scale Mean: 4.8333, Variance: 2.8788, Correlation: -.0309, Alpha: .6263
- Scale Mean: 4.8333, Variance: 2.6970, Correlation: .1598, Alpha: .5899
- Scale Mean: 5.2500, Variance: 1.6591, Correlation: .7433, Alpha: .3623
- Scale Mean: 4.9167, Variance: 2.4470, Correlation: .2737, Alpha: .5635
- Scale Mean: 5.3333, Variance: 1.5152, Correlation: .9084, Alpha: .2800
- Scale Mean: 5.0000, Variance: 2.9091, Correlation: -.1179, Alpha: .6806
- Scale Mean: 5.2500, Variance: 1.6591, Correlation: .7433, Alpha: .3623

Alpha = .5906, Standardized item alpha = .4310 *** Q11 has zero variance

Group 4

Item 17, *NPs beliefs about pharmaceutical company influence on other nurse practitioners* was felt to be unrelated to any other question in the survey as it addresses NPs beliefs about other NPs practice. The remainder of the survey items address the NPs personal interactions, experiences and demographics. For this reason, this item stands alone in the group. This is a single item with a dichotomous response and could
not be tested for internal consistency using Cronbach Alpha. Seventy-eight percent of respondents believe that other NPs are influenced by their pharmaceutical company interactions while 12% did not believe their peers were influenced. This item was retained.

Group 5

Group 5, demographics, did not require a test of internal consistency.

Summary

Based on the Cronbach Alpha findings and the opinions of expert NPs, changes were made to some of the item groupings, as discussed above. Items 11, 21, 22, 23, and 32 were deleted. Items 24, 25, 27, and 28 were collapsed into a new, combined question. Based on these changes, the survey tool was renumbered appropriately. The final groupings for the revised survey tool can be found in table 10. The pilot survey and the final revised survey used for the study can be found in appendix D.
<table>
<thead>
<tr>
<th>Survey Grouping</th>
<th>Survey Items</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beliefs about pharmaceutical influence on personal practice</td>
<td>1, 10e</td>
</tr>
<tr>
<td>Beliefs about the appropriateness of accepting pharmaceutical company gifts</td>
<td>2, 4a, 4b, 4c, 4d, 4e, 4f, 4g, 4h, 4i, 4j, 4k</td>
</tr>
<tr>
<td>Personal practices related to accepting pharmaceutical company gifts</td>
<td>8a, 8b, 8c, 8d, 8e, 8f, 8g, 8h, 8i, 8j, 9, 10b</td>
</tr>
<tr>
<td>Beliefs about the reliability and accuracy of pharmaceutical company product information</td>
<td>10a, 10c, 10d</td>
</tr>
<tr>
<td>Beliefs about pharmaceutical company influence on other nurse practitioners</td>
<td>7</td>
</tr>
<tr>
<td>Reasons NPs changed prescribing practices after pharmaceutical company interaction</td>
<td>5, 6a, 6b, 6c, 6d, 6e, 6f, 6g, 6h</td>
</tr>
<tr>
<td>Beliefs about adequacy of NP program information about NP / pharmaceutical company interaction</td>
<td>13</td>
</tr>
<tr>
<td>Factors affecting prescription choices by NPs</td>
<td>3a, 3b</td>
</tr>
<tr>
<td>Demographics</td>
<td>11, 12, 14, 15, 16, 17, 18, 19, 20</td>
</tr>
</tbody>
</table>

Site and Sample Selection

The sample for this study was obtained from the ANCC and NCC Nurse Practitioner certification lists. An alternate method of obtaining names for the survey would be to request the NP licensure mailing lists from each state. This method was deemed less appropriate than the certification mailing lists as NP licenses can be renewed in some states without a continuing education requirement therefore there is no guarantee that the NPs included in the State Board of Nursing sample would be practicing in their field.
Both ANCC and NCC are able to randomly select, by computer, the requested sample from the total population of NPs in their certification database. This allowed for simple random sampling of subjects. Random selection occurred across gender lines, NP specialty, and geography. Additionally, the ANCC and NCC lists generally utilize NPs home mailing addresses rather than employment addresses. The researcher felt this would increase the accuracy of the mailing lists, as it avoided sending surveys to NPs who may have changed employment since their last certification.

Utilization of the ANCC and NCC certification databases ensured the NPs included in the survey were practicing, had practiced within the last five years, or had graduated from an NP program within the last five years. These NPs would have been required to attend a specified number of hours of continuing education programming within the last five years making it likely that they had been exposed to current clinical practice issues and recent pharmaceutical and practice changes.

The study was conducted in three states: Pennsylvania, New York and Florida. These states were chosen in order to access NPs in a wide range of practice settings, serving a variety of patient populations, with multiple specialty practices, and with a diversity of educational backgrounds and years of NP experience, across a wide geographic area. Although Pennsylvania and Florida do not require national certification to practice at this time (2004), the three states selected all have a diverse geography with urban centers, and suburban and rural communities plus very large NP populations; New York 9,789, Pennsylvania 5,230, Florida 6,114 (Pearson, 2002). These numbers are only
exceeded by California, which has 11,028 NPs in the state (Pearson, 2002). An NP is conducting this study and it is expected that other NPs, in the interest of the profession, will respond to the survey.

Data Collection Plan

This study utilized a questionnaire mailed to a total of 1,000 NPs in Florida, Pennsylvania and New York states. A sample population of 1000 NPs was selected based on the Creative Research Systems sample size calculator (Creative Research Systems, 2002). The sample size calculator demonstrates that a total of 377 completed, returned, surveys would provide a 95% confidence level with a confidence interval of $P < .05$ while 645 returned, completed, surveys would provide a confidence level of 99% with a confidence interval of $P < .05$. The survey was a pen and paper design with an enclosed, postage paid, self-addressed reply envelope included in order to facilitate return. The surveys were coded for tracking purposes utilizing a numeric coding system.

The researcher rejected using electronic surveys because an online survey tool would require the respondent to enter an identification code at the time of online survey completion. This presents an obstacle to completion of the survey, as it requires the NP to have the survey in-hand at the same time they are logged onto a computer. Some NPs may not have computers at home and may only have access to them at their work site. Those NPs having computers at home would need to go to the computer with the survey in-hand in order to complete the survey. Allowing the respondent to complete the survey, put it into the response envelope and be finished with it at the first encounter was thought to increase response rates and diminish the possibility of surveys being misplaced or lost before the NP logs onto a computer. Surveys were mailed with a cover letter explaining
the purpose of the study, identifying that IRB approval had been obtained, and requesting that participants complete the survey and return it within three weeks, with a specific deadline date indicated. The direct mailing containing the survey, a cover letter describing the study and assurance of anonymity, a self addressed, stamped envelope and two 3” x 5” cards were mailed to the sample population in early 2003. Surveys were sent by U.S. postal service and were coded for tracking purposes.

A second mailing was sent to non-respondents four weeks after the initial mailing. As completed surveys were received, data entry commenced. A completed, returned survey was deemed agreement to participate in the study, as identified in the cover letter. Survey analysis commenced ten weeks after the initial mailing was sent out.

The literature shows that an incentive such as a small amount of cash ($1.00), opportunity to win a gift, or even a tea bag or bookmark enclosed with surveys, can increase the survey response rate by 20% to 60% (Berry & Kanouse, 1987; Church, 1993; Wiersma, 2000; Willimack, Schuman, Pennel, & Lepkowski, 1995). This is believed to occur because the respondent perceives the establishment of a relationship between themselves and the researcher when they accept the incentive offered by the researcher. Despite the success of this approach, there has been criticism of incentive use, primarily because of concerns that providing incentives to participates in research activities sets a problematic precedent requiring future researchers to provide incentives in order to obtain participant participation (National Center for Health Services Research, 1997; Sheatsley & Loft, 1981). Aday (1996, pg. 287) notes that a non-monetary incentive for professionals to complete a survey may be their interest in the survey. Offering survey
participants the opportunity to obtain the completed survey results may simply be incentive enough for them to take the time to complete the survey. Therefore, as an additional incentive, the subjects were offered the opportunity to obtain the final data from the study. The survey cover letter also offered participants the opportunity to request the completed survey results. Participants who desired a copy of the survey results were instructed to return the enclosed postage paid 3”x 5” card with, their name and mailing address, to the investigator indicating their desire to receive the survey results. Written copies of the survey results were sent to these participants by U.S. mail.

The survey respondents had the opportunity to win one of four $50.00 gift certificates to Amazon Books, if the survey is completed and returned. Information about this incentive was included in the cover letter. Survey respondents who wished to be considered for the gift certificate completed a separate check box on the request-for-survey-results 3” x 5” postage paid index card. These 3” x 5” cards were returned under separate cover and compiled. One month after the initial surveys had been mailed, a follow up letter with a second copy of the survey will be mailed to non-respondents in an attempt to increase the response rate. Approximately eight weeks after the initial surveys were mailed to the sample population, gift certificate winners were selected by a random drawing. A chance of winning one of the four gift certificates was approximately 1-in-113 based on 451 returned surveys.

Although some may view the use of incentives in this study as an example of an attempt to affect NPs behaviors through influence, almost a mirror to the survey itself, the researcher believes that the importance of the data to be collected requires incentives be used in order to garner a significant response to the survey.
Delimitations

The results of this study, although generalizable to NP populations in Pennsylvania, Florida and New York, are not generalizable to a national population of certified NPs as regional variation may influence NPs interactions with pharmaceutical company representatives. Sample bias may occur as the AANP and NAPNAP certification databases will not be used and only nationally certified NPs will be surveyed. There is no information in the literature about why NPs may choose to become credentialed by ANCC rather than AANP. Both the AACN and NCC certification examinations in Adult NP and Family NP cover the same content areas and are honored nationwide. The lack of understanding about this decision, choosing AANP or NCBPNP/N rather than ANCC for certification, may exclude a portion of the practicing NP population from the sample. Additionally, the NCBPNP/N database will not be used, as a practice requirement is not mandatory for re-certification. Although 41 states required national certification in 2004, the states of Florida and Pennsylvania did not require national certification to practice at that time. However, due to the number of nationally certified NPs in these states, and the geographic make-up of the states, it was deemed necessary to use Florida and Pennsylvania in this survey. This choice may result in some sample bias as NPs who work in these states who have chosen to become nationally certified may demonstrate characteristics different from non-certified NPs in those states.

Limitations

Certain NPs may choose not to complete and return the survey as some may view questions related to accepting gifts from pharmaceutical companies as personal
information. Others may be concerned about the ethical or moral implications of receiving such gifts and not want the researcher to have this information about their personal practice.

There may be sampling bias as there may not be equal population distribution by state, practice type, specialty and geographic location. However, the efficacy of random computer sampling from the ANCC and NCC databases make this the most effective method of sample identification. Some NPs may have moved since their last certification update in which case addresses may be invalid. These surveys may be forwarded by the postal service, or if the NP moved some time ago, returned to the researcher. Utilizing U.S. mail will allow equal access to all potential participants.

Finally, as this survey is self-report, there may be some under estimation or over estimation of the extent of exposure to pharmaceutical company education, promotions and gifts either because of distance from the event encounter or because the NP does not wish to accurately identify his or her behaviors. Some NPs may also overestimate or underestimate their encounters with pharmaceutical representatives, and or number of promotional products or gifts received.

Data Analysis Plan

This study answered the following questions: a) Does the receipt of pharmaceutical company sponsored educational programs, promotional products, and gifts influence NP prescribing beliefs and practices? b) Does the frequency of NP/pharmaceutical interaction influence the NP’s prescribing beliefs or prescribing practices? c) Does the age, race, sex, demographic region in which the NP practices, years of NP of practice, educational preparation or specialty practice type of the NP
affect their pharmaceutical company interaction? d) What are the NP’s beliefs about the accuracy and usefulness of information obtained from pharmaceutical company educational programs, sales representatives, promotional products and gifts? e) do NPs change or modify their prescribing after pharmaceutical company interaction?, f) do NPs recognize the influence pharmaceutical company interactions have on their prescribing practice and how does that relate to their perception of the influence?, g) what is the importance of sample availability to the NPs practice?, h) Do NPs believe it is appropriate to accept sample drugs for their patients?, i) how useful do NPs believe pharmaceutical company information is to their practice? j) Do NPs believe pharmaceutical companies play an important role in patient and NP education?, k) Would NPs continue to see pharmaceutical company representatives if they provided items or information the NP viewed as useful to their practice?, and l) are NPs behaviors congruent with their beliefs about accepting pharmaceutical company promotions, products and gifts?, and finally, m) what, if any, influence does direct-to-consumer marketing have on NPs prescribing practice?

The dependent variables were defined as (a) self-reported prescribing beliefs and practices of NPs, and (b) NPs self-reported belief in the accuracy and usefulness of product information received through educational programs, promotions and gifts. Independent variables were defined as (a) number of encounters with pharmaceutical company representatives, (b) receipt of pharmaceutical samples for professional or personal use, (c) receipt of other gifts including textbooks, medical products and supplies such as stethoscopes, penlights, patient teaching materials and food.
Data from this correlational study were analyzed using the Statistical Package for the Social Sciences (SPSS) version 10. The following hypotheses were tested: (a) More frequent interactions with pharmaceutical company representatives will result in greater perceived influence on the prescribing practices of the nurse practitioner and (b) The geographic location of the NPs practice (urban, suburban or rural) will influence the number of self-reported interactions with pharmaceutical company programs, promotions and gifts.
CHAPTER 4: ANALYSIS OF THE DATA

Introduction

The purpose of this study was to assess the correlation between Nurse Practitioner (NP) self-reported prescribing behaviors and practices and self-reported pharmaceutical company interactions.

Data for this study were obtained using an original survey derived from review of the literature and expert review. The statistical analysis presented in this research study uses the data obtained from the sample population (certified nurse practitioners) to infer whether or not the hypotheses should be accepted or rejected (Bluman, 1992). Data analysis is descriptive in order to organize, summarize, and understand the self-reported influences on NPs prescribing practices as they relate to pharmaceutical company interaction. Findings are reported in the following order: Survey demographics, demographics of NP sample population, survey analyses, hypotheses, and questions.

Survey Demographics

A total of 1,000 surveys were sent by U.S. mail to certified NPs in the states of Pennsylvania, New York and Florida. The first mailing was sent on February 15, 2004 with a follow-up mailing to the same 1,000 NPs on March 15, 2004. A deadline of April 30, 2004 was established for receiving survey returns. Participants were offered two incentives to complete the survey. 1) A copy of the survey results could be requested (372 respondents requested survey results) and 2) the opportunity to be entered into a drawing for one of four Amazon.com gift certificates for $50.00. The drawing for the gift certificates occurred on May 15, 2004 and winners received their certificates by June 1, 2004. A total of 473 certified nurse practitioners from three states returned their
surveys; 393 completed the survey and 58 indicated that had not prescribed medications for patients or had not practiced during the last five years. A gross response rate of 56% was achieved for the mailed sample. Of the 1,000 surveys sent, 149 were returned as undeliverable due to change of address or unknown at that address. Four hundred fifty-one surveys were returned by the closing date for data collection, with 393 surveys complete and used in data analysis. An additional 58 surveys were returned but not used for data analysis as the NP indicated that he or she had not prescribed medication for patients or practiced as an NP within the five years preceding the survey, a survey response option. Twenty-two surveys were returned after the closing date for data collection. These 22 surveys were not used for the study. Table 11 illustrates survey responses.

Table 11 - Survey Responses

<table>
<thead>
<tr>
<th>Total Surveys Mailed</th>
<th>Undeliverable</th>
<th>Returned after Closing Date</th>
<th>Not practiced within 5 years</th>
<th>Used in Data Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,000</td>
<td>149</td>
<td>22</td>
<td>58</td>
<td>393</td>
</tr>
</tbody>
</table>

There are a variety of opinions in the literature about acceptable levels of mailed survey response rates ranging from 20% to 90% (Aday, 1996; Benke & Hermanson, 1987; Creative Research Systems, 2002; Schloss & Smith, 1999; Statistical confidence in a survey, 2003; Smith, 2002; Wiersma, 2000). This study utilized the Creative Research
Systems sample size calculator (Creative Research Systems, 2002). The sample size calculator demonstrates that a total of 377 completed, returned, surveys would provide a 95% confidence level with a confidence interval of $P < .05$ for this survey. A completed survey response rate of 393 surveys was obtained. However, with a response rate of 56%, data analysis must take into account the potential for non-respondent bias, the potential that some percentage of the non-respondent population may not have responded to the survey questions in the same way as the 56% of respondent surveys.

Sample Population Demographics

An almost equal geographic distribution of respondents occurred among the 393 surveys used with 34% (n=134) respondents from New York State, 32% (n=124) respondents from Florida and 31% (n=122) respondents from Pennsylvania. Thirteen respondents (3.3%) did not have their primary practice site in Pennsylvania, New York or Florida, however, they do live in those states. These 13 surveys were used in data analysis.

The majority of respondents (n=202) practice in urban settings while 139 practice in suburban settings and 52 practice in rural settings, as defined by the NP. Table 12 displays the respondents’ state and location of primary practice.
Table 12 - State and Location of primary practice

<table>
<thead>
<tr>
<th>Clinical practice site</th>
<th>State</th>
<th>Count</th>
<th>Percent</th>
<th>Count</th>
<th>Percent</th>
<th>Count</th>
<th>Percent</th>
<th>Count</th>
<th>Percent</th>
<th>Total</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>FL</td>
<td>PA</td>
<td>NY</td>
<td>Other</td>
<td>FL</td>
<td>PA</td>
<td>NY</td>
<td>Other</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urban</td>
<td></td>
<td>73</td>
<td>40</td>
<td>84</td>
<td>5</td>
<td>202</td>
<td>19.8</td>
<td>41.6</td>
<td>2.5</td>
<td>100.0</td>
<td>100.0</td>
</tr>
<tr>
<td>Percent</td>
<td></td>
<td>36.1</td>
<td>19.8</td>
<td>41.6</td>
<td>2.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suburban</td>
<td></td>
<td>39</td>
<td>52</td>
<td>41</td>
<td>7</td>
<td>139</td>
<td>28.1</td>
<td>37.4</td>
<td>29.5</td>
<td>5.0</td>
<td>100.0</td>
</tr>
<tr>
<td>Percent</td>
<td></td>
<td>28.1</td>
<td>37.4</td>
<td>29.5</td>
<td>5.0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rural</td>
<td></td>
<td>12</td>
<td>30</td>
<td>9</td>
<td>1</td>
<td>52</td>
<td>23.1</td>
<td>57.7</td>
<td>17.3</td>
<td>1.9</td>
<td>100.0</td>
</tr>
<tr>
<td>Percent</td>
<td></td>
<td>23.1</td>
<td>57.7</td>
<td>17.3</td>
<td>1.9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>124</td>
<td>122</td>
<td>134</td>
<td>13</td>
<td>393</td>
<td>31.6</td>
<td>31.0</td>
<td>34.1</td>
<td>3.3</td>
<td>100.0</td>
</tr>
</tbody>
</table>

The majority of the survey respondents were female (94%). This is reflective of the nursing profession as a whole, which is predominately female. Table 13 displays the age and gender of the respondents. The mode was 31 to 40 years of age with no respondents over the age of 60 years.
Table 13 - Demographics – Gender and Age

<table>
<thead>
<tr>
<th>Gender</th>
<th>Count</th>
<th>% of Total</th>
<th>Age</th>
<th>Count</th>
<th>% of Total</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>84</td>
<td>21.4%</td>
<td>20-30</td>
<td>195</td>
<td>49.6%</td>
<td>370</td>
</tr>
<tr>
<td></td>
<td>87</td>
<td>22.1%</td>
<td>31-40</td>
<td>87</td>
<td>21.4%</td>
<td>23</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>1.0%</td>
<td>41-50</td>
<td>92</td>
<td>23.4%</td>
<td>94.1%</td>
</tr>
<tr>
<td>Male</td>
<td>5</td>
<td>1.3%</td>
<td>51-60</td>
<td>4</td>
<td>1.0%</td>
<td>5.9%</td>
</tr>
<tr>
<td></td>
<td>23</td>
<td></td>
<td>Total</td>
<td>393</td>
<td>100.0%</td>
<td></td>
</tr>
</tbody>
</table>

Survey participants were asked to indicate their highest level of education and years of both nursing and NP experience. The majority of survey respondents (85%, n= 336) were MSN prepared. Table 14 displays the educational preparation of the survey respondents.

Table 14 - Educational Preparation of Survey Respondents.

<table>
<thead>
<tr>
<th>Degree</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valid</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diplom</td>
<td>17</td>
<td>4.3</td>
<td>4.3</td>
<td>4.3</td>
</tr>
<tr>
<td>Associate</td>
<td>11</td>
<td>2.8</td>
<td>2.8</td>
<td>7.1</td>
</tr>
<tr>
<td>Bachelors</td>
<td>24</td>
<td>6.1</td>
<td>6.1</td>
<td>13.2</td>
</tr>
<tr>
<td>Master</td>
<td>336</td>
<td>85.5</td>
<td>85.5</td>
<td>98.7</td>
</tr>
<tr>
<td>Doctorat</td>
<td>3</td>
<td>.8</td>
<td>.8</td>
<td>99.5</td>
</tr>
<tr>
<td>Post-Master's</td>
<td>2</td>
<td>.5</td>
<td>.5</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>393</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>

Over one third of survey respondents (35.6%, n=140) had 11 to 15 years of nursing experience, and 77.1% had five or less years of NP experience (n=303). Table 15
shows the total years of nursing experience, cross-referenced with the number of years of NP experience, for the sample population.

Table 15 – Demographics: Total Years of Nursing and NP experience

<table>
<thead>
<tr>
<th>Years of NP experience * Total years of nursing experience Crosstabulation</th>
<th>Total years of nursing experience</th>
<th>1-5</th>
<th>6-10</th>
<th>11-15</th>
<th>16-20</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Count</td>
<td>88</td>
<td>98</td>
<td>93</td>
<td>24</td>
<td>303</td>
</tr>
<tr>
<td></td>
<td>% of Total</td>
<td>22.4%</td>
<td>24.9%</td>
<td>23.7%</td>
<td>6.1%</td>
<td>77.1%</td>
</tr>
<tr>
<td>1-5</td>
<td>Count</td>
<td>13</td>
<td>38</td>
<td>15</td>
<td>66</td>
<td></td>
</tr>
<tr>
<td></td>
<td>% of Total</td>
<td>3.3%</td>
<td>9.7%</td>
<td>3.8%</td>
<td>16.8%</td>
<td></td>
</tr>
<tr>
<td>6-10</td>
<td>Count</td>
<td>9</td>
<td>13</td>
<td>2.3%</td>
<td>3.3%</td>
<td>5.6%</td>
</tr>
<tr>
<td></td>
<td>% of Total</td>
<td>2.3%</td>
<td>9.7%</td>
<td>3.8%</td>
<td>16.8%</td>
<td></td>
</tr>
<tr>
<td>11-15</td>
<td>Count</td>
<td>2</td>
<td>2</td>
<td>.5%</td>
<td>.5%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>% of Total</td>
<td>2.3%</td>
<td>9.7%</td>
<td>3.8%</td>
<td>16.8%</td>
<td></td>
</tr>
<tr>
<td>16-20</td>
<td>Count</td>
<td>88</td>
<td>111</td>
<td>140</td>
<td>54</td>
<td>393</td>
</tr>
<tr>
<td></td>
<td>% of Total</td>
<td>22.4%</td>
<td>28.2%</td>
<td>35.6%</td>
<td>13.7%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

Respondents were also asked to identify the patient population with whom they most frequently practice. If the NP practiced with more than one population type they were asked to identify the type of practice in which they spent most of their clinical time (what was their major patient population). Each respondent selected only one patient practice population. The largest group of respondents (n=105, 26.7%) was NPs working in adult specialty practices such as cardiology, orthopedics, dermatology, surgery and others. NPs working in women’s health care were the second largest response group at 20.6% (n=81) while NPs working in family practices and pediatric specialty practices made up the third largest group with 45 respondents (11.5%) each. These four practice populations account for 70.3% of the total responses. Figure 3 displays primary practice populations of the NPs who responded to the survey.
The survey sample population was obtained from the mailing lists of two national NP certifying bodies, ANCC and NCC. All survey respondents were certified in at least one specialty area and 7% of respondents (n=29) held more than one national certification. There was a preponderance of Family Nurse Practitioners (FNPs) responding to the survey (36.1%) with 142 respondents. Women’s Health Care NPs (WHCNPs) were the second largest group represented with 87 returned surveys (22.1%)
and Adult Primary Care NPs (APCNPs) with 80 respondents (20.4%) rounded out the top three represented groups. Table 16 displays the specialty practice certification type of the respondents.

Table 16 - Specialty Practice Certification Type of the Respondents

<table>
<thead>
<tr>
<th>National Certification</th>
<th>Respondents</th>
<th>Percent of Respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family NP</td>
<td>142</td>
<td>36.1%</td>
</tr>
<tr>
<td>Women’s Health Care</td>
<td>87</td>
<td>22.1%</td>
</tr>
<tr>
<td>Adult Primary Care</td>
<td>80</td>
<td>20.4%</td>
</tr>
<tr>
<td>Neonatal</td>
<td>53</td>
<td>13.5%</td>
</tr>
<tr>
<td>Adult Psychiatric</td>
<td>16</td>
<td>4.1%</td>
</tr>
<tr>
<td>Geriatric</td>
<td>16</td>
<td>4.1%</td>
</tr>
<tr>
<td>Acute Care</td>
<td>15</td>
<td>3.8%</td>
</tr>
<tr>
<td>Family Psychiatric</td>
<td>2</td>
<td>0.5%</td>
</tr>
<tr>
<td>Other</td>
<td>14</td>
<td>3.6%</td>
</tr>
</tbody>
</table>

Survey Analyses

Hypotheses

HO 1

More frequent interactions with pharmaceutical company representatives will result in greater perceived influence on the prescribing practices of the nurse practitioner.

To address this hypothesis, it was necessary to determine the correlation between the self-reported frequency of interaction between NPs and pharmaceutical company representatives (survey question 11) and the NPs self-reported
belief about pharmaceutical company influence on prescribing behavior and practice (survey question 1).

Responses to survey question 11 indicated the monthly frequency with which NPs interact with pharmaceutical company representatives at: clinical practice, at education meetings, continuing education conferences, grand rounds or other events. Sixty-eight percent of respondents (n=267) reported that they interacted with pharmaceutical representatives one to four times monthly, 16% five to nine times monthly, 5% ten to fourteen times monthly and 5% interact with pharmaceutical representatives more than fourteen times monthly. Twenty-four NPs (6%) reported no monthly interactions. Figure 4 displays the frequency of reported NP-Pharmaceutical company interactions monthly.

![Monthly NP-Pharmaceutical Company Interactions](image)

Figure 4 - NP-Pharmaceutical Company Monthly Interactions
Responses to survey question 1 indicate the degree to which respondents believe that their prescribing practices are influenced by pharmaceutical company sponsored gifts such as pens, note pads, textbooks; promotions such as drug samples for patients; educational programs at conferences, dinners or practice sites?. Fifty one percent of respondents (n=201) indicated that their prescribing practices and behaviors are influenced by pharmaceutical company interactions while 48.3% (n=190) indicated they were not influenced. Two respondents (0.6%) wrote in that they are sometimes influenced and but did not circle a response number. These data can be seen in table 17.

Table 17 - Frequency of Interaction and Belief of Company Influence

<table>
<thead>
<tr>
<th>Belief of company influence (q1)</th>
<th>Frequency of interaction with representatives (q11)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>1-4</td>
</tr>
<tr>
<td>no</td>
<td>Count</td>
<td></td>
</tr>
<tr>
<td></td>
<td>17</td>
<td>137</td>
</tr>
<tr>
<td></td>
<td>% of Total</td>
<td>4.3%</td>
</tr>
<tr>
<td>yes</td>
<td>Count</td>
<td></td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>129</td>
</tr>
<tr>
<td></td>
<td>% of Total</td>
<td>1.8%</td>
</tr>
<tr>
<td>sometimes</td>
<td>Count</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>% of Total</td>
<td>.3%</td>
</tr>
<tr>
<td>both</td>
<td>Count</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>% of Total</td>
<td>.3%</td>
</tr>
<tr>
<td>Total</td>
<td>Count</td>
<td></td>
</tr>
<tr>
<td></td>
<td>24</td>
<td>267</td>
</tr>
<tr>
<td></td>
<td>% of Total</td>
<td>6.1%</td>
</tr>
</tbody>
</table>

Spearman Correlation was significant for this question (p= <0.001) indicating a strong correlation between interaction with pharmaceutical companies and the NPs beliefs about being influenced by those interactions. Chi Square was also significant for this question $X^2(4, N = 393) p = <0.001.$
Among NPs reporting no monthly interactions with pharmaceutical company representatives, some may have annual encounters, up to 11 a year, at professional education programs, dinners or other sponsored events. Therefore, some of these NPs may actually interact with pharmaceutical company representatives less than monthly, but still encounter and interact with them several times a year.

Sixteen of the 24 NPs who indicated they do not interact with representatives monthly stated they work in neonatal intensive care units and have minimal or no access to pharmaceutical representatives. One neonatal NP wrote that instead of seeing pharmaceutical company representatives she saw baby formula representatives, which she considered very similar.

Further analysis was undertaken to determine if there were differences between those who interact with pharmaceutical representatives and those who reported no interaction. The data set was collapsed from four groups to two groups, representing those NPs who stated they never interacted with pharmaceutical companies (n=24, 6.1%) and those who do interact with pharmaceutical companies (n=369, 94%). This data is displayed in table 18.

Table 18 – NP Interaction with Representatives

<table>
<thead>
<tr>
<th></th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>No interaction</td>
<td>24</td>
<td>6.1</td>
<td>6.1</td>
<td>6.1</td>
</tr>
<tr>
<td>Have interaction</td>
<td>369</td>
<td>93.9</td>
<td>93.9</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>393</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>
The respondents self-reported beliefs about pharmaceutical company influence on their prescribing behavior, survey question 1, was correlated to survey question 11, the average number of reported interactions. Statistical analysis was performed using Chi Square. For those NPs who stated they have pharmaceutical company interaction (interaction > 1 per month), there is no statistically significant difference in whether or not they believed they are influenced by the encounters $X^2(3, N = 393), p= 0.231$. Therefore, the hypothesis, more frequent interactions with pharmaceutical company representatives will result in greater perceived influence on the prescribing practices of the nurse practitioner is rejected.

**HO 2**

The geographic location of the NPs practice (urban, suburban or rural) will influence the number of self-reported interactions with pharmaceutical company programs, promotions and gifts.

Survey question 18 asked the NPs *where is your primary clinical practice site located? (If more than one site, please select the site in which you see the most patients).* Correlation of the number of pharmaceutical company interactions and the NPs clinical practice site (urban, suburban, rural) was then run. Spearman Rho found a statistically high level of significance ($p= 0.008$) between the location of the clinical practice site and number of pharmaceutical company interactions. For respondents who have one or more pharmaceutical company interactions monthly, the number of urban NPs who have pharmaceutical company interaction is statistically significant (urban > rural $p= <0.001$; urban >suburban $p= 0.004$). Thus, urban NPs have more pharmaceutical company interactions monthly than suburban NPs and both
urban and suburban NPs have more monthly pharmaceutical company interactions than rural NPs. Therefore, the hypothesis, the geographic location of the NPs practice (urban, suburban or rural) will influence the number of self-reported interactions with pharmaceutical company programs, promotions and gifts, is accepted. Interestingly, for NPs who reported no pharmaceutical company interaction, a statistically significant number of urban NPs had no interaction than either suburban or rural NPs (urban > suburban p= 0.022; urban > rural P= <0.001). This may be due in part to populations of NPs who work in isolated urban settings such as intensive care units, operating suites and, neonatal ICUs, where pharmaceutical company interaction is restricted by the patient care environment.

Questions

The following is analysis of the data tool grouped according to topic.

A. Questions 5 and 11- Change or modification in prescribing after pharmaceutical company interaction

In order to identify whether the number of NP-pharmaceutical company interactions has any relationship to the NPs prescriptive changes, survey question 5, have you ever modified or changed your prescribing after a pharmaceutical company interaction and survey question 11, average number of monthly pharmaceutical company interactions were correlated. Eighty percent of respondents (n=313) said they had changed or modified their prescribing practice after a pharmaceutical company encounter while 20% of respondents (n=80) said they had never changed or modified their prescribing practice after such encounters. Spearman correlation shows statistical significance (p=< 0.001) indicating a strong relationship between the number of
pharmaceutical company encounters and the NPs self-reported change or modification in their prescribing behavior.

The data set was collapsed from four groups to two groups, to determine if there were differences between NPs who stated they never interacted with pharmaceutical companies (n=24, 6.1%) and those who do interact with pharmaceutical companies (n=369, 94%).

Correlation between the 94% of respondent NPs who have pharmaceutical company interaction and their self-reported change or modification in prescribing after an interaction shows that 77.6% (n=305) of the respondent NPs sometimes change their prescribing after pharmaceutical encounters while 20.4% (n=80) never change their prescribing practice after an encounter and 2% (n=8) report always changing their prescribing practice after a pharmaceutical company sponsored interaction (more NPs change sometimes than never or always). More NPs never change their prescribing practice after an encounter than always change (p= < 0.001) and there is no statistically significant difference in the other groups, category 2 & 3 (p = 0.070).

B. Questions 5 and 1 - Change in prescribing versus perceived influence

Data were analyzed identity if any correlation exists between the NPs self-reported change or modification of prescribing practice (survey question 5,) and the NPs belief about pharmaceutical company influence on their prescribing practice (survey question 1).

Eighty percent of respondents (n=313) said they had changed or modified their prescribing practice after a pharmaceutical company interaction while 20% of respondents (n=80) said they had never changed or modified their prescribing practice
after encounters. However, only 48% of respondent NPs stated they did not feel they were influenced by pharmaceutical encounters while 51% felt they were influenced (Table 19).

Table 19 – Belief about Influence and Prescribing Change after Encounters

<table>
<thead>
<tr>
<th>Believing of Company Influence * Prescribing Changes After</th>
<th>Never</th>
<th>2</th>
<th>3</th>
<th>Always</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Believing of influenc</td>
<td>no</td>
<td>Coun</td>
<td>61</td>
<td>82</td>
<td>45</td>
</tr>
<tr>
<td>% of</td>
<td>15.5%</td>
<td>20.9%</td>
<td>11.5%</td>
<td>.5%</td>
<td>48.3%</td>
</tr>
<tr>
<td>yes</td>
<td>Coun % of</td>
<td>19</td>
<td>90</td>
<td>88</td>
<td>6</td>
</tr>
<tr>
<td>% of</td>
<td>4.8%</td>
<td>22.9%</td>
<td>22.4%</td>
<td>1.5%</td>
<td>51.7%</td>
</tr>
<tr>
<td>Total</td>
<td>Coun % of</td>
<td>80</td>
<td>172</td>
<td>133</td>
<td>8</td>
</tr>
<tr>
<td>% of</td>
<td>20.4%</td>
<td>43.8%</td>
<td>33.8%</td>
<td>2.0%</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Chi-square analysis demonstrates this significance (p= <0.001). Further examination with Wilcoxon Signed Ranks Test validates this significance (p= <0.001) indicating that the number of NPs who actually change or modify their prescribing behavior after one or more pharmaceutical company encounters is significantly greater than the number of NPs who believe they are not influenced by those encounters.

When asked about perceptions of influence by pharmaceutical companies on other NPs prescribing behaviors, 274 NPs (69.7%) reported believing other NPs are influenced by their pharmaceutical company interactions. This is in contrast to the 203 NPs (51.7%) who believe they are influenced by these same encounters. Chi Square shows this 18% discrepancy in NP beliefs to be statistically significant (p= < 0.001).
The comparatively small number of NPs in this study who stated they had never changed their prescribing practice after pharmaceutical company encounters (6.1%, n=24) may be different in other geographic regions of the country.

**C. Question 6 - Reasons for prescribing change after pharmaceutical company interaction**

Respondents were asked to specify why they had changed or modified their prescribing practice after attending a pharmaceutical company sponsored event from a list of eight possible reasons. Most NPs selected more than one reason for changing or modifying their prescribing with a mean of 4.478 reasons. The most frequently cited reason was more ‘effective for the problem’ (74.6%, n= 293), followed by ‘as effective with less side effects’ (71.2%, n=280), and ‘as effective and less costly’ (68.4%, n=269) (figure 5).
Many NPs wrote comments, as invited, at the end of the survey and some of these pertained to changes or modifications in practice after interactions. Six write-in comments addressed the fact that samples are not allowed in their practice site. Twenty-nine of the 36 write-in comments mention how important it is to have samples available in the office. The complete list of write-in comments can be found in Appendix F. A few of the write-in comments addressing the importance of sample availability follow in table 20:
Table 20 – Sample Survey Comments

<table>
<thead>
<tr>
<th>Survey Number</th>
<th>Comment</th>
<th>Practice Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>29</td>
<td>I also volunteer at a clinic that relies heavily on samples with limited resources available. Sample availability strongly affects what the patent is given (as does cost).</td>
<td>Occupational Health</td>
</tr>
<tr>
<td>70</td>
<td>Samples are sometimes the only way my patients have of receiving needed meds. I feel fortunate that we can provide meds when our patients can’t afford them</td>
<td>Adult Primary Care</td>
</tr>
<tr>
<td>186</td>
<td>I run a free family practice clinic 1 day a week and depend on drug reps samples to give away</td>
<td>Geriatric Long Term Care</td>
</tr>
<tr>
<td>143</td>
<td>Cost effective medication selection is important in the population of clients I see.</td>
<td>Adult Primary Care</td>
</tr>
<tr>
<td>190</td>
<td>I use samples as a trial for side effects before pt’s purchase the full script</td>
<td>Family Practice</td>
</tr>
<tr>
<td>39</td>
<td>Practices influenced because I am more aware of their products</td>
<td>Cardiology</td>
</tr>
<tr>
<td>263</td>
<td>My patients however must have free samples until we wake up and provide universal health insurance. Samples are great for the uninsured</td>
<td>Geriatric primary care</td>
</tr>
<tr>
<td>376</td>
<td>Samples are great for the uninsured</td>
<td>Geriatrics</td>
</tr>
<tr>
<td>307</td>
<td>Drug reps do not visit NICUs [neonatal intensive care units] very frequently. We do tend to see formula reps more often (I consider these extremely similar)</td>
<td>Neonatal ICU</td>
</tr>
</tbody>
</table>

Other issues cited as influencing prescribing practice after pharmaceutical company interaction included: 1) third party payers (insurance carriers) who only allow certain medications to be prescribed under their coverage plans, 2) hospital or institutional formularies, which identify which drugs, are able to be prescribed in the facility and are carried by the institutions’ pharmacy 3) influence such as when the NP is more aware of the pharmaceutical products because of an
interaction, 4) cost to the patient, and 5) lack of patient health insurance to pay for medications.

D. Question 3b and 6 - Importance of Sample Availability

NPs were asked in survey question 3b, *when selecting a prescription drug for your patients, how important is having samples available in the office when choosing which drug to prescribe?* Sixty percent of the respondents stated that having samples available in the office was very important or somewhat important in choosing which prescription drug to select for their patients (figure 6). This is reflective of the number of write-in comments on the survey, addressing the importance of samples.

![Importance of sample availability](image)

**Figure 6 – Importance of Sample Availability**
Survey question 6 asked, *if you have ever changed or modified your prescribing practice after a pharmaceutical company sponsored event, which of the following factors affected your decision?* Having samples available in the office was choice 6f. Fifty five percent of the respondents (n=217) stated that they had modified or changed their prescribing practice after a pharmaceutical company sponsored event because sample medications were available in the office for their patients.

**E. Question 4 - Appropriateness of accepting sample drugs for patient use**

Survey question 4 asked the NP to rate the appropriateness of accepting sample drugs for your patients. Only 17% (n=67) of NPs felt it inappropriate or very inappropriate to accept prescription medication samples for their patients while 82% of the respondents felt it appropriate or very appropriate to accept samples for patient use.

The number of write-in comments that address the issue highlights the importance of free sample medications in the practice site. Comments such as “sample availability strongly affects what the patient is given”, “free samples for geriatric patients have been helpful in compliance with medications for those who are unable to afford the medications”, “samples are great for the uninsured”, “I prefer to try a patient on samples before they spend their own money on a medication that they may not be able tolerate”, “I think the positive aspect of the drug companies is the free sample for patients without prescription coverage. I find this to be very helpful”, “samples are important to our practice as many of our patients can’t afford the needed meds without the samples”, “I would say I am not influenced by pens, notepads, dinners in the office, but I am influenced by what samples are available in the office”, “Most of patients I see have no insurance. I rely on samples” and simply, “samples have been very beneficial”.
F. **Question 10a - Usefulness of pharmaceutical company information**

Survey question 10a asked the NP to indicate strength of agreement or disagreement with the statement *pharmaceutical representatives provide useful information about pharmaceutical products*. Eighty eight percent (n=348) of respondents agreed or strongly agree that pharmaceutical companies provide useful information about pharmaceutical products.

G. **Question 10d - NPs perception of bias in pharmaceutical company information**

Survey question 10d asked the NP to indicate strength of agreement or disagreement with the statement *pharmaceutical representatives provide unbiased information about pharmaceutical products*. Only 15% of respondents agreed or strongly agreed that the information provided by pharmaceutical company representatives is unbiased. Eighty five percent of respondents felt the pharmaceutical company information was biased to some degree. This finding is further illustrated by survey comments such as: “I do feel this information is biased (naturally) and this is why I do not let it influence my prescribing”, “I am cautious about info given by sales representatives. Most do not have medical or clinical background and parrot information they have been fed by marketing divisions”, “Reps are biased”, “Sometimes reps present a biased viewpoint pointing only to the positive studies/aspects of their drug”, “The drug reps often flash research studies that may or may not be valid as a way to persuade me to prescribe”, and “I think NPs are smart enough to use reps stuff to better serve patient populations, staff, etc, and not be influenced by their used car salesman tactics”. With the above comments in mind, the question arose, who are the 15% of NPs who believe pharmaceutical company information is unbiased? Correlation of those NPs who agreed
or strongly agreed that pharmaceutical company information is unbiased with practice site, gender and specialty practice produced the following results.

A statistically significant number of females believed the information to be unbiased \( (p = <0.001) \) when compared with their male counterparts. More urban and suburban NPs believed the information to be unbiased than rural NPs \( (\text{urban and rural } p = <0.001, \text{suburban and rural } p = <0.002) \). There was no significant difference between urban and suburban NP populations \( (p=0.555) \). Looking at practice populations, the Spearman analysis for this correlation was not significant due to low numbers in some of the cells.

H. Question 10c - Pharmaceutical company role in education

Survey question 10c then asked the NPs to indicate strength of agreement or disagreement with the statement \textit{pharmaceutical representatives provide an important education function}. Eighty two percent of the respondents agreed or strongly agreed that pharmaceutical companies provide an important education function. This data is corroborated by the NPs comments on the survey, some of which were very specific. “I believe samples and educational materials are extremely useful”, “I like the dosing charts for antibiotics”, “I find pharmaceutical reps very helpful and informative”, “I enjoy interacting with most reps because they have the ability to answer specific questions or get the answer in an efficient manner”, “I enjoy the updates and articles the reps bring”, “I have to admit a free lunch brought to me on a busy day is nice sometimes”, “I also get patients signed up for pharm company free medication programs”, “Drug reps sponsored activities often provide venue for learning, CEU (continuing education units) and networking”, I believe that pharmaceutical reps are helpful in providing information and
samples to my patients”, “We do see reps occasionally for education/lectures…”, and finally, “Since starting to practice I have learned a great deal by attending drug company sponsored educational activity. I have found this educational help invaluable…”.

However, 18% of the respondents felt pharmaceutical companies did not provide an important education function. Who are the NPs who believe this? Correlation of the three factors gender, practice site and specialty practice type revealed the following significant finding. More rural NPs believe pharmaceutical companies provide an important education function than either urban or suburban NPs (urban > rural  p= <0.001, suburban > rural p=0.001). There was no statistically significant difference between urban and suburban (p= 0.051) NP populations, gender or practice populations.

I. Question 13 - Preparation in NP Education Program

NPs were asked if they felt they were adequately prepared during their initial NP program to interact with pharmaceutical company representatives. Survey question 13 asked the NP to indicate their level of agreement or disagreement with the statement during my nurse practitioner education program I was given adequate information concerning how a nurse practitioner should interact with pharmaceutical representatives so that I could make informed prescribing decisions. Sixty two percent of the respondents strongly disagreed with the statement and a total of 87% of the NPs disagreed or strongly disagreed that they were given adequate information in their NP education program (figure 7).
Figure 7 – NP program provided adequate information about NP-pharmaceutical company interaction

J. Question 9 - Repeat Encounters

Question 9 asked, if you received an item useful to you in your practice such as an educational monograph, product information, patient samples, note pads or pens, from a pharmaceutical representative, how likely would you be to see that pharmaceutical representative again? Eighty nine percent (n=350) of the respondents stated they would be likely or very likely to see a pharmaceutical representative again if they had provided an item useful to them in their practice. Less than 9% stated it was somewhat unlikely they would see the representative again and only 2% stated it was not very likely they would see the representative again in their practice.
K. Question 8 – Gifts accepted by NP respondents

Question 8 asked the respondents; *have you ever received any of the following promotional gifts or products from pharmaceutical representatives in you clinical practice site, at an educational dinner or luncheon, grand rounds, local or national conferences or by mail?* Office supplies was the most frequently accepted gift with 99% (n = 389) of NPs acknowledging they accepted small office supplies such as pens, coffee mugs, paper clips or notepads. Educational materials for patients was second with 95% (n = 374), food brought to the clinical practice site by pharmaceutical representatives was third with 94% (n = 371) and food at educational meetings rounded out the top four gift with 78% (n = 341). Figure 8 illustrates the remaining responses.

![Gifts and Promotions Received by NP Respondents](image)

Figure 8 - Gifts and Promotions Received by NP Respondents
L. Questions 4 and 8 - Beliefs about appropriateness of accepting promotions, products, and gifts versus behaviors related to accepting gifts

NPs were asked in survey question 4 to rate their opinion of the appropriateness of accepting specific promotional products, gifts and events related to their practice. Survey question 8 asked the NPs to identify which, if any, of the same list of promotional products, gifts or events they had actually accepted. A correlation was performed for the two questions. A two-tiered Spearman’s rho found the correlation to be statistically significant for all items identified (Table 21).
### Table 21 – Beliefs versus behavior regarding accepting pharmaceutical company promotions, products and gifts

<table>
<thead>
<tr>
<th>Item</th>
<th>Office Supply</th>
<th>Food in office</th>
<th>Antibiotic guides, etc.</th>
<th>Food at meeting</th>
<th>Sample drugs patients</th>
<th>Trips &amp; events</th>
<th>Honoraria</th>
<th>Sample drugs Personal</th>
<th>Patient educations materials</th>
<th>Sample drugs Family</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office Supplies</td>
<td>Correlation Coefficient (2-tailed)</td>
<td>-0.14</td>
<td>0.004</td>
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<tr>
<td>Food in office</td>
<td>Correlation Coefficient (2-tailed)</td>
<td></td>
<td></td>
<td>-0.23</td>
<td>0.000</td>
<td></td>
<td></td>
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<tr>
<td>Antibiotic guides, etc</td>
<td>Correlation Coefficient (2-tailed)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>-0.14</td>
<td>0.007</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Food at meetings</td>
<td>Correlation Coefficient (2-tailed)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>-0.22</td>
<td>0.000</td>
<td></td>
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<tr>
<td>Sample drugs patients</td>
<td>Correlation Coefficient (2-tailed)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>-0.29</td>
<td>0.000</td>
<td></td>
<td></td>
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<tr>
<td>Trips &amp; events</td>
<td>Correlation Coefficient (2-tailed)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>-0.17</td>
<td>0.000</td>
<td></td>
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<tr>
<td>Honorarium</td>
<td>Correlation Coefficient (2-tailed)</td>
<td></td>
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<td></td>
<td></td>
<td>-0.18</td>
<td>0.000</td>
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<tr>
<td>Sample drugs Personal</td>
<td>Correlation Coefficient (2-tailed)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>-0.33</td>
<td>0.000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient educations materials</td>
<td>Correlation Coefficient (2-tailed)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>-0.20</td>
<td>0.000</td>
<td></td>
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<tr>
<td>Sample drugs Family</td>
<td>Correlation Coefficient (2-tailed)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>-0.29</td>
<td>0.000</td>
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</table>
These findings demonstrate that NPs’ beliefs about accepting pharmaceutical company promotions and gifts are not congruent with their actions in accepting these items. Although the correlations are small, the results are strongly significant.

M. Question 3b and 6e - Direct-to-Consumer Marketing

Finally, the issue of the potential influence of direct-to-consumer marketing on the NPs practice was addressed. Survey question 3b asked the NP to indicate how important a patient’s request for a specific drug is when choosing which drug to prescribe. Sixty two percent of the respondents stated that a patient’s request for a specific drug was very important or somewhat important in their prescriptive decision-making while 37% of respondents felt it was not important to their prescriptive decisions. Survey question 12 asked during the last year, how many times a month have you had a patient request a specific drug because they have seen it advertised on television, billboards, magazines or other media sources or because a friend or relative suggested it? Eighty nine percent of respondents stated they had at least one patient request a month for a specific drug, and frequently many more, as a result of direct to consumer marketing (figure 9).
Survey question 6 then asked the NP if you have ever changed or modified your prescribing practices after attending a pharmaceutical company sponsored event, which of the following factors affected your decision? Thirty seven percent (n=146) of the NPs stated they had changed or modified their prescribing practice because the patient requested the drug.

Further analysis examined the correlation between the importance of patient request for a specific drug and the NPs change or modification in practice due to a patient request and after a pharmaceutical company interaction. Spearman analysis for this correlation was not significant due to low numbers in some of the cells.
Chapter Summary

**HO 1**

Results of data analysis reject hypothesis 1, more frequent interactions with pharmaceutical company representatives will result in greater perceived influence on the prescribing practices of the nurse practitioner. NPs who have some pharmaceutical company interaction (interaction > 1 per month), show no statistically significant difference in whether or not they believe they are influenced by pharmaceutical company interactions. An unexpected finding is that the number of NPs who actually change their prescribing practice after a pharmaceutical company interaction is significantly greater than the number of NPs who believe they are influenced by the encounter.

**HO 2**

Hypotheses two, the geographic location of the NPs practice (urban, suburban or rural) will influence the number of self-reported interactions with pharmaceutical company programs, promotions and gifts, is accepted. Urban NPs have more interactions with pharmaceutical representatives than suburban or rural NPs. However, more urban NPs also report no pharmaceutical company interaction than either suburban or rural NPs. This may be due in part to NPs who work in isolated urban settings such as intensive care units, operating suites and neonatal ICUs, where pharmaceutical company interaction is restricted by the patient care environment.

*Change or Modification in Prescribing after Pharmaceutical Company Interaction.*

Correlation between the 94% of respondent NPs who do have pharmaceutical company interaction and their self-reported change or
modification in prescribing shows that more NPs sometimes change their prescribing after pharmaceutical encounters than never change their practice or always change their practice.

**Change in Prescribing Practices versus perceived Influence.**

Although only 20% of the respondents stated they had never changed or modified their prescribing practices after a pharmaceutical company interaction, 48% of the NPs felt they were not influenced by those interactions. The number of NPs who actually change or modify their prescribing behavior after one or more pharmaceutical company encounters is significantly greater than the number of NPs who believe they are not influenced by those encounters.

**Reasons for Prescribing Change after Pharmaceutical Company Interaction.**

Most NPs reported more than one reason for changing or modifying their prescribing with a mean of 4.478 reasons. The most frequently cited reason was ‘more effective for the problem’ (74.6%, n= 293), followed by ‘as effective with less side effects’ (71.2%, n=280), and ‘as effective and less costly’ (68.4%, n=269).

**Importance of Sample Availability.**

Sixty percent of the respondents stated that having samples available in the office was very important or somewhat important in choosing which prescription drug to select for their patients. Fifty five percent of respondents stated that they had modified or changed their prescribing practice after a pharmaceutical company sponsored event because samples medications were available in the office for their patients.
Appropriateness of Accepting Sample Drugs for Patient Use.

Eighty two percent of respondents felt it appropriate or very appropriate to accept samples for patient use.

Usefulness of Pharmaceutical Company Information.

Eighty eight percent of respondents agreed or strongly agreed that pharmaceutical companies provide useful information about pharmaceutical products.

NPs Perception of Bias in Pharmaceutical Company Information.

Eighty five percent of respondents felt pharmaceutical company information provided to them was biased to some degree. More females believed the information to be unbiased than their male counterparts. More urban and suburban NPs believed the information to be unbiased than rural NPs.

Pharmaceutical Company Role in Education.

Eighty two percent of respondents agreed or strongly agreed that pharmaceutical companies provide an important education function. Eighteen percent of respondents felt pharmaceutical companies did not provide an important education function. More urban and suburban NPs believe pharmaceutical companies do not provide an important education function than rural NPs.

Preparation in NP Education Program.

Eighty seven percent of NPs felt they were not given adequate information in their NP education program concerning how a nurse practitioner should interact with pharmaceutical representatives in order to make informed prescribing decisions.
Repeat Encounters.

Eighty nine percent of respondents stated they would be likely or very likely to see a pharmaceutical representative again if they had provided an item useful to them in their practice.

Beliefs about Appropriateness of Accepting Promotions, Products, and Gifts versus Behaviors Related to Accepting Gifts

The findings demonstrate that NPs’ beliefs about accepting pharmaceutical company promotions and gifts are not congruent with their actions in accepting these items.

Direct –to-Consumer Marketing.

Sixty two percent of respondents stated that patient request for a specific drug was very important or somewhat important in their prescriptive decision-making. Eighty nine percent of NPs reported at least one patient request monthly for a specific drug as a result of direct to consumer advertising. Thirty seven percent of the NPs stated they had changed or modified their prescribing practice because of a patient request for a specific drug.
Table 22 - Summary of Hypotheses and Survey Findings

| Hypothesis                                                                 | Results                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|----------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------
| HO1. More frequent interactions with pharmaceutical company representatives will result in greater perceived influence on the prescribing practices of the nurse practitioner. | Rejected. There is no statistically significant difference between NPs who have one pharmaceutical interaction and NPs who have multiple interactions monthly.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| HO2. The geographic location of the NPs practice (urban, suburban or rural) will influence the number of self-reported interactions with pharmaceutical company programs, promotions and gifts. | Accepted. More urban NPs interact with pharmaceutical companies than suburban or rural NPs. However, more urban NPs also report no pharmaceutical company interaction when compared with either suburban or rural NPs (sub population of NPs in ICU’s, OR’s, neonatal units?)                                                                                                   |

| Questions                                                                 | Results                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|----------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------
<p>| A. Change or modification in prescribing after pharmaceutical company interaction | More NPs sometimes change their prescribing after pharmaceutical encounters (78%) than never change their prescribing (20%) or always change their prescribing (2%) after encounters                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| B. Change in prescribing practices versus perceived influence.        | The number of NPs who actually change or modify their prescribing behavior after one or more pharmaceutical company encounters is significantly greater than the number of NPs who believe they are not influenced by those encounters                                                                                      |
| C. Beliefs about appropriateness of accepting promotions, products, and gifts versus behaviors related to accepting gifts | Findings demonstrate that NPs’ stated beliefs about accepting pharmaceutical company products, promotions, and gifts are not congruent with their actions in accepting these items.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| D. NPs reasons for prescribing change after pharmaceutical company interaction | Most NPs reported more than one reason for changing or modifying their prescribing after pharmaceutical company interaction. The most frequently cited reasons were; more effective for the problem, as effective with less side effects, as effective for the problem and less costly                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |</p>
<table>
<thead>
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<tbody>
<tr>
<td>E. Importance of Sample Availability.</td>
<td>60% of the respondents stated that having samples available in the office was important in choosing which prescription drug to select for their patients. 55% percent of respondents stated that they had modified or changed their prescribing practice after a pharmaceutical company sponsored event because samples medications were available in the office for their patients.</td>
</tr>
<tr>
<td>F. Appropriateness of accepting sample drugs for patient use</td>
<td>82% of respondents felt it appropriate to accept samples for patient use.</td>
</tr>
<tr>
<td>G. Usefulness of pharmaceutical company information.</td>
<td>88% percent of respondents agreed that pharmaceutical companies provide useful information about pharmaceutical products.</td>
</tr>
<tr>
<td>H. NPs perception of bias in pharmaceutical company information.</td>
<td>85% of respondents felt pharmaceutical company information provided to them was biased to some degree. More females believed the information to be unbiased than males. More urban and suburban NPs believed the information to be unbiased than rural NPs.</td>
</tr>
<tr>
<td>I. Pharmaceutical company role in education</td>
<td>82% of respondents agreed that pharmaceutical companies provide an important education function. More rural NPs believe pharmaceutical companies provide an important education function than urban or suburban NPs.</td>
</tr>
<tr>
<td>J. Preparation in NP Education Program.</td>
<td>87% of NPs felt they did not receive adequate information in their NP education program about NP-pharmaceutical company interaction.</td>
</tr>
<tr>
<td>K. Gifts accepted by NP respondents</td>
<td>99% of NPs have accepted small office supplies such as pens, coffee mugs, paper clips or notepads. 95% accepted patient education materials, 94% accepted food brought to the clinical practice site by pharmaceutical representatives and 78% accepted food at educational meetings.</td>
</tr>
<tr>
<td>L. Repeat Encounters.</td>
<td>89% of respondents stated they would be likely to see a pharmaceutical representative again if they had provided an item useful to them in their practice.</td>
</tr>
<tr>
<td>M. Direct –to-Consumer Marketing.</td>
<td>62% of respondents stated patient request for a specific drug was important in their prescriptive decision-making. 89% of NPs reported at least one patient request monthly for a specific drug as a result of direct to consumer advertising. 37% stated they had changed or modified their prescribing practice because of a patient request for a specific drug.</td>
</tr>
</tbody>
</table>
CHAPTER 5: SUMMARY AND IMPLICATIONS FOR FURTHER RESEARCH

Introduction

This study explored the influence of pharmaceutical company promotions, products and gifts on the self-reported prescribing beliefs and practices of certified nurse practitioners in three states. The purpose of this study was to assess the correlation between Nurse Practitioner’s (NP) self-reported pharmaceutical company interactions and their self-reported prescribing behaviors and practices. During the course of the study, several additional questions related to the NPs beliefs and practices were identified.

At the beginning of this study, three stakeholder groups were identified: practicing NPs, NP faculty, and professional NP organizations including state boards of nursing. Two additional stakeholder groups emerged during data analysis. It was felt that the results of this study would 1) assist NPs in identifying influences that affect their personal prescribing practices, allowing them to modify their behaviors if warranted, 2) assist faculty in NP programs to identify influences on NPs prescribing practices and incorporate information about those issues when developing or revising curricula, and 3) begin to build a base of information about NPs prescribing practices that may be used by NP professional organizations in establishing guidelines for NP-pharmaceutical company interactions such as those developed by many physician organizations. The two additional stakeholder groups identified are pharmaceutical companies and patients.

Pharmaceutical companies spend millions of dollars annually on marketing their products. Knowing how their marketing influences the NP population is important information. Some patients, who are already beginning to notice pharmaceutical
company marketing through direct-to-consumer advertising and news media reports, will want to know how this marketing may affect their health care providers’ prescriptive choices and whether these promotions and gifts adversely, or positively, affect prescribed medications. The conclusions and implications of this study will be addressed in relation to these five stakeholder groups.

Practicing Nurse Practitioners

The first hypothesis asserted that the number of NP-pharmaceutical company interactions would affect the NPs beliefs about being influenced. That is, the more NP-pharmaceutical company interactions, the more likely the NP would be to believe that he or she was influenced by the interactions. As would be expected, NPs who stated they had no pharmaceutical company interaction did not feel they were influenced at all. However, for the group that cited pharmaceutical company interaction (one or more encounters monthly) there was no significant relationship between the numbers of NP pharmaceutical interactions and the NPs beliefs about whether or not they were influenced. It appears that an NP who has only one pharmaceutical company encounter is just as likely to recognize the potential influence of that encounter as an NP who has 14 or more encounters monthly. Conversely, the NP with multiple pharmaceutical company interactions is just as likely to be influenced, and not recognize that influence, as an NP who has only one encounter. The quality of the encounter, perhaps the benefit the NP perceives from the encounter, may be more significant than the actual number of interactions between the NP and the pharmaceutical representative. The perceived benefit may be a benefit to the practicing NP herself, or a perceived benefit to his or her patients. Therefore, the more beneficial the NPs view the encounter, the more likely they
would be to interact with pharmaceutical representatives again. This conclusion is corroborated by the 89% of respondents who stated they would be likely to see a pharmaceutical representative again if the representative had provided an item useful in their practice.

This study did not specifically ask the NP respondents to identify what pharmaceutical company products, promotions and gifts they found useful to their practice. However, we may assume that the items NP respondents selected on the products, promotions and gifts list on the survey, and addressed by the write-in comments, could be considered useful to them. These items range from office supplies such as pens and coffee cups to small, inexpensive, antibiotic guides, to patient education materials, educational dinners and lunches, granting of continuing education credits and sample medications for the office practice. Two items were identified as being highly valued by the NPs: sample medications for patients and pharmaceutical company education programs. These two items, and other key findings, are discussed below.

Sample Medications

The first item NPs identified as important to their practice was pharmaceutical samples for patients. This finding was expected based on the review of the literature and are reflected in the NP respondents’ comments. Reasons for sample use include:

- NPs work with a high percentage of indigent and underserved populations, resulting in a high percentage of patients in the practice without prescription coverage
- Samples are used as a method of trialing a specific drug, especially expensive drugs before writing a prescription for the patient to fill
• Sample medications are used as a means to start a patient on a drug immediately, perhaps antibiotics or pain medication, prior to the patient filling the written prescription, or for patients seen in an off-hours practice such as an emergency department or urgent care center.

• Samples are used as a source of short term medication dispensing for patients without health insurance who can not afford medications and who may be eligible for pharmaceutical company free medication programs for ongoing medication maintenance.

The comments from this survey are reflective of information in the literature. However, one implication that can be drawn from this data is that there are patient populations that NPs manage entirely on free sample medications. The researcher expected that NPS working with indigent or under-insured populations would write prescriptions for low-cost generic drugs, rather than start patients on expensive, newer, sample drugs. Indigent patients are those patients who fall through the cracks of the health insurance and coverage system and may not qualify for Medicaid, employer health benefits or pharmaceutical company free medication programs. However, contrary to the researchers expectation, the data infer that a significant number of NPs manage patients on samples alone, rather than starting with low-cost generic drug choices. The following are a few of the write-in comments about sample use and importance. They come from NPs with a variety of practice populations in varying geographic locations.

• Samples are sometimes the only way my patients have of receiving needed meds. I feel fortunate that we can provide meds when our patients can’t afford them.

• As a rural practice, many of my patients fall into the “working poor”, uninsured group. I use free samples to treat those who cannot afford or at least to reduce their financial burden.
Believe me, I work in an underprivileged area and look to use samples for my patients who can’t afford meds
I give samples to patients who don’t even have medical assistance
Most of patients I see have no insurance. I rely on samples
Most NPs see large percentage of their practice with indigent or "working poor” populations. If not for samples, many of these patients would not be able to start treatment due to expense
I run a free family practice clinic 1 day a week and depend on drug reps samples to give away
I like to have birth control pill samples for instructions and demonstration to the patient, as many insurance policies do not cover contraception for patients. I like having samples for them.
Samples are important to our practice as many of our patients can’t afford the needed meds without the samples.
Samples are great for the uninsured
Samples provided for our clinic have truly been “life savers” for those oncology patients with chronic pain (Vioxx samples) and nausea (Zofram) and no insurance coverage
Samples are great for the uninsured
Free samples for geriatric patients have been helpful in compliance with meds for those who are unable to afford the medications

The researcher’s assumption was that NPs would report dispensing a large number of sample medications to patients who are indigent or underserved. Therefore, they would use more drug samples because of lack of insurance. These assumptions were upheld by the comments of the respondents. However, the inference from these comments is slightly different from anticipated in that NPs are dispensing free sample medications rather than prescribe less expensive alternatives for their patients.

The importance of sample medications for dispensing is not an issue that appears in the physician literature addressing pharmaceutical company influence. This feedback from NPs appears to be unique to the NP population. However, PAs and MDs may see similar patient populations and may well have the same opinions and beliefs about the importance of sample availability. In-depth investigation into how NPs utilize sample medications should be the focus of further research. Additionally, a study of NP sample
medication dispensing should be undertaken, to include income and health insurance coverage of the NPs’ patient population and the percentage of NP patients who are managed entirely on sample medications.

Pharmaceutical Company Education Programs

The second item repeatedly mentioned as useful to the NPs practice was pharmaceutical company sponsored education programs, both for health care providers and pharmaceutical company sponsored patient education literature. In fact, 34% (n=133) of the respondent NPs stated they had changed a patient’s medication after a pharmaceutical company encounter due, at least in part, to education materials being available from the pharmaceutical company.

Another aspect of the pharmaceutical company education programs, and perhaps the one most important to practicing NPs, is the pharmaceutical company sponsored education program. Since the early 2000’s, pharmaceutical companies have begun to recognize the importance of non-physician health care providers in both marketing and promoting pharmaceutical products. Both NPs and PAs have been increasingly targeted for educational dinners, office visits and online, audio and interactive education programs aimed at promoting the company’s products. Most NPs in the survey group found these education programs to be very useful. Issues cited included new research and data monographs, resource text such as antibiotic prescribing guides, access to experts in specialty practice fields through education symposia, and obtaining free continuing education units (CEU’s). All NPs need some number of CEU’s in order to re-certify in their specialty area and/or for state licensure or certification as an NP. Many of these
pharmaceutical sponsored CEU events are convenient for the NP as they are offered in a variety of formats from interactive online, to audiotapes, from self-study modules to office lunches and dinner at three and four star restaurants. Selected NPs comments concerning these activities are below:

- Since starting to practice I have learned a great deal by attending drug company sponsored educational activity. I have found this educational help invaluable
- I do feel the information that they provide very helpful. Especially recent studies and data essential to my prescribing practice.
- Drug reps sponsored activities often provide venue for learning, CEU and networking
- They [pharmaceutical companies] are the only ones who provide free, accessible contact with experienced practitioners
- I enjoy interacting with most reps because they have the ability to answer specific questions or get the answer in an efficient manner.
- I find pharmaceutical reps very helpful and informative. It helps keep me up my knowledge of new medications and changes to treatment guidelines.
- I like the dosing charts for antibiotics.
- I find it very helpful to talk to reps. They summarize information in the prescribing guide which I don’t always have time to read and inform me of new indications and new research for a drug.
- They should give away less junk and provide more educational seminars (I like nice dinners but that is not why I go)
- Educational programs at conferences and dinners
- Even if the reps did not supply lunch, I would still take the time to briefly talk with them re: new indications, warning, etc. regarding their drugs.
- I believe samples and educational materials are extremely useful.
- The educational material and studies they provide with re: to efficacy, etc…are important.

*Buyer Behavior - Stimulus-Response Model*

The Buyer Behavior - Stimulus-Response Model (S-R) is one of many used by marketing professionals to promote products. It illustrates the many factors that go into marking choices and decisions by pharmaceutical companies and others wishing to sell a product or service. One can assume the purpose of most pharmaceutical company incentives such as samples and education programs is to influence or persuade NPs to change their prescribing behavior and prescribe a drug from the sponsor company’s”
array of products. Generally, S-R models assume that an incentive of some type, with appropriate modification for specific groups and populations, will result in a response that can be predicted by the marketer; that is, the marketer’s offer to take a health care provider to a high priced restaurant for dinner and an educational program about a new drug, or a new use for an existing drug, will result in the healthcare provider prescribing more of the pharmaceutical company’s product presented at the dinner.

In the S-R model, marketing questions and other factors enter the “black box” known as the customer (in this case, the NP) and produce certain responses. Pharmaceutical company marketing personnel must try to decide how the NP thinks and emotionally responds to the stimulus offered (dinner, continuing education credits, gifts, sample medications). The NP buyer characteristics will influence how they understand, interpret and perceive the stimuli. This is both a cognitive and an emotional response to the stimulus. Then, a decision-making process occurs which ultimately determines what, if any, buying (or prescribing) behavior the NP exhibits.

The literature assumes the stimulus for the NP in this scenario is the free dinner, the response is going to the restaurant, and the reward is continuing education credits. Pharmaceutical company motivation for providing the dinner event is obviously a potential change in the NPs prescribing behavior, resulting in the NP writing more prescriptions for product X. Therefore, in this stimulus-response-reward model, the reward of increased pharmaceutical sales goes to the pharmaceutical company and the NP gets dinner at a nice restaurant and CEU’s.
NP Stimulus = offer of a free dinner and continuing education credits
NP Response = NP goes to dinner event
NP Reward = free dinner and continuing education credits

The buyer stimulus-response model is similar to the Elaboration Likelihood Model (ELM) of persuasion theory. Both theories require both emotion and cognition in order for the individual to be persuaded. ELM cites motivation to change as 1) the individuals' personal involvement or interest in the issue, 2) their ability to process persuasive arguments and attention factors, and 3) whether they have the time or inclination to focus on the issue. Petty and Cacioppo (1985) found that the less the individuals interest in the issue, the less attention they paid to the information presented and the less motivated they were to cognitively process the argument. When motivation for the issue was low, peripheral cues became more important (Jowett & O’Donnell, 1999).

A New Model

The model suggested by this study makes a different assumption; i.e. that the real reward in this scenario goes not to the pharmaceutical company in the form of increased sales, but instead, to the NP. This new model combines the premise of the ELM and the buyer stimulus response models but views the pharmaceutical company-NP interaction in a different way. When an NP, PA or MD is invited to dinner at a highly priced restaurant, the assumption in the literature is that the dinner (or free gift, money or other incentive product) is, in itself, the reward for the health care provider. This new combination model makes the assumption that the reward is not the dinner or CEU’s, but rather the information received as a result of accepting the incentive. This is a clear
departure from the concept that NP’s or MD’s change their prescribing practice because they receive a gift, in this case a nice dinner. The decision to attend a pharmaceutical company sponsored event, involves several elements including: 1) interest level in the topic 2) investment of time to attend, and 3) the worth of this event compared to other like events. This is the “black box” area of the stimulus-response-reward model where the invitee makes a series of decisions that result in a determination to attend or not attend the function. The data suggests attending a pharmaceutical company sponsored event provides the NP the opportunity to carve out a protected period of time from their busy schedule in which they have the time to actually listen to a presentation. I refer to this period of time as protected-reflective time. This is a block of time which, without an incentive to “make the time”; the health care provider would never have carved out of their schedule. This period of protected-reflective time allows the health care provider the time to listen to an educational presentation, discuss and debate the issues with the presenter and other health care providers in a learning environment. This opportunity permits the health care provider to then reflect on the information received, weigh the choices and make a critical decision about whether or not this new drug or therapy might be appropriate for their patient population. The attendee also has the opportunity to discuss the information with his or her peers and integrate their opinions into his or her decision-making. Often, without the protected-reflective time offered by these educational programs at dinner meetings, professional educational programs or other sponsored events, the health care provider may not take the time to hear the information presented at the program and therefore not be able to make a critical, informed decision about a new product.
This new theory of protected-reflective time is echoed by comments on the returned surveys.

- I agree that money used for dinner programs/seminars can be high, however, *this is the time slot where I am not seeing patients and am able to digest the information.*
- They [pharmaceutical companies] are the only ones who provide *free, accessible contact with experienced practitioners (who are almost always) very informed about their general topics and usually happy to be a source of information.*
- Drug reps sponsored activities often provide venue for *learning, CEU and networking*
- I attend dinners for education *and to hear cases of use, problems, success by other health care providers.* I like to think I have a “thoughtful practice”. The information can only be helpful - *how I use it is my choice.*

Many NPs also wrote in comments about the need for sample medications for their patients and their beliefs about their ability to “cut through the hype” and make informed clinical decisions based on the data rather than the “trinkets”.

- I am cautious about info given by sales representatives. Most do not have medical or clinical background and parrot information they have been fed by marketing divisions.
- Yes, I take their samples and goods, but I still prescribe according to supportive research studies of the products
- I enjoy the updates and articles the reps bring but I try to keep a level head and evaluate for myself.
- If a company can convince me with the research that their drug is better or cheaper, I will use it. The junk never influences my decision
- So although drug reps may “push their product” we feel the samples for our children are worth a few minutes of hype!
- I think NPs are smart enough to use reps stuff to better serve patient populations, staff, etc, etc. and not be influenced by their used car salesman tactics
- The information can only be helpful - *how I use it is my choice.*
- Changed prescribing after educational program – sometimes, after receiving a gift – never
- I find it somewhat unethical however I have been guilty on occasion attending dinners that were given to our entire practice.

These comments are also reflective of a model that requires both emotion and cognition in order decide whether to be persuaded or not. The NPs comments reflect
both emotional aspects of the process (caution, enjoyment, feelings, and guilt) as well as aspects of their cognitive process (“prescribe according to supportive research”, “keep a level head and evaluate for myself”, “thoughtful practice…how I use it is my choice”.

Perceived Pharmaceutical Company Influence and Prescribing Behavior

Studies have shown that physicians are influenced by pharmaceutical company interactions and, in fact, are not aware of the extent of that influence on their prescribing behaviors and practices (Steinman, Shlipak & McPhee, 2001; Wazana, 2000). Likewise, this study demonstrates that NPs are also influenced by pharmaceutical company interaction and often do not recognize this influence. That is, 51% of the NP respondents believed they were influenced by pharmaceutical encounters and 80% report they changed their prescribing practices after such an encounter.

There remains the discrepancy between the 48% of NPs who do not believed they are influenced by pharmaceutical encounters and the 80% of NPs who report having changed their prescribing practices after such an event. The data indicates that 32% of the NPs surveyed did not recognize any relationship between exposure to product information through education programs, office visits, or other methods, and changes in their own prescribing behavior. Survey results indicate that the number of NPs who actually change or modify their prescribing behavior after one or more pharmaceutical company encounters is significantly greater than the number of NPs who believe they are not influenced by those encounters. This finding indicates a lack of understanding by NPs about the nature of influence.
Survey results also revealed a statistically significant difference in NPs perception of whether or not pharmaceutical company products, promotions, and gifts influence their own prescribing practices, and whether or not these influence their NP colleagues same encounters. While 69.7% of the NP respondents felt their fellow NPs were influenced by pharmaceutical company interactions, only 51.7% of the same NP respondents felt their own prescribing behaviors were influenced by pharmaceutical company interactions. This 18% discrepancy between NPs beliefs about influence on their personal prescribing practices and their perceptions about other NPs level of influence, although statically significant, is actually lower than results in the MD literature. Steinman’s (2000) study asked medical residents about the appropriateness of accepting promotions and gifts from pharmaceutical companies and the influence of these items on their prescribing behavior. His study found that 84% of medical residents believed their fellow medical residents were influenced by pharmaceutical company promotions and gifts while only 39% of the same medical residents felt their own prescribing behavior was influenced by the pharmaceutical company promotions and gifts. The data in this study show that NPs are not realistic about the effect of pharmaceutical company influence on their own practice. It appears that they may be able to identify and assess the effect of pharmaceutical company’s influence on their peers, yet fail to recognize it in their own practice.

NP Reasons for Prescriptive Changes after Pharmaceutical Company Interaction

NP responses to the survey identified an average of 4.478 reasons for changing prescribing behavior after a pharmaceutical company encounter. The top four choices in
rank order are; 1) were more effective for the problem, 2) as effective with less side effects, 3) as effective and less costly, and 4) a new alternative for my patient. These reasons are reflected in the NPs comments on the survey and are congruent with the literature addressing what NPs believe to be important to their practice. The fact that NPs are influenced to change their prescribing after a pharmaceutical company interaction, in and of itself, is less of an issue than why the NP chooses to change his or her prescribing after the encounter. If the change occurs because of a period of protected reflective time at a dinner meeting or because of a critical review of the literature revealing a more effective drug alternative for the patient because of cost, taste, route, or number of medications a day taken by the patient, the influence would be deemed positive. That is, the encounter provided the NP with the necessary information to provide better care for his or her patients. If, however, a gift or promotional product is the reason for the prescriptive change, the patient could potentially suffer the consequences of a less effective drug, a more costly drug or frequent medication schedules which may be disruptive to the patients’ daily life. None of the NPs surveyed identified a free gift or dinner as the reason for changing their prescribing practices. However, the potential of either the influence of the free gift (dinner, coffee mug, CEU’s, etc.) or a sense of obligation the pharmaceutical company representative, much like the sense of obligation evoked when receiving an unsolicited gift in the mail to encourage completion of a survey, cannot be eliminated based on this study. One NP commented “I have found this [pharmaceutical company] educational help invaluable, but often feel expected to prescribe their drug”, and another stated “I find it somewhat unethical, however I have been guilty on occasion attending dinners that were given to our entire practice”. 
Another respondent noted, “Maybe you should ask, would I go to a presentation that did not include dinner. Answer-maybe”. For these respondents, the influence of the gift alone (dinner, trinkets, pens, etc.) could be the motivating factor in their prescriptive change.

Further, data from this survey shows that more NPs change their prescribing practices after a pharmaceutical company encounter (78%) than never change their prescribing after such an encounter (20%). The results indicate that the pharmaceutical company stands a good to excellent chance of the NP changing his or her prescribing once an encounter has occurred. From a pharmaceutical company standpoint, the effort is probably worth the return. The issue for NPs becomes, is the time and energy involved in engaging pharmaceutical companies worth it? Results raise the question, to what degree do prescribing changes occur after a pharmaceutical company interaction due to the NPs sense of obligation to respond in kind to “freebies”? Or is the decision a calculated move on the NPs part to obtain what they need to improve practice?

The survey comments appear to support the NPs recognition of the marketing game and their willingness to endure the hype in order to obtain what their patients need. Eighty-nine percent of the survey respondents said they would be likely or very likely to see a pharmaceutical company representative again if they had provided an item useful to them in their practice. If NPs recognize the “game” and can and do manipulate the marketers to obtain what they need for themselves and for their patients in order to provide better care, how much more could NPs accomplish in an organized approach to pharmaceutical companies with respect to improving care for patients instead of the
individual hit and miss approach currently employed. Melanie Balestra, President of the American College of Nurse Practitioners affirmed that NPs prescribe more than 350 million drugs for patients each year. She noted the need for NPs and pharmaceutical companies to work together to improve patient care and outcomes and to continue to learn. She encouraged NPs to attend professional conferences and interact with pharmaceutical companies for mutual benefit (Balestra, 2004).

Small Gifts

The majority of NP respondents to this survey reported no interest in office supplies such as pens, pencils, clocks and coffee mugs although 99% of the NPs had accepted these items and 72% felt it appropriate or very appropriate to accept them. Fifteen NP respondents stated they thought the money spent of these items should be channeled into more valuable uses such as lowering the cost of medications or increasing education programs. Some of these comments are:

- The trinkets (coffee mugs) could be forgotten in my opinion
- I do feel the pharmaceutical companies spend too much time on superficial giveaways
- I am not influenced by trinkets
- I would say I am not influenced by pens, notepads
- If pharmaceutical companies spent less on marketing (pens, clocks, note pads, etc.) and lowered the cost of the drugs, samples wouldn’t be as great a need.

Non-medical items are left in the office but are not an influence on my prescribing practice
I could really care less about the JUNK that they (the pharmaceutical companies) give us. Rarely do I find something useful

They should give away less junk and provide more educational seminars (I like nice dinners but that is not why I go), decrease advertising so they can offer a drug at a lower cost and have more patient assistance programs.

The gifts such as pens, notepads, etc. is not an influence.

Survey results indicate that pharmaceutical companies could save money by discarding promotional “trinkets” and invest their money more effectively in educational programs for NPs. It should be noted however, that 99% of the NPs in this study have accepted at least some of these items and 72% thought it appropriate or very appropriate to accept them. As a marketing tool, it is unclear how influential having a product name in constant view might be to the pharmaceutical company’s goal of promoting their product. Clearly, many offices, clinics and practices use pens, coffee mugs and candy bowls, filled daily with a pharmaceutical product name or logo items in clear sight. Further, the survey did not consider the “dribble down” or “pass-on” effect of these inexpensive promotional products. This study has no estimate of the number of pens, coffee mugs or note pads with names and logos that go home with NPs, office staff and patients. These more subtle influences may be known and anticipated by the pharmaceutical companies and justify the cost. A study looking at name recognition for specific drug products associated with promotional items in practice would be warranted.

Patient request for specific medication

Sixty-two percent of the NP respondents revealed that patient requests for a specific drug was important in their prescriptive decision-making while 89% of NPs
reported at least one patient request monthly for a specific drug as a result of direct to consumer advertising. However, only 37% reported changing or modifying their prescribing practice because of a patient request for a specific drug. This may reflect the NPs’ commitment to patient education while caring for their health and wellness. Direct-to-consumer advertising is often misunderstood or incomplete from the patients’ perspective. This has been attributed to a lack of balance in the advertising, change in tempo and presentation style during the listing of adverse effects, the use of medical terminology during the advertisement and other marketing techniques that result in only 34% of consumers being able to identify that the drug may not work for everyone (Kaphingst & DeJong, 2004).

It is often the path of least resistance for health care providers to write out a prescription or give out the sample that the patient asks for, whether it is indicated or appropriate for the presenting complaint. Writing a prescription and instructing the patient with directions on how to appropriately use the drug takes several minutes. Taking the time to explain to the patient why the requested drug is not appropriate for the presenting complaint takes significantly more time. A perfect case in point is the patient who arrives in the office with a request for “an antibiotic for my cold”. After the history and examination, the NP diagnosis the patient with a viral illness, a condition for which an antibiotic is neither required, nor appropriate. The NP must then take the time to explain the difference between a bacterial and a viral illness, the history and physical exam findings that support his or her diagnosis, and the rationale for the medication (if any) that is prescribed or ordered in lieu of the requested antibiotic, all in language understandable by the patient. Occasionally, an argument ensues and the patient will
demands the requested antibiotic. The NP then needs to restate the case and attempt to help the patient understand the clinical situation. This process requires significantly more time than simply writing out a prescription. Eighty-nine percent of respondents reported at least one request by a patient for a specific drug monthly, yet only 37% had actually changed or modified their prescribing because of the patient request. This is indicative of the NPs ability to withstand the direct-to-consumer marketing onslaught and continue to evaluate each patient and their requests on an individual basis.

The fact that only 62% percent of the respondents stated that patient request for a specific drug was very important or somewhat important in their prescriptive decision-making was surprising. The researcher would assume that all NPs would consider a patient request very important or at least somewhat important when making prescriptive decisions. This less than 100% response may be reaction to the availability of sample medications in the practice. That is, if the NP knows that there is no sample of the requested medication available, and the patient does not have prescription insurance and would be unable to afford the prescription for the requested drug, perhaps the NP lowers the importance of the patients’ request, knowing that what the patient wants is simply not available to them.

The physician literature reveals concern about MDs responses to patients’ requests for specific drugs, especially due to DTC marketing. Wolfe noted, “There is evidence that many drug advertisements are not balanced or accurate and duped gatekeepers may not adequately resist patients’ exhortations to write a prescription” (2002, p.525). These concerns were mirrored by a British Journal of Medicine (2002) study that examined U.S. and a Canadian primary care practice sites to determine
whether or not MDs were influenced by their patients’ requests for prescription drugs. After controlling for many of the variables, the authors concluded that the patient’s request for a prescription medication significantly influenced the choice of drugs that physicians prescribed. “In most cases physicians prescribed requested medications but were often ambivalent about the choice of treatment” (Mantes, et al., 2002, pg. 279). Similar issues should be further investigated in the NP population, looking for variations in responses to patient’s requests for specific drugs and NPs rationale for denying or honoring such requests.

Nursing Faculty

Nursing faculty are the second stakeholder group identified in this study. Results revealed that 87% of NP respondents felt their NP program did not provide them with adequate information about NP-pharmaceutical company interaction. This perception appears to indicate a gap in content material in NP education programs. Although the question did not ask NPs what was lacking in their education or how it should be addressed, responses such as “I have found this educational help invaluable, but often feel expected to prescribe their drug” and “I have been guilty on occasion attending dinners that were given to our entire practice” indicate that some NPs are not comfortable in these pharmaceutical company interactions. The ethical issues imbedded in NP-pharmaceutical company interaction should be threaded throughout NP curricula.

Curriculum content for NPs needs to include influence theory and marketing tactics. Health policy or health promotion courses could include assignments that examine the influence of pharmaceutical company programs such as sample medications
and free prescription programs on prescribing practice. Students could identify areas in which they feel pharmaceutical companies might have an impact or improve care for patient populations or groups. Content might also include critique of pharmaceutical company educational materials for reading level and messages. Students could then suggest improvements or revisions. Research courses need to not only address critical reading of research data from studies and monographs, but also need to directly tie this content into how the pharmaceutical company presents clinical data supporting their findings. Pharmaceutical company monographs and literature generally indicate that their drug product is the best. A valuable exercise would be to have NP students critique 2 pharmaceutical company presentations or monographs about why similar drugs are the best for a specific health care problem such as diabetes, hypertension or hypercholesteremia. The student would then identify the missing pieces, data inconsistencies, or research methodology inadequacies in the material presented on the health care problem. This assignment would give the NP student an opportunity to critically analyze research data and identify the potential spin placed on the drug for marketing purposes. In a clinical course, NP students could be assigned to investigate the marketing materials for a specific drug, present those findings to the class, and well armed with information, approach the pharmaceutical representative to ask questions related to the research findings. The results of such exercises would be a heightened level of confidence for the student NP in reading pharmaceutical company research reports, addressing questions with representatives and receiving feedback, and ultimately, becoming more informed prescribers and consumers of pharmaceutical products.
Professional Nursing Organizations

The third stakeholder identified in this study is professional nursing organizations and State Boards of Nursing. These organizations develop standards of care, professional guidelines and scope of practice statements. Results of this study demonstrate that NPs are influenced by pharmaceutical company interaction, promotions and gifts. Further, the data has shown that at least some NPs are not aware of the influence exerted by the pharmaceutical companies and that 87% of NPs do not feel they were given adequate information in their initial NP program concerning how a nurse practitioner should interact with pharmaceutical representatives in order to make informed prescribing decisions. These findings have implications for professional nursing organizations.

NP Professional Organizations

NP professional groups are the organizations that practicing NPs, other professionals and the legal system recognize to delineate roles, propose education program guidelines and standards of care for the profession. Nurse Practitioner professional organizations such as the American Academy of Nurse Practitioners and the American College of Nurse Practitioners, and specialty NP groups such as the Association of Women's Health, Obstetric and Neonatal Nurses are comprised of individuals with clinical, educational and political expertise in NP practice. Professional Standards of Care and Position Statements are developed in response to pressing social, economic and educational imperatives within the profession or healthcare delivery system. Existing Position Statements include topics such as prescriptive privileges, role, nurse practitioner curriculum, end-of-life care, and nurse practitioners and direct-to-consumer advertising.
As early as 1990 the American College of Physicians stated its concern about the influence of pharmaceutical company sponsored educational programs and gifts on physicians’ and medical students’ prescribing practices. Even with such guidelines in place, many physicians were still unaware of the problem. In 2002, the American College of Physicians issued a second position statement on physician-pharmaceutical company interaction. This new statement reiterated the need for awareness of the implications of pharmaceutical company sponsored education and its influence on prescribing practices and recommended that all medical students, residents and physicians receive training on this issue (Coyle, 2002b).

Results of this study indicate that professional NP organizations need to develop a Position Statement on NP-Pharmaceutical Company interaction. Further, adding NP-pharmaceutical interaction, as a topic in the Position Statement on Nurse Practitioner Education should be considered. This recognition of the interaction between the pharmaceutical industry and the practicing NP would be an important step in the acknowledging that pharmaceutical influence extends well beyond the physician population.

Several NP professional organizations such as the American Academy of Nurse Practitioners (AANP), American College of Nurse Practitioners (ACNP) and the National Organization of Nurse Practitioner Faculties (NONPF) sponsor continuing education programs, conferences, CE events and professional publications. Results from this study demonstrate that NPs do not feel comfortable with influence theory and marketing content. This content should to be addressed through these professional venues.
In a workshop format, NPs could investigate the marketing materials for a specific drug through a group presentation format. A short presentation on influence and marketing could precede the participants breaking into small work groups. With the assistance of the workshop facilitator, NPs could examine the literature, discuss the findings, and present those findings to the workshop group. The results of such a workshop group would be a heightened level of confidence for the NP in reading pharmaceutical company research reports, addressing questions with representatives and receiving feedback. Similar information could be published in NP professional journals. Ultimately, this would help the practicing NP become a more informed prescriber and consumer of pharmaceutical products and services.

National Organization of Nurse Practitioner Faculties

The National Organization of Nurse Practitioner Faculties (NONPF) develops curricular guidelines for NP education. NONPF’s document The Criteria for Evaluation of Nurse Practitioner Programs (NONPF, 1997) and the Curriculum Guidelines and Program Standards for Nurse Practitioner Education (NONPF, 1995) are acknowledged by nursing program accrediting bodies, the National League for Nursing Accrediting Commission and the American Association of Colleges of Nursing, as the framework for NP curriculum. The results of this study point to the need for the integration of issues related to NP-pharmaceutical company interaction into every NP curriculum.

State Boards of Nursing

State Boards of Nursing (SBN) are responsible for the Scope of Practice for nurses and nurse practitioners, although in some cases SBNs share that responsibility with a physician board. SBN are ultimately responsible for nursing licensure and certification
including development of the nurses Scope of Practice and any continuing education requirements imposed on nurse and nurse practitioner re-licensure. Most SBN’s require some continuing education credits for re-licensure and also some pharmacology continuing education credits for NPs.

The results of this study indicate that State Boards of Nursing should ensure that not all NP pharmacology continuing education credits are obtained through pharmaceutical company sponsored education programs. Having NPs obtain some of their required pharmacology continuing credits through professional nursing journal self-learning modules, nursing continuing education programs, or collegiate pharmacology courses and updates, would ensure that not all the pharmacology credits obtained by the NP originate with pharmaceutical company marketing sources.

Pharmaceutical Companies

The results of this study may influence pharmaceutical companies to work with NPs collaboratively for the benefit of both and for the patient. Pharmaceutical companies need to reach out to NPs through educational programs about new drug products and new indications for older drugs. This will result in increased patient management information available to the NP. Further, this collaboration opens lines of communication between the two groups and allows both pharmaceutical companies and NPs to better understand the knowledge base and resources available within the two groups. Ultimately, it allows the NP and the pharmaceutical company to interact at levels such as those identified below.
1. NPs should be recruited for patient guideline panels and steering groups and be involved in the development of patient education materials. NP insights into patients, families and communities can be an invaluable asset to pharmaceutical company education committees and programs, not only in program development but also in preparation of education materials to accompany new and older pharmaceutical products. NPs can also be valuable assets to pharmaceutical companies as presenters at seminars, conferences and programs for both patients and healthcare professionals.

2. Program planning is an area in which pharmaceutical companies significantly under use NPs as a resources. Pharmaceutical companies need to approach NPs to serve on patient education panels, “think tanks” and information gathering sessions. As nurses are repeatedly identified as the most trusted profession in public opinion surveys, NPs working closely with patients, families and community resources can provide a perspective different from physicians and Pas. An example might be the emphasis NPs in this study placed on the availability of sample medications for patients in their practices. As patient advocates, NPs could brainstorm with pharmaceutical companies to identify target populations and communities for pharmaceutical company support, identify criteria for free sample medication distribution based on the needs of patient populations and communities rather than the more prevalent system of indiscriminate distribution. Pharmaceutical companies distribute sample medications in an effort to increase sales of their profit-producing product lines. However, perhaps there are additional, as yet unidentified, ways to support underserved populations for which NPs have the key.
3. NPs and pharmaceutical companies could also increase their interaction is in the area of clinical trials research. NPs work with a variety of populations across all ages, ethnic, social and illness continuaums. These clinical practices could well support clinical trials research while providing a service to patients in the practice.

4. NPs need to highlight their special expertise and offer to work with the pharmaceutical companies for the mutual benefit of patients. Pharmaceutical companies need to provide NPs with their articles and monographs highlighting the company’s products, to provide educational materials and resources for patients and to continue to work with NPs to provide pharmaceutical coverage for indigent and underserved patients through sample medications and access to pharmaceutical programs. Pharmaceutical companies need to know exactly what NPs “find useful to their practice”.

5. Finally, NPs should approach pharmaceutical companies to fund NP research on patient populations, NP outcomes, and community based needs. Further, additional, research on NPs utilization of pharmaceutical company services and samples is necessary, and should be developed through partnerships linking practicing NPs and pharmaceutical companies. NPs need to collaborate with the pharmaceutical companies in supporting NP education as they become more informed consumers of pharmaceutical company services.

Patients

The fifth stakeholder group identified in this research is patients. Pharmaceutical companies target patients through direct-to-consumer marketing (DTC) using the media including television, newspapers and magazines. Pharmaceutical company information is
also available through brochures and pamphlets, in health care providers’ offices, and online through pharmaceutical company websites.

This study has demonstrated that DTC marketing has an impact on NP-patient interaction. Eighty-nine percent of the respondent NPs reported at least one patient request monthly for a specific drug and 62% of respondent NPs reported that patient request for a specific drug was important or very important to their prescribing choices. As pharmaceutical research become more accessible to the general public through news reports, advertising and website access, patients who already notice pharmaceutical company marketing through DTC advertising, will want to know how their requests for specific drugs affects their health care providers’ prescriptive choices. Further, advocacy organizations such as the American Association of Retired Persons (AARP) who are involved in healthcare spending analyses and lobbying will want to know the impact pharmaceutical spending on DTC advertising has on prescription medication costs. Additionally, these organizations need to know how DTC marketing affects the prescriber, ultimately influencing the patients’ prescribed medications.

Patients are the end users of prescription medications. The availability of sample medications at a practice site should be assumed to be an important issue for patients. Patients need to ask their healthcare provider about prescription drugs that may be helpful to their medical condition when they see them advertised. However, there needs to be balance in the advertising permitted in DTC marketing. Patients and advocacy organizations need to critically assess the prescription drug information provided through DTC marketing. Informational brochures, articles, and television programming
explaining influence and pharmaceutical company marketing of prescription drugs should be developed and disseminated.

Conclusions

NPs are influenced by their interactions with pharmaceutical companies. This does not mean that pharmaceutical company-NP interactions are negative. There are many benefits to NP-pharmaceutical company affiliation that result in increased access to medications for patients, education opportunities for NPs, educational resources for patients and potentially, increasing opportunities for NP-pharmaceutical company cooperation in education and research. However, the practicing NP needs to be able to recognize and acknowledge the influence of pharmaceutical company promotions in order to utilize the information appropriately in the service of the patient.

NPs value pharmaceutical interactions and recognize the benefits accrued. Like their physician counterparts, some NPs do not recognize the influence pharmaceutical companies have on their prescribing practice. Professional nursing organizations need to develop position statements on NP-pharmaceutical company interaction, educators need to integrate pharmaceutical marketing and influence issues into their curricula and practicing NPs need to become critical users of pharmaceutical company services.
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Appendix A: American College of Physicians Physician–Industry Relations

POSITION PAPER


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This is part 1 of a 2-part paper on ethics and physician-industry relationships. Part 1 offers advice to individual physicians; gives recommendations to medical education providers and medical professional societies.

Physicians and industry have a shared interest in advancing medical knowledge. Nonetheless, the primary ethic of the physician is to promote the patient’s best interests, while the primary ethic of industry is to promote profitability. Although partnerships between physicians and industry can result in impressive medical advances, they also create opportunities for bias and can result in unfavorable public perceptions.

Many physicians and physicians-in-training think they are impervious to commercial influence. However, recent studies show that accepting industry hospitality and gifts, even drug samples, can compromise judgment about medical information and subsequent decisions about patient care. It is up to the physician to judge whether a gift is acceptable. A very general guideline is that it is ethical to accept modest gifts that advance medical practice. It is clearly unethical to accept gifts or services that obligate the physician to reciprocate.

Conflicts of interest can arise from other financial ties between physicians and industry, whether to outside companies or self-owned businesses. Such ties include honorariums for speaking or writing about a company’s product, payment for participating in clinic-based research, and referrals to medical resources. All of these relationships have the potential to influence a physician’s attitudes and practices. This paper explores the ethical quandaries involved and offers guidelines for ethical business relationships.

In 1990, the American College of Physicians published a position statement titled "Physicians and the Pharmaceutical Industry" to address ethical issues in relationships between industry and the medical profession (1). The statement, which was prompted in large part by evidence of the drug industry’s influence on physician behavior and concern for professional integrity and patient care, examined potential conflicts of interest in relationships with industry and provided ethical advice in certain areas. Since the statement was originally released, evidence of industry’s influence on medical practice, research, and education has continued to emerge, and physician-industry relationships have multiplied. Once again, the American College of Physicians–American Society of Internal Medicine reminds physicians and industry to be vigilant about potential conflicts and ethical problems. The College recognizes that while there are no easy answers to many ethical questions, guidance in certain areas can be useful.
This is part 1 of a 2-part paper on ethics and physician-industry relationships. In part 1, the College offers recommendations to individual physicians, mainly clinicians and clinician-researchers, regarding acceptance of gifts and other financial relationships with industry. It addresses medical education providers and medical professional societies that accept corporate funding for organizational projects or membership events, such as meetings and symposiums.

Despite the introduction in the early 1990s of ethical standards for physicians regarding physician-industry relationships, concerns persist and evidence accumulates that commercial rewards can unduly affect clinical judgment (2-9). Industry allocates substantial resources to promote its products to physicians. In 1999, the pharmaceutical industry spent nearly $8.0 billion (U.S.) to send sales representatives to physician offices and to exhibit products at medical conferences and events (10). Such costly corporate overtures raise questions about undue influence and could undermine genuine educational efforts.

In addition to the pharmaceutical industry, physicians are increasingly courted by newly emerging industries (biotechnology, pharmacogenetics, e-commerce), and potential conflicts of interest, whether real or perceived, are pervasive. Physicians meet industry representatives at the office and at professional meetings, collaborate in community-based research, and develop or invest in health-related industries. In all of these spheres, partnered activities often offer important opportunities to advance medical knowledge and patient care, but they also create an opportunity for the introduction of bias.

This paper offers two positions to help guide individual physicians in making ethical decisions about interacting with industry. The positions are based on the profession’s fundamental principles of responsibility, that is, acting in a patient’s best interests (beneficence), protecting the patient from harm (nonmaleficence), having respect for the patient and fostering informed choice (autonomy), and promoting equity in health care (justice). To uphold these principles, the primary purpose of entering relationships with industry should be the enhancement of patient care and medical knowledge. While the ethics of medicine and the ethics of business sometimes diverge, both are legitimate, and a thoughtful collaboration of physicians and industry can result in the best of patient care.

**Position 1. Industry Gifts, Hospitality, Services, and Subsidies**

The acceptance of individual gifts, hospitality, trips, and subsidies of all types from industry by an individual physician is strongly discouraged. Physicians should not accept gifts, hospitality, services, and subsidies from industry if acceptance might diminish, or appear to others to diminish, the objectivity of professional judgment. Helpful questions for gauging whether a gift relationship is ethically appropriate include 1) What would my patients think about this arrangement? What would the public think? How would I feel if the relationship was disclosed through the media? 2) What is the purpose of the industry offer? 3) What would my colleagues think about this arrangement? What would I think if my own physician accepted this offer?

**Rationale**

Physicians understand that to maintain their professional objectivity they must be mindful of potential biases in medical information (7, 11). In fact, the entire infrastructure of science and
much of physician education is built on the fundamental notion of eliminating, or at least controlling for, the many and powerful biases inherent in generating and interpreting scientific data. Ethically and professionally, the objective evaluation of medical information is critical for deciding on best clinical practices (beneficence) and avoiding risks to patient safety (nonmaleficence) (12-14). Thus, physicians have an obligation to themselves, their profession, and society to evaluate, correct for, and eliminate potential bias in medical information from all sources.

Recent studies and reports have examined industry influence on physician objectivity and behavior (15, 16), particularly prescribing practices, formulary choices, and assessment of medical information (3, 7, 17-25). Physicians frequently do not recognize that their decisions have been affected by commercial gifts and services (26) and in fact deny industry’s influence (3, 15, 17-22), even when such enticements as all-expenses-paid trips to luxury resorts are provided (23). Research, however, shows a strong correlation between receiving industry benefits and favoring their products (23, 25, 27).

What Would My Patients Think about This Arrangement?

The dictates of professionalism require the physician to decline any industry gift or service that might be perceived to bias their judgment, regardless of whether a bias actually materializes. A perception that a physician is dispensing medical advice on the basis of commercial influence is likely to undermine a patient’s trust not only in the physician’s competence but also in the physician’s pledge to put patients’ welfare ahead of self-interest. Recent research on patient attitudes shows that patients are more likely than physicians to perceive industry gifts as inappropriate or influential on medical practice (19, 28, 29). More particularly, a significant number of patients believe that industry gifts bias their physicians’ prescription practices and ultimately drive up medical costs. Patients make a distinction, however, between acceptable and unacceptable gifts. Most think that inexpensive incentives designed for office use (pens, notepads) and patient care (drug samples, medical texts) do not have a negative effect on health care. They are much more likely, however, to disapprove of items for personal use (radios, coffeemakers), especially as the gifts become more costly (dinners, trips) (28, 29).

What Is the Purpose of the Industry Offer?

The potential for bias in industry-prepared information becomes especially precarious when such information is accompanied by a gift or free service. Even when the amenity is medically related, a major aspect of the offer involves the establishment of a gift relationship, a phenomenon much studied in social science research. In culture after culture, there has emerged “a vivid sense of the immense pervasiveness of the social obligation” that a gift elicits (30). Social scientists agree that the prevailing purpose of the gift is to establish the identity of the donor in the mind of the recipient and to oblige the recipient to reciprocate (30-32). It is not just lavish amenities that are in question. The acceptance of even small gifts can affect clinical judgment and heighten the perception (as well as the reality) of a conflict of interest (12).

From a certain perspective, drug samples can be characterized as "gifts." Because physicians can distribute such medications to patients at no apparent cost (33), the practice may seem to promote the profession’s core principle of equitable access and justice in health care. The practice does allow the patient to try out a new medication before being committed to an expense. However, the sample mainly serves to encourage physicians to prescribe the new product. Research shows that once a patient exhausts a free supply of medication, the physician typically writes a prescription for the same brand (33, 34). Because few samples are for older or less expensive products (35), higher patient costs generally result. Moreover, physicians and their families and staff use approximately one third of the samples (33, 34, 36, 37), which illustrates how the practice fosters access to physicians’ offices and encourages a gift relationship.
In addition to drug samples, industry may distribute product literature or "patient care services," such as education aids or disease management software. It is understandable that, in a busy practice, physicians would welcome industry's materials and technologies to keep themselves and their patients current with the latest developments in the medical field. Physicians must keep in mind, however, that industry-supplied medical information, although neutrally packaged, is in fact promotional (4). Physicians should never rely solely on industry-provided information or services as a substitute for an objective review of the literature and understanding of patients’ conditions.

**What Would My Colleagues Think about This Arrangement?**

The issue of industry gifts, hospitality, and subsidies arises as early as medical school and residency programs (18, 20-22, 27, 38-42). Medical students and physicians-in-training often have opportunities to receive instructional materials, medical equipment, or even educational dinner programs. While it is recognized that such arrangements can benefit the medical education experience and that medical students and residents have unique financial and work circumstances, it is also necessary to note that medical training includes instruction on professional ethics, including appropriate relationships with industry. Medical students, physicians-in-training, and practicing physicians should apply the same ethical standards to their interactions with industry (43).

Physicians do not always agree about the appropriateness of gifts. Ideally, physicians should not accept any promotional gifts or amenities, whatever their value or utility, if they have the potential to cloud professional judgment and compromise patient care. As a practical matter, many physicians are comfortable with limiting their acceptance of gifts to items that enhance medical practice or knowledge and that are of modest value. Differences of opinion will undoubtedly arise because of the ways in which an item or service is valued in different practice environments and communities. Nonetheless, such debates are important because they remind physicians of the need to gauge regularly whether a gift relationship is ethically appropriate.

**Recommendations**

The inherent difficulty in defining what makes a gift appropriate has, to an extent, contributed to lapses in judgment by otherwise ethical persons. It is difficult to set with any precision a monetary value that would render a gift unacceptable. There is no consensus model for determining relative value, and one will not be recommended here. Instead, some specific guidance is offered in the following examples of generally acceptable industry gifts: inexpensive gifts for office use (such as pens and calendars), low-cost gifts of an educational or patient-care nature (such as medical books), and modest hospitality (such as a reception or other food and drink) that is connected with a legitimate educational program.

Understandably, even these "generally acceptable" examples are subject to interpretation and will frustrate some readers. Together with the fundamental questions listed in Position 1, physicians should use these recommendations as guides in making a good-faith effort to evaluate the potential for influence and to determine what kinds of amenities are ethically appropriate to accept. It is unethical for physicians to accept any industry gift or subsidy that is predicated on recommending a particular product or taking a particular clinical action. The preceding examples cannot and should not be used as a perfunctory substitute for self-appraisal.
Position 2. Financial Relationships between Physicians and Industry

Physicians who have financial relationships with industry, whether as researchers, speakers, consultants, investors, owners, partners, employees, or otherwise, must not in any way compromise their objective clinical judgment or the best interests of patients or research subjects. Physicians must disclose their financial interest in any medical facilities or office-based research to which they refer or recruit patients.

Rationale

Like gifts, financial relationships between physicians and industry can jeopardize professional objectivity. While collaborations in pharmaceutical development and biotechnology are often effective spearheads for advancing therapies and patient care, research and investment ties can create dual commitments or conflicts of interest (12) and risk the confidentiality of patient information. Some physicians own, hold stock in, or have other financial stakes in the medical industry and biotechnology; others work for industry as researchers or are university-based researchers who receive industry grants. Increasingly, clinicians are invited to act as industry consultants or to participate in clinical trials of newly developed drugs or devices, often by enrolling their own patients as subjects (12, 44).

Ownership or Other Financial Interest in Medical Resources

Physician ownership or other financial interest in medical equipment, health care facilities, laboratories, and other medically related resources raises ethical and legal concerns that physician self-interest may lead to inappropriate self-referrals or overuse of resources. For example, one study found that physician-owned clinics generated 50% more patient visits than independent clinics, suggesting that self-referral had induced unnecessary demand (45). Because a physician’s primary duty is to act in the best interests of patients, physicians cannot allow financial arrangements to influence their judgment about what constitutes an appropriate level of care. It is unethical for physicians to overutilize resources or make unnecessary referrals to goods and services for their own financial benefit. It is also unethical to participate in any arrangement that links income generation explicitly or implicitly to equipment or facility usage or revenues generated by investor-physicians. There are instances, of course, in which self-referrals are acceptable, such as in remote or isolated settings where there is a dearth of alternative medical resources. In any event, if physicians refer patients to resources in which they have a material interest, they need to disclose their financial investments and, to the extent practicable, specify alternative sources of goods and services (12).

Consulting, Speaking, or Writing on Behalf of Industry

Industry may pay clinicians well to act as consultants, speak on behalf of a company, or participate in community-based industry trials. As a rule of thumb, related payments from industry are acceptable for teaching and for research that advances medical and professional knowledge (for example, honorariums for presentations at symposiums), commensurate with the extent of the physician’s services and reasonable travel expenses.

Physicians should guard against conflicts of interest when invited to consult or speak for pay on behalf of a company. It is likely that a company will retain only individuals who make statements or recommendations that are favorable to its products, thus compromising the physician’s scientific objectivity. Physicians should accept honorariums only for services provided and must
disclose any industry sponsorship or affiliation and other potential conflicts of interest to formal lecture audiences and publication editors (31, 46).

Physicians should also be circumspect if asked to deliver educational programming developed by a medical education and communication company. Such companies, which are largely financed through the pharmaceutical industry, are for-profit developers and vendors of continuing medical education (47). It is important that physicians retained as lecturers in such settings control the content of the educational modules they deliver rather than allow their presentations to be scripted by the company. Lecturers should screen industry-prepared presentation aids (such as slides and reference materials) to ensure their objectivity and should accept, modify, or refuse them on that basis. Presenters using such materials should disclose their source to audience members.

Paid efforts to influence the profession or public opinion about specific medical products are particularly suspect. It is unethical, for example, for physicians to accept commissions for articles, editorials, or medical journal reviews that are actually ghostwritten by industry or public relations firms in an attempt to “manage the press” about certain products or services (48).

**Participation in Industry-Sponsored Research**

Participation in practice-based research can contribute to our understanding of the benefits and risks of a new product, thereby promoting medicine’s underlying principles of beneficence and nonmaleficence. Still, physicians are responsible for ensuring that any clinical research in which they participate is potentially of significant value and is ethically conducted (12, 49). In particular, physicians invited to join "postmarketing studies" that require the prescribing of a company’s product need to consider the scientific validity of the research and its potential to enhance medical progress (44, 50, 51). Physicians should not participate in studies that are, in effect, thinly disguised promotional schemes to entice physicians to use new products.

Physicians also have an ethical obligation, based on the principle of patient autonomy and informed choice, to disclose their commercial ties to patients who are prospective study participants (12). Physicians who involve their own patients in office-based trials must also be aware of potential conflicts between what is best for the patient-subject and what is optimal for the conduct of the research. In weighing the two interests, clinicians must consider their role as physician first and as investigator second (12, 52). It is reasonable for the clinician to receive compensation commensurate with time and expenses incurred in study recruitment. However, physicians may not accept compensation simply for referring their patients to an industry study, regardless of whether the physician directly participates in the trial. Known as "finder’s fees," such arrangements represent pure profit and create an inherent conflict with the best interests of the patient (12, 49, 53).

Finally, physicians involved in commercial trials must guard against bias in publishing research outcomes. Several studies show that physicians with financial ties to pharmaceutical manufacturers are significantly more likely than independent reviewers to report findings that support the sponsor’s drugs; likewise, they are less likely to report unfavorable findings (48, 54-57). To maintain objectivity, it is recommended that physicians secure pre-performance agreements with sponsors ensuring that negative results will not be quashed and that findings will be made publicly accessible. Physicians should also be aware that the International Committee of Medical Journal Editors recently agreed not to publish any studies conducted under conditions in which the sponsor can control the data or prevent publication (58). If a company explicitly or implicitly encourages a physician to suppress particular outcomes, the physician must not participate in the research and should report the incident to the institutional review board overseeing the research, and to the U.S. Food and Drug Administration if the research is a drug trial.
Dealing with Institutional Product Bias

Physicians employed by managed care organizations are obligated to abide by drug formularies and practices of pharmacy benefit management. Formularies specify a list of drugs that are considered most useful and cost-effective, and managed care organizations often limit reimbursement to these drugs. Pharmacy benefit management companies, which increasingly are owned by pharmaceutical manufacturers, act as intermediaries among pharmacies, pharmaceutical companies, physicians, and third-party payers to review prescribing practices and negotiate prescription prices. Pharmacy benefit management companies have access to confidential patient records and may try to influence changes in patients’ drug regimens, sometimes to reduce costs and sometimes to favor a manufacturer (59, 60). Current state and federal policies regarding third-party access are not consistent and can, at times, jeopardize the confidentiality of patient information. Cost savings are certainly encouraged, especially as a matter of justice and equity in health care. However, any agreement to change drugs should be evidence-based, not company-biased. If faced with institutional bias in drug formularies, individual physicians should be prepared to insist on waivers for unlisted drugs when it is in the best interests of their patients.

Electronic Technology

Finally, the development of "e-commerce" has led to ethical issues not envisioned in the 1990 position paper. Since that time, the importance of electronic commerce and Internet technology to the practice of medicine has increased dramatically. Health care systems in the 21st century will undoubtedly take advantage of electronic technology to collect and analyze clinical data, support consumer access to health information, and complement the physician’s management of patient care (13).

As valuable as consumer access is, information provided electronically can be biased by its sponsor. To mitigate this potential conflict, physicians who have a material interest in "e-health" businesses or who interact with Internet hosts to publish their own Web sites have an obligation to control the site’s medical content and regularly maintain it. Such sites should disclose all sources of industry support and clearly distinguish any commercial advertisements or sponsored content from substantive content, both in form and in placement. Physicians with commercially sponsored Web sites also need to alert users if a sponsor plans to conduct any online tracking.

Conclusion

The guidelines offered here identify several examples of financial and other material relationships between physicians and industry, but the list is not exhaustive. As opportunities for commercial ties continue to grow, physicians should be increasingly wary of threats to their professionalism and independent judgment about patient care. Providers of medical education and professional medical societies face similar problems of potential influence. Part 2 of this statement on industry relations will address the ethical risks and responsibilities of professional medical associations and educators.
From the American College of Physicians–American Society of Internal Medicine, Philadelphia, Pennsylvania.

*This paper was written by Susan L. Coyle, PhD, and was developed by the American College of Physicians–American Society of Internal Medicine (ACP-ASIM) Ethics and Human Rights Committee. Members of the ACP-ASIM Ethics and Human Rights Committee were William E. Golden, MD (Chair); David W. Potts, MD (Vice Chair); Harmon H. Davis II, MD; David A. Fleming, MD; Susan Dorr Goold, MD; Vincent E. Herrin, MD; Jay A. Jacobson, MD; Risa Lavizzo-Mourey, MD, MBA (Past Chair); Joanne Lynn, MD; and Daniel P. Sulmasy, OFM, MD, PhD. Lois Snyder, JD, Director of ACP-ASIM’s Center for Ethics and Professionalism, provided principal staff support. This paper was approved by the ACP-ASIM Board of Regents on 15 July 2001.

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POSITION PAPER

Physician–Industry Relations. Part 2: Organizational Issues

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This is part 2 of a 2-part paper on ethics and physician-industry relationships. Offers advice to individual physicians; part 2 gives recommendations to medical education providers and medical professional societies.

Industry often sponsors programs for graduate and continuing medical education, as well as major events of medical professional societies. Industry is an abundant source of advances in medicine and technology and plays a crucial role in disseminating up-to-date medical information. Although industry information fills an important need, studies suggest that it is often biased.

Providers of graduate and continuing medical education have a duty to present objective and balanced information to their participants; thus, they should not accept any funds that are contingent on a sponsor’s ability to shape programming. Medical educators need to evaluate and control the planning, content, and delivery of education provided under their auspices. They should disclose industry sponsorship to students, faculty, and continuing medical education participants and should adopt explicit organizational policies about acceptable and unacceptable interactions with industry.

Medical professional societies have a duty to promote the independent judgment and professionalism of their members. Organizers of industry-sponsored meetings should clearly separate product promotion from impartial medical education. Adopting specific policies for dealing with industry sponsorship can also help professional societies guard against outside influence. The American College of Physicians–American Society of Internal Medicine’s core ethical principles for external funding and relationships serve as an example.

In 1990, the American College of Physicians published a position statement titled "Physicians and the Pharmaceutical Industry," which addressed industry relations with individual physicians and medical professional groups (1). The statement was prompted in large part by evidence of the drug industry’s influence on medicine and the ensuing concern for professional integrity and patient care. Since that time, the influence of industry on medical practice, research, and education has continued to increase, as have physician-industry relationships. In response, the American College of Physicians–American Society of Internal Medicine (ACP-ASIM) has prepared an updated, 2-part set of ethical positions, addresses individual physicians and their relationships with industry through gifts and collaborative activities. The current paper, which is part 2, addresses ethical concerns relevant to medical education providers, academic units that accept industry support, and medical professional societies.

A responsible and productive alliance between medical organizations and industry is crucial for medical progress. At the same time, providers of graduate medical education (GME) and continuing medical education (CME) and medical professional societies are also responsible for regulating their dealings with industry. These groups should evaluate their external funding relationships not only for prospective benefits but also for potential conflicts of interest and other ethical problems, such as real or perceived improprieties and bias in the materials they offer, their policies, and projects they undertake.
Given the rapid pace of technological developments and therapeutic advancements in medicine and biotechnology, both students and practicing physicians rely on education providers and professional societies for objective, up-to-date health care information. Commercially sponsored information offered in such settings can be biased in favor of manufacturers and has the potential to unduly affect the independent judgment of medical professionals (2-5). To help overcome this conflict, this paper offers two positions on the external funding of educational programming and activities of medical professional societies. The College’s positions described in part 1 are numbered 1 and 2; the positions appearing here are numbered 3 and 4.

**Position 3. Industry-Supported Graduate and Continuing Medical Education**

*Public and private GME and CME providers that accept industry support for educational programs should be aware of potential conflicts of interest and should develop and enforce explicit policies that maintain complete control of program planning, content, and delivery. (This position addresses education providers that accept industry support, not industry-held educational programs.)*

**Rationale**

Continuing medical education is a multibillion-dollar business (6), and the role of the health care industry is considerable (7). The commercial role is expected only to grow as new, for-profit medical education and communication companies begin providing CME (8). Industry support of GME is difficult to quantify but is potentially of great importance. A 1990 survey of internal medicine residency programs revealed that 90% of program directors allowed industry to sponsor educational conferences for their students; of these, 30% reported not having alternative funds for such events (9).

Continuing medical education is critically important for physicians to keep abreast of the latest developments in patient care. Indeed, physicians have sometimes been slow to adopt efficacious new therapies into routine clinical practice and therefore to improve patient care (10). Because industry is an abundant source of advances in medicine and technology, its desire to quickly disperse information about its products helps to fill an important need (11). The presentation of medical information, however, must be objective, and this becomes the responsibility of medical education providers and medical professional societies.

Commercial funding for CME usually takes the form of general course grants or speaker funds, although it is sometimes provided for hospitality and travel expenses related to educational symposiums. Many medical schools also accept commercial sponsorship of educational conferences, as well as funds for student organizations, publications, and awards (2). While support for GME and CME is often welcomed, commercial support can create an opportunity for the subtle or not so subtle introduction of bias through industry-oriented programming. For example, a study of CME courses funded by rival manufacturers showed that course contents were biased in favor of each funder’s product (12). Further study showed that physicians who attended industry-supported CMEs subsequently altered their prescription practices in favor of the funder’s products (13).
Education provided through a reputable academic institution or medical professional society is expected to offer expert teaching and “best evidence” information (14). However, professional impartiality about what constitutes best evidence can be tested if industry selects the teacher or underwrites the program. To enhance the impartiality of CME, groups such as the Accreditation Council for Continuing Medical Education (ACCME) have recommended guidelines for relationships between educators and industry (15). The guidelines advise CME providers to plan for balanced program content and ensure that their programs are free of commercial bias for or against any product or service. While the ACCME guidelines are a step in the right direction, commentators have noted that they are not difficult to skirt (3, 8).

Medical education organizations have an obligation to the profession and society to evaluate and correct for potential bias. When faculty or speakers must use trade names in a GME or CME presentation, they should cite similar products or services of several companies rather than focusing on a single supporting company. Faculty, deans, and program directors should also promote sensitivity to potential biases by providing specific education to help their students, physician trainees, and medical fellows evaluate industry-provided information. For education and sensitivity training to be successful, however, faculty must act as positive role models. Chief residents and medical school faculty members should set ethical examples to students by conducting their relationships with industry in a highly principled manner and disclosing their own commercial ties.

Medical education providers must also administer the budgets of any programming provided under their auspices. If an organization allows industry-sponsored hospitality, the hospitality should be modest and arranged so that social activities do not compete with educational events (15). Providers of CME must also control access to registrants’ mailing addresses and should disclose any commercial support to registrants through general program materials. Providers should ban the distribution of promotional materials in educational sessions unless the materials are clearly related to instruction.

Medical education programs are also responsible for discussing industry sponsorship with invited speakers, including support for such presentation aids as slides or literature reviews. This disclosure will give speakers the opportunity to screen the aids and accept or refuse them (16), or make modifications to ensure objectivity. (Speakers who use industry-developed aids should disclose that information to the audience.) In addition, faculty and program directors should disclose any support they receive individually as consultants, investigators, or shareholders, and they should be sure that their relationships are explicitly listed in the CME program (16, 17). Finally, faculty and program directors may accept industry honorariums or subsidies only for services rendered and, if applicable, reasonable travel expenses.

In sum, it is unethical for academic institutions and educational organizations to accept any support that is explicitly or implicitly conditioned on industry’s opportunity to influence the selection of instructors, speakers, invitees, topics, or content and materials of educational sessions. To reflect this position, medical education providers should adopt and enforce specific organizational policies about acceptable and unacceptable interactions with industry (9).

Position 4. Support for Medical Society Activities

Medical professional societies that accept industry support or other external funding should be aware of potential bias and conflicts of interest and should develop and enforce explicit policies
that preserve the independent judgment and professionalism of their members and maintain the ethical standards and credibility of the society.

Rationale

Medical professional societies share the physician’s duty to advocate and act in the best interest of the patient and society, and they are expected to serve as independent and trustworthy sources of health care information and education for members and the public. In developing specific projects or meetings to achieve these goals, many professional associations seek external funding to defray costs. While such arrangements are legitimate, they can result in dual commitments or conflicts of interest. External funding has the potential to alter an organization’s agenda, influence its policy positions, or weaken its credibility (18). To avert potential conflict or bias, which in turn may affect members, professional societies need to adopt specific institutional policies governing their relationships with industry.

One of the premier events of the medical professional society is its annual or semiannual membership meeting, at which scientific sessions, symposiums, workshops, and exhibitions are offered to disseminate medical knowledge and enhance clinical skills. Such meetings offer excellent opportunities to educate members about issues of bias in medical information and to present ethical positions on physician-industry relationships. These meetings usually also offer the opportunity for commercially sponsored exhibits and events.

Physician organizations and professional societies need to conduct professional meetings in a highly principled manner. To be sure, industry’s presence can have positive effects. Industry is a significant source of innovative development in medicine and is responsible for informing physicians about the benefits (and risks) of promising diagnostic and therapeutic discoveries. However, industry presence at medical society events may divert interest from the scientific agenda and detract from the meeting’s focus on professionalism and other organizational goals. In addition, industry attractions create potentially fertile ground for providing biased medical information. To lessen this possibility, meeting organizers should ensure that product promotion activities are separated from impartial medical information. Presentation of industry findings and product developments, whether through displays or teaching exercises, should take place only in designated exhibition space or in funded lectures that the program clearly identifies as being independently organized and separate from official scientific sessions.

To help preserve members’ independence of views, medical societies also need to ensure that meeting programs are balanced and reflect the needs and interests of members and patients, not sponsors. To prevent any real or apparent corporate favoritism, and to stay true to the organization’s core missions, medical professional societies should avoid endorsing specific products and services. ACP-ASIM policy, for example, sets out specific criteria for vetting requests for corporate endorsements to avoid influencing internal policy or promoting an agenda to serve external interests. Other medical professional societies are encouraged to adopt such internal policies.

Professional groups should also develop policies to guide the acceptance and disclosure of industry and other external funding and to avoid reliance on outside sources of support. The College recently adopted a set of core ethical principles to guide its dealings with external funding sources and to serve as an example for other professional societies as they develop their own policies. These principles can be found in the Appendix.
Conclusion

The positions discussed here and in part 1 are derived from medicine’s basic responsibilities to advocate for and protect a patient’s best interests and pave the way for informed choice. To these ends, medical education providers and medical professional societies should avoid all industry interactions that might diminish, or appear to others to diminish, their objectivity or concern for patients’ best interests. To do otherwise is to endanger the integrity of the profession and the public confidence it enjoys.

Appendix: ACP-ASIM Core Principles for External Funding and Relationships, as Approved by the Board of Regents on 15 July 2001

Commercial, government, foundation, and other funding and relationships can help the College promote its goals and its mission of enhancing the quality and effectiveness of health care. However, some financial arrangements might bias, or be seen to bias, the College as an independent, trustworthy, and credible source of health care information, policy, and education.

The following principles should guide financial and other relationships with outside organizations. (See also the College’s corporate endorsement and conflict of interest policies. To obtain copies, contact Lois Snyder at 215-351-2835.)

1. The College’s values, its mission, and its commitment to professionalism and excellence in medicine must drive all external relationships and externally funded activities.
2. Relationships with external organizations and funders should promote the health and welfare of the public or patient care. Member benefits resulting from external arrangements should enhance professionalism and physician practice.
3. In representing the College in external relationships, College leadership and staff must adhere to the values and ethical standards of the organization and should act to promote professionalism and trust in the organization and the medical profession.
4. External funding arrangements and external relationships must be disclosed to relevant parties on a regular basis and with sufficient detail and visibility to allow concerned parties to reach independent conclusions about potential sources of influence and real or perceived conflicts of interest.
5. Specific instances in which a financial arrangement or relationship might have the potential to influence the College’s actual or perceived independence, credibility, and trustworthiness should undergo College review to minimize or eliminate such influence.
6. The College should monitor its overall reliance on commercial sources of funding and ensure that its core activities could continue if such support were diminished.

From the American College of Physicians–American Society of Internal Medicine, Philadelphia, Pennsylvania.

*This paper was written by Susan L. Coyle, PhD, and was developed by the American College of Physicians–American Society of Internal Medicine (ACP-ASIM) Ethics and Human Rights
Committee. Members of the ACP-ASIM Ethics and Human Rights Committee were William E. Golden, MD (Chair); David W. Potts, MD (Vice Chair); Harmon H. Davis II, MD; David A. Fleming, MD; Susan Dorr Goold, MD; Vincent E. Herrin, MD; Jay A. Jacobson, MD; Risa Lavizzo-Mourey, MD, MBA (Past Chair); Joanne Lynn, MD; and Daniel P. Sulmasy, OFM, MD, PhD. Lois Snyder, JD, Director of ACP-ASIM’s Center for Ethics and Professionalism, provided principal staff support. This paper was approved by the ACP-ASIM Board of Regents on 15 July 2001.

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APPENDIX B: AMERICAN MEDICAL ASSOCIATION - GIFTS TO PHYSICIANS FROM THE INDUSTRY

AMERICAN MEDICAL ASSOCIATION

Professional Resources

Gifts to physicians from industry

The following opinion of the Council on Ethical and Judicial Affairs of the American Medical Association, issued December 1990, has been incorporated into the AMA's Code of Medical Ethics.

Opinion 8.061

Many gifts given to physicians by companies in the pharmaceutical, device, and medical equipment industries serve an important and socially beneficial function. For example, companies have long provided funds for educational seminars and conferences. However, there has been growing concern about certain gifts from industry to physicians. Some gifts that reflect customary practices of industry may not be consistent with the Principles of Medical Ethics. To avoid the acceptance of inappropriate gifts, physicians should observe the following guidelines:

Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. Accordingly, textbooks, modest meals, and other gifts are appropriate if they serve a genuine educational function. Cash payments should not be accepted. The use of drug samples for personal or family use is permissible as long as these practices do not interfere with patient access to drug samples. It would not be acceptable for non-retired physicians to request free pharmaceuticals for personal use or use by family members. (I)

Individual gifts of minimal value are permissible as long as the gifts are related to the physician's work (e.g., pens and notepads).

The Council on Ethical and Judicial Affairs defines a legitimate "conference" or "meeting" as any activity, held at an appropriate location where, (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering, and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented. An appropriate disclosure of financial support or conflict of interest should be made.

Subsidies to underwrite the costs of continuing medical education conferences or professional meetings can contribute to the improvement of patient care and therefore are permissible. Since the giving of a subsidy directly to a physician by a company's representative may create a relationship that could influence the use of the company's products, any subsidy should be accepted by the conference's sponsor who in turn can use the money to reduce the conference's registration fee. Payments to defray the costs of a conference should not be accepted directly from the company by the physicians attending the conference.

Subsidies from industry should not be accepted directly or indirectly to pay for the costs of travel, lodging, or other personal expenses of physicians attending conferences or meetings, nor should subsidies be accepted to compensate for the physicians' time. Subsidies for hospitality should not be accepted outside of modest meals or social events held as a part of a conference or meeting. It is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel,
lodging, and meal expenses. It is also appropriate for consultants who provide genuine services to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging, and meal expenses. Token consulting or advisory arrangements cannot be used to justify the compensation of physicians for their time or their travel, lodging, and other out-of-pocket expenses.

Scholarship or other special funds to permit medical students, residents, and fellows to attend carefully selected educational conferences may be permissible as long as the selection of students, residents, or fellows who will receive the funds is made by the academic or training institution. Carefully selected educational conferences are generally defined as the major educational, scientific or policymaking meetings of national, regional or specialty medical associations.

No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physician’s prescribing practices. In addition, when companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods, and materials should belong to the organizers of the conferences or lectures.


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E-Addendum II: Council on Ethical and Judicial Affairs Clarification of Gifts to Physicians from Industry (E-8.061)

Opinion 8.061, "Gifts to Physicians from Industry" is intended to provide ethical guidance to physicians. Other parties involved in the health care sector, including the pharmaceutical, devices and medical equipment industries and related entities or business partners, should view the guidelines as indicative of standards of conduct for the medical profession. Ultimately, it is the responsibility of individual physicians to minimize conflicts of interest that may be at odds with the best interest of patients and to access the necessary information to inform medical recommendations.

The guidelines apply to all forms of gifts, whether they are offered in person, through intermediaries, or through the Internet. Similarly, limitations on subsidies for educational activities should apply regardless of the setting in which, or the medium through which, the educational activity is offered.

General Questions

(a) Do the guidelines apply only to pharmaceutical, device, and equipment manufacturers?

"Industry" includes all "proprietary health-related entities that might create a conflict of interest."

Guideline 1

Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. Accordingly, textbooks, modest meals and other gifts are appropriate if they serve a genuine educational function. Cash payments should not be accepted. The use of drug samples for personal or family use is permissible as long as these practices do not interfere with patient access to drug samples. It would not be acceptable for non-retired physicians to request free pharmaceuticals for personal use or for use by family members.

(a) May physicians accept gram stain test kits, stethoscopes or other diagnostic equipment?

Diagnostic equipment primarily benefits the patient. Hence, such gifts are permissible as long as they are not of substantial value. In considering the value of the gift, the relevant measure is not the cost to the company of providing the gift. Rather, the relevant measure is the cost to the physician if the physician purchased the gift on the open market.

(b) May companies invite physicians to a dinner with a speaker and donate $100 to a charity or medical school on behalf of the physician?

There are positive aspects to the proposal. The donations would be used for a worthy cause, and the physicians would receive important information about patient care. There is a direct personal benefit to the physician as well, however. An organization that is important to the physician - and one that the physician might have ordinarily felt obligated to make a contribution to - receives financial support as a result of the physician's decision to attend the meeting. On balance, physicians should make their own judgment about these inducements. If the charity is predetermined without the physician's input, there would seem to be little problem with the arrangement.

(c) May contributions to a professional society's general fund be accepted from industry?

The guidelines are designed to deal with gifts from industry which affect, or could appear to affect, the judgment of individual practicing physicians. In general, a professional society should make its own judgment about gifts from industry to the society itself.

(d) When companies invite physicians to a dinner with a speaker, what are the relevant guidelines?
First, the dinner must be a modest meal. Second, the guideline does allow gifts that primarily benefit patients and that are not of substantial value. Accordingly, textbooks and other gifts that primarily benefit patient care and that have a value to the physician in the general range of $100 are permissible. When educational meetings occur in conjunction with a social event such as a meal, the educational component must have independent value, such as a presentation by an authoritative speaker other than a sales representative of the company. Also, the meal should be a modest one similar to what a physician routinely might have when dining at his or her own expense. In an office or hospital encounter with a company representative, it is permissible to accept a meal of nominal value, such as a sandwich or snack.

(e) May physicians accept vouchers that reimburse them for uncompensated care they have provided?

No. Such a voucher would result directly in increased income for the physician.

(f) May physicians accumulate "points" by attending several educational or promotional meetings and then choose a gift from a catalogue of education options?

This guideline permits gifts only if they are not of substantial value. If accumulation of points would result in physicians receiving a substantial gift by combining insubstantial gifts over a relatively short period of time, it would be inappropriate.

(g) May physicians accept gift certificates for educational materials when attending promotional or educational events?

The Council views gift certificates as a grey area which is not per se prohibited by the guidelines. Medical text books are explicitly approved as gifts under the guidelines. A gift certificate for educational materials, i.e., for the selection by the physician from an exclusively medical text book catalogue, would not seem to be materially different. The issue is whether the gift certificate gives the recipient such control as to make the certificate similar to cash. As with charitable donations, pre-selection by the sponsor removes any question. It is up to the individual physician to make the final judgment.

(h) May physicians accept drug samples or other free pharmaceuticals for personal use or use by family members?

The Council's guidelines permit personal or family use of free pharmaceuticals (i) in emergencies and other cases where the immediate use of a drug is indicated, (ii) on a trial basis to assess tolerance and (iii) for the treatment of acute conditions requiring short courses of inexpensive therapy, as permitted by Opinion E-8.19: Self-Treatment or Treatment of Immediate Family Members. It would not be acceptable for physicians to accept free pharmaceuticals for the long-term treatment of chronic conditions.

(i) May companies invite physicians to a dinner with a speaker and offer them a large number of gifts from which to choose one?

In general, the greater the freedom of choice given to the physician, the more the offer seems like cash. A large number of gifts presented to physicians who attend a dinner would therefore be inappropriate.

There is no precise way of deciding an appropriate upper limit on the amount of choice that is acceptable. However, it is important that a specific limit be chosen to ensure clarity in the guidelines. A limit of eight has been chosen because it permits flexibility but prevents undue freedom of choice. Each of the choices must have a value to the physicians of no more than $100.

(j) May physicians charge for their time with industry representatives or otherwise receive material compensation for participation in a detail visit?

Guideline 1 states that gifts in the form of cash payments should not be accepted. Also, Guideline 6 makes clear that, in the context of the industry-physician relationship, only physicians who provide genuine services may receive reasonable compensation. When considering the time a physician spends with an industry representative, it is the representative who offers a service, namely the presentation of information. The physician is a beneficiary of the service. Overall, these guidelines do not view that physicians should be
compensated for the time spent participating in educational activities, nor for time spent receiving detail information from an industry representative.

Guideline 2

Individual gifts of minimal value are permissible as long as the gifts are related to the physician’s work (e.g., pens and notepads).

(a) May physicians, individually or through their practice group, accept electronic equipment, such as hand held devices or computers, intended to facilitate their ability to receive detail information electronically?

Although Guideline 2 recognizes that gifts related to a physician’s practice may be appropriate, it also makes clear that these gifts must remain of minimal value. It is not appropriate for physicians to accept expensive hardware or software equipment even though one purpose only may pertain to industry-related activities of a modest value.

Guideline 3

The Council on Ethical and Judicial Affairs defines a legitimate "conference" or "meeting" as any activity, held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented. An appropriate disclosure of financial support or conflict of interest should be made.

Guideline 4

Subsidies to underwrite the costs of continuing medical education conferences or professional meetings can contribute to the improvement of patient care and therefore are permissible. Since the giving of a subsidy directly to a physician by a company’s sales representative may create a relationship which could influence the use of the company's products, any subsidy should be accepted by the conference’s sponsor who in turn can use the money to reduce the conference's registration fee. Payments to defray the costs of a conference should not be accepted directly from the company by the physicians attending the conference.

(a) Are conference subsidies from the educational division of a company covered by the guidelines?

Yes. When the Council says "any subsidy," it would not matter whether the subsidy comes from the sales division, the educational division or some other section of the company.

(b) May a company or its intermediary send physicians a check or voucher to offset the registration fee at a specific conference or a conference of the physician's choice?

Physicians should not directly accept checks or certificates which would be used to offset registration fees. The gift of a reduced registration should be made across the board and through the accredited sponsor.

Guideline 5

Subsidies from industry should not be accepted directly or indirectly to pay for the costs of travel, lodging or other personal expenses of physicians attending conferences or meetings, nor should subsidies be accepted to compensate for the physicians’ time. Subsidies for hospitality should not be accepted outside of modest meals or social events held as a part of a conference or meeting. It is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging and meal expenses. It is also appropriate for consultants who provide genuine services to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging and meal expenses. Token consulting or advisory
arrangements cannot be used to justify the compensation of physicians for their time or their travel, lodging, and other out-of-pocket expenses.

(a) If a company invites physicians to visit its facilities for a tour or to become educated about one of its products, may the company pay travel expenses and honoraria?

This question has come up in the context of a rehabilitation facility that wants physicians to know of its existence so that they may refer their patients to the facility. It has also come up in the context of surgical device or equipment manufacturers who want physicians to become familiar with their products.

In general, travel expenses should not be reimbursed, nor should honoraria be paid for the visiting physician's time since the presentations are analogous to a pharmaceutical company's educational or promotional meetings. The Council recognizes that medical devices, equipment and other technologies may require, in some circumstances, special evaluation or training in proper usage which can not practicably be provided except on site. Medical specialties are in a better position to advise physicians regarding the appropriateness of reimbursement with regard to these trips. In cases where the company insists on such visits as a means of protection from liability for improper usage, physicians and their specialties should make the judgment. In no case would honoraria be appropriate and any travel expenses should be only those strictly necessary.

(b) If the company invites physicians to visit its facilities for review and comment on a product, to discuss their independent research projects or to explore the potential for collaborative research, may the company pay travel expenses and an honorarium?

If the physician is providing genuine services, reasonable compensation for time and travel expenses can be given. However, token advisory or consulting arrangements cannot be used to justify compensation.

(c) May a company hold a sweepstakes for physicians in which five entrants receive a trip to the Virgin Islands or airfare to the medical meeting of their choice?

No. The use of a sweepstakes or raffle to deliver a gift does not affect the permissibility of the gift. Since the sweepstakes is not open to the public, the guidelines apply in full force.

(d) If a company convenes a group of physicians to recruit clinical investigators or convenes a group of clinical investigators for a meeting to discuss their results, may the company pay for their travel expenses?

Expenses may be paid if the meetings serve a genuine research purpose. One guide to their propriety would be whether the NIH conducts similar meetings when it sponsors multi-center clinical trials. When travel subsidies are acceptable, the guidelines emphasize that they be used to pay only for "reasonable" expenses. The reasonableness of expenses would depend on a number of considerations. For example, meetings are likely to be problematic if overseas locations are used for exclusively domestic investigators. It would be inappropriate to pay for recreation or entertainment beyond the kind of modest hospitality described in this guideline.

(e) How can a physician tell whether there is a "genuine research purpose?"

A number of factors can be considered. Signs that a genuine research purpose exists include the facts that there are (1) a valid study protocol, (2) recruitment of physicians with appropriate qualifications or expertise, and (3) recruitment of an appropriate number of physicians in light of the number of study participants needed for statistical evaluation.

(f) May a company compensate physicians for their time and travel expenses when they participate in focus groups?

Yes. As long as the focus groups serve a genuine and exclusive research purpose and are not used for promotional purposes, physicians may be compensated for time and travel expenses. The number of physicians used in a particular focus group or in multiple focus groups should be an appropriate size to accomplish the research purpose, but no larger.
(g) Do the restrictions on travel, lodging and meals apply to educational programs run by medical schools, professional societies or other accredited organizations which are funded by industry, or do they apply only to programs developed and run by industry?

The restrictions apply to all conferences or meetings which are funded by industry. The Council drew no distinction on the basis of the organizer of the conference or meeting. The Council felt that the gift of travel expenses is too substantial even when the conference is run by a non-industry sponsor. (Industry includes all "proprietary health-related entities that might create a conflict of interest.")

(h) May company funds be used for travel expenses and honoraria for bona fide faculty at educational meetings?

This guideline draws a distinction between attendees and faculty. As was stated, "[i]t is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging, and meal expenses."

Companies need to be mindful of the guidelines of the Accreditation Council on Continuing Medical Education. According to those guidelines, "[f]unds from a commercial source should be in the form of an educational grant made payable to the CME sponsor for the support of programming."

(i) May travel expenses be reimbursed for physicians presenting a poster or a "free paper" at a scientific conference?

Reimbursement may be accepted only by bona fide faculty. The presentation of a poster or a free paper does not by itself qualify a person as a member of the conference faculty for purposes of these guidelines.

(j) When a professional association schedules a long-range planning meeting, is it appropriate for industry to subsidize the travel expenses of the meeting participants?

The guidelines are designed to deal with gifts from industry which affect, or could appear to affect the judgment of individual practicing physicians. In general, a professional society should make its own judgment about gifts from industry to the society itself.

(k) May continuing medical education conferences be held in the Bahamas, Europe or South America?

There are no restrictions on the location of conferences as long as the attendees are paying their own travel expenses.

(l) May travel expenses be accepted by physicians who are being trained as speakers or faculty for educational conferences and meetings?

In general, no. If a physician is presenting as an independent expert at a CME event both the training and its reimbursement raise questions about independence. In addition, the training is a gift because the physician's role is generally more analogous to that of an attendee than a participant. Speaker training sessions can be distinguished from meetings (See 5d) with leading researchers, sponsored by a company, designed primarily for an exchange of information about important developments or treatments, including the sponsor's own research, for which reimbursement for travel may be appropriate.

(m) What kinds of social events during conferences and meetings may be subsidized by industry?

Social events should satisfy three criteria. First, the value of the event to the physician should be modest. Second, the event should facilitate discussion among attendees and/or discussion between attendees and faculty. Third, the educational part of the conference should account for a substantial majority of the total time accounted for by the educational activities and social events together. Events that would be viewed (as in the succeeding question) as lavish or expensive should be avoided. But modest social activities that are not elaborate or unusual are permissible, e.g., inexpensive boat rides, barbecues, entertainment that draws
on the local performers. In general, any such events which are a part of the conference program should be open to all registrants.

(n) May a company rent an expensive entertainment complex for a evening during a medical conference and invite the physicians attending the conference?

No. The guidelines permit only modest hospitality.

(o) If physicians attending a conference engage in interactive exchange, may their travel expenses be paid by industry?

No. Mere interactive exchange would not constitute genuine consulting services.

(p) If a company schedules a conference and provides meals for the attendees that fall within the guidelines, may the company also pay for the costs of the meals for spouses?

If a meal falls within the guidelines, then the physician’s spouse may be included.

(q) May companies donate funds to sponsor a professional society’s charity golf tournament?

Yes. But it is sensible if physicians who play in the tournament make some contribution themselves to the event.

(r) If a company invites a group of consultants to a meeting and a consultant brings a spouse, may the company pay the costs of lodging or meals of the spouse? Does it matter if the meal is part of the program for the consultants?

Since the costs of having a spouse share a hotel room or join a modest meal are nominal, it is permissible for the company to subsidize those costs. However, if the total subsidies become substantial, then they become unacceptable.

Guideline 6

Scholarship or other special funds to permit medical students, residents, and fellows to attend carefully selected educational conferences may be permissible as long as the selection of students, residents, or fellows who will receive the funds is made by the academic or training institution. Carefully selected educational conferences are generally defined as the major educational, scientific or policy-making meetings of national, regional or specialty medical associations.

(a) When a company subsidizes the travel expenses of residents to an appropriately selected conference, may the residents receive the subsidy directly from the company?

Funds for scholarships or other special funds should be given to the academic departments or the accredited sponsor of the conference. The disbursement of funds can then be made by the departments or the conference sponsor.

(b) What is meant by "carefully selected educational conferences?"

The intent of Guideline 6 is to ensure that financial hardship does not prevent students, residents and fellows from attending major educational conferences. For example, we did not want to deny cardiology fellows the opportunity to attend the annual scientific meeting of the American College of Cardiology or orthopedic surgery residents the opportunity to attend the annual scientific meeting of the American Academy of Orthopedic Surgeons. However, it was not the intent of the guideline to permit reimbursement of travel expenses in other circumstances, such as when conferences or symposia are designed specifically for students, residents or fellows.
Accordingly, "carefully selected educational conferences" should be interpreted as follows: funds may be used for the reasonable travel and lodging expenses of students, residents and fellows to attend the major educational, scientific or policymaking meetings of national, regional or specialty medical associations.

The Council recognizes that there may be some exceptional conferences for all physicians or even for just students, residents, or fellows that do not fall within this definition of carefully selected educational conferences but that meet the spirit of Guideline 6. Accordingly, the Council will consider proposals for travel and lodging subsidies for such conferences on a case-by-case basis and grant approval to those that meet the spirit of the guidelines.

Guideline 7

No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physician's prescribing practices. In addition, when companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods, and materials should belong to the organizers of the conferences or lectures.

(a) May companies send their top prescribers, purchasers, or referrers on cruises?

No. There can be no link between prescribing or referring patterns and gifts. In addition, travel expenses, including cruises, are not permissible.

(b) May the funding company itself develop the complete educational program that is sponsored by an accredited continuing medical education sponsor?

No. The funding company may finance the development of the program through its grant to the sponsor, but the accredited sponsor must have responsibility and control over the content and faculty of conferences, meetings, or lectures. Neither the funding company nor an independent consulting firm should develop the complete educational program for approval by the accredited sponsor.

(c) How much input may a funding company have in the development of a conference, meeting, or lectures?

The guidelines of the Accreditation Council on Continuing Medical Education on commercial support of continuing medical education address this question.

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents research-based pharmaceutical and biotechnology companies. Our members develop and market new medicines to enable patients to live longer and healthier lives.

Ethical relationships with healthcare professionals are critical to our mission of helping patients by developing and marketing new medicines. An important part of achieving this mission is ensuring that healthcare professionals have the latest, most accurate information available regarding prescription medicines, which play an ever-increasing role in patient healthcare. This document focuses on our interactions with healthcare professionals that relate to the marketing of our products.

Preamble

Effective marketing of medicines ensures that patients have access to the products they need and that the products are used correctly for maximum patient benefit. Our relationships with healthcare professionals are critical to achieving these goals because they enable us to –

- inform healthcare professionals about the benefits and risks of our products,
- provide scientific and educational information,
- support medical research and education, and
- obtain feedback and advice about our products through consultation with medical experts.

In interacting with the medical community, we are committed to following the highest ethical standards as well as all legal requirements. We are also concerned that our interactions with healthcare professionals not be perceived as inappropriate by patients or the public at large. This Code is to reinforce our intention that our interactions with healthcare professionals are to benefit patients and to
enhance the practice of medicine. The Code is based on the principle that a healthcare professional’s care of patients should be based, and should be perceived as being based, solely on each patient’s medical needs and the healthcare professional’s medical knowledge and experience. Therefore, PhRMA adopts, effective July 1, 2002, the following voluntary Code on relationships with healthcare professionals. This Code addresses interactions with marketed products and related pre-launch activities. It does not address relationships with clinical investigators relating to pre-approval studies.

4 Our relationships with healthcare professionals are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing healthcare professionals about products, providing scientific and educational information, and supporting medical research and education.

6 Informational presentations and discussions by industry representatives and others speaking on behalf of a company provide valuable scientific and educational benefits. In connection with such presentations or discussions, occasional meals (but no entertainment/recreational events) may be offered so long as they: (a) are modest as judged by local standards; and (b) occur in a venue and manner conducive to informational communication and provide scientific or educational value. Inclusion of a healthcare professional’s spouse or other guests is not appropriate. Offering “take-out” meals or meals to be eaten without a company representative being present (such as “dine & dash” programs) is not appropriate.
Continuing medical education (CME) or other third-party scientific and educational conferences or professional meetings can contribute to the improvement of patient care and therefore, financial support from companies is permissible. Since the giving of any subsidy directly to a healthcare professional by a company may be viewed as an inappropriate cash gift, any financial support should be given to the conference’s sponsor which, in turn, can use the money to reduce the overall conference registration fee for all attendees. In addition, when companies underwrite medical conferences or meetings other than their own, responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the organizers of the conferences or meetings in accordance with their guidelines.

Financial support should not be offered for the costs of travel, lodging, or other personal expenses of non-faculty healthcare professionals attending CME or other third-party scientific or educational conferences or professional meetings, either directly to the individuals attending the conference or indirectly to the conference’s sponsor (except as set out in section 6 below). Similarly, funding should not be offered to compensate for the time spent by healthcare professionals attending the conference or meeting.

Financial support for meals or receptions may be provided to the CME sponsors who in turn can provide meals or receptions for all attendees. A company may also provide meals or receptions directly at such events if it complies with the sponsoring organization’s guidelines. In either of the above situations, the meals or receptions should be modest and be conducive to discussion among faculty and attendees, and the amount of time at the meals or receptions should be clearly subordinated to the amount of time spent at the educational activities of the meeting.

A conference or meeting shall mean any activity, held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentations should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented.
It is appropriate for consultants who provide services to be offered reasonable compensation for those services and to be offered reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing those services. Compensation and reimbursement that would be inappropriate in other contexts can be acceptable for bona fide consultants in connection with their consulting arrangements. Token consulting or advisory arrangements should not be used to justify compensating healthcare professionals for their time or their travel, lodging, and other out-of-pocket expenses. The following factors support the existence of a bona fide consulting arrangement (not all factors may be relevant to any particular arrangement):

- A written contract specifies the nature of the services to be provided and the basis for payment of those services;
- A legitimate need for the services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants;
- The criteria for selecting consultants are directly related to the identified purpose and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria;
- The number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified purpose;
- The retaining company maintains records concerning and makes appropriate use of the services provided by consultants;
- The venue and circumstances of any meeting with consultants are conducive to the consulting services and activities related to the services are the primary focus of the meeting, and any social or entertainment events are clearly subordinate in terms of time and emphasis.

It is not appropriate to pay honoraria or travel or lodging expenses to non-consultants at company-sponsored meetings including attendees who participate in interactive sessions.
12 It is appropriate for healthcare professionals who participate in programs intended to recruit and train speakers for company sponsored speaker bureaus to be offered reasonable compensation for their time, considering the value of the type of services provided, and to be offered reimbursement for reasonable travel, lodging, and meal expenses, when (1) the participants receive extensive training on the company’s drug products and compliance with FDA regulatory requirements for communications about such products, (2) this training will result in the participants providing a valuable service to the company, and (3) the participants meet the criteria for consultants (as discussed in part 4.a. above).

14 Financial assistance for scholarships or other educational funds to permit medical students, residents, fellows, and other healthcare professionals in training to attend carefully selected educational conferences may be offered so long as the selection of individuals who will receive the funds is made by the academic or training institution. “Carefully selected educational conferences” are generally defined as the major educational, scientific, or policy-making meetings of national, regional, or specialty medical associations.
Items primarily for the benefit of patients may be offered to healthcare professionals if they are not of substantial value ($100 or less). For example, an anatomical model for use in an examination room primarily involves a patient benefit, whereas a VCR or CD player does not. Items should not be offered on more than an occasional basis, even if each individual item is appropriate. Providing product samples for patient use in accordance with the Prescription Drug Marketing Act is acceptable.

Items of minimal value may be offered if they are primarily associated with a healthcare professional’s practice (such as pens, notepads, and similar “reminder” items with company or product logos).

Items intended for the personal benefit of healthcare professionals (such as floral arrangements, artwork, music CDs or tickets to a sporting event) should not be offered.

Payments in cash or cash equivalents (such as gift certificates) should not be offered to healthcare professionals either directly or indirectly, except as compensation for bona fide services (as described in parts 4 and 5). Cash or equivalent payments of any kind create a potential appearance of impropriety or conflict of interest.

No grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items should be provided or offered to a healthcare professional in exchange for prescribing products or for a commitment to continue prescribing products. Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a healthcare professional’s prescribing practices.
Each member company is strongly encouraged to adopt procedures to assure adherence to this Code.
APPENDIX D: PILOT SURVEY TOOL

The Influence of Pharmaceutical Company Sponsored Educational Programs, Promotions and Gifts on the Self-Reported Prescribing Beliefs and Practices of Certified Nurse Practitioners in Three States

Please answer the following questions based on your experience as a Nurse Practitioner over the last five years, except where otherwise indicated. If you have not practiced and/or have not prescribed medications for patients during the last five years, please indicate so below and return the survey, completing only questions 35 - 43.

If you have any additional comments please feel free to make them on the reverse side of this, or any other page of the survey.

Again, thank you for your time!

_______ I have not practiced as a nurse practitioner and/or have not prescribed medications for patients during the last five years
Nurse Practitioner Prescribing Practices Survey

1. Do you believe your prescribing practices are influenced by pharmaceutical company sponsored gifts such as pens, note pads, textbooks; promotions such as drug samples for patients; or educational programs at conferences, dinners or your office?
   
   A. Yes          B. No

2. Do you believe it is appropriate to accept promotional products, drug samples, educational information or programming, or gifts from pharmaceutical company representatives?
   
   Never       Always
   1  2  3       4

When selecting a prescription drug for your patients, how important are each of the following factors when choosing which drug to prescribe?

Very Important     Not Important
1  2  3             4

3. Patient request for a specific drug  1  2  3  4
4. Samples available in the office  1  2  3  4

5. Please rate your opinion of the appropriateness of accepting each of the following pharmaceutical promotional products, gifts and events related to your practice

Very Appropriate     Very Inappropriate
1  2  3             4

A. pens, notepads, coffee mugs, paperclips, small desk clocks  1  2  3  4
B. dinner, lunch, snacks or other foods in your clinical practice site while listening to a presentation about  1  2  3  4
pharmaceutical product information

C. antibiotic and other pocket guides, textbooks, calculators 1 2 3 4

D. conference registration fees 1 2 3 4

E. breakfast lunch or dinner educational meeting
   at a restaurant or conference 1 2 3 4

F. sample drugs for your patients 1 2 3 4

G. day trip or event such as theater, concert or sports event which
   includes an educational presentation which is paid for by a
   pharmaceutical company 1 2 3 4

H. receipt of an honorarium for consultation or a speaking
   engagement supported by a pharmaceutical company (consultation or
   meeting presentation) 1 2 3 4

I. sample drugs for your personal use 1 2 3 4

J. patient education materials 1 2 3 4

K. sample drugs for use by your family members 1 2 3 4

6. On average, how many times a month do you interact with pharmaceutical company
   representatives while attending: your clinical practice, at educational meetings,
   continuing education conferences, grand rounds or other events? Please select only
   ONE.
   
   a. 0
   b. 1-4
   c. 5-9
   d. 10-14
   e. more than 14 times per month

7. I have changed or modified my prescribing practice after
   attending a pharmaceutical company sponsored educational
   program or presentation or after receiving promotional items.
   (if disagree, please skip to question 17)

   Agree   Disagree
If you have ever changed or modified your prescribing practices after attending a pharmaceutical company sponsored event, which of the following factors affected your decision? The drug was:

8. As effective and less costly  Yes No
9. More effective for the problem  Yes No
10. As effective had less side effects  Yes No
11. As effective and had more convenient dosing for the patient  Yes No
12. Product had associated patient education materials  Yes No
13. A new alternative for my patient (a combination drug, a new class of drug, etc.)  Yes No
14. Requested by the patient  Yes No
15. Samples available in the office  Yes No
16. More palatable (taste) or a new route of administration available  Yes No

17. Do you believe other Nurse Practitioners’ prescribing practices are influenced by pharmaceutical company sponsored gifts such as pens, note pads, textbooks; promotions such as drug samples for patients; or educational programs at conferences, dinners or their offices?

   A. Yes  B. No

18. Have you ever received any of the following promotional gifts or products from pharmaceutical representatives in you clinical practice site, at an educational dinner or luncheon, grand rounds, local or national conferences or by mail? Please circle the corresponding response:

   A. pens, notepads, coffee mugs, paperclips, small desk clocks  Yes No
   B. dinner, lunch, snacks or other foods in your clinical practice site while listening to a presentation about pharmaceutical product information  Yes No
   C. antibiotic and other pocket guides, textbooks, calculators  Yes No
   D. conference registration fees  Yes No
   E. breakfast lunch or dinner educational meeting at a restaurant or conference  Yes No
   F. sample drugs for your patients  Yes No
F. day trip or event such as theater, concert or sports event which includes an educational presentation which is paid for by a pharmaceutical company Yes No

H. receipt of an honorarium for consultation or a speaking engagement supported by a pharmaceutical company (consultation or meeting presentation) Yes No

I. sample drugs for your personal use Yes No

J. patient education materials Yes No

K. sample drugs for use by your family members Yes No

19. During the last year, on average, how many times a month have you had a patient request a specific drug because they have seen it advertised on television, billboards, magazines or other media sources or because a friend or relative has suggested it?

A. 0  B. 1-5  C. 6-10  D. 11-15  E. 16-20  F. >20

20. If you received an item useful to you in your practice such as an educational monograph, product information, patient samples, note pads or pens, from a pharmaceutical representative, how likely would you be to see that pharmaceutical representative again?

Not Very Likely  Very Likely

1  2  3  4

Carefully read the statements below and indicate your strength of agreement or disagreement by circling the corresponding number

Strongly agree  Strongly Disagree

1  2  3  4

21. Pharmaceutical representatives provide useful information about pharmaceutical products 1 2 3 4

22. I would continue to meet with pharmaceutical representatives even if they no longer provided drug samples for my practice 1 2 3 4
23. Pharmaceutical companies provide an important education function

24. Pharmaceutical representatives provide unbiased information about their products

25. Pharmaceutical company sponsored educational programs do not affect my prescribing practices

Please rate the following statement based upon your recollection of your initial NP education program.

<table>
<thead>
<tr>
<th>Strongly agree</th>
<th>Strongly Disagree</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

26. During my nurse practitioner education program I was given adequate information concerning how a nurse practitioner should interact with pharmaceutical representatives so that I could make informed prescribing decisions

| 1 | 2 | 3 | 4 |

Please complete the following demographic data by circling the most appropriate response

27. Age
   A. 20-30    B. 31-40    C. 41-50    D. 51-60    E. 61-70    F. >70

28. Gender
   A. Female   B. Male

29. Highest degree obtained
   A. Diploma   B. Associate Degree   C. Bachelors degree
30. State in which you have your primary practice site (please select just one):
   A. FL     B. PA     C. NY     D. Other __________________

31. Total number years of nursing experience (RN and NP)
   A. 1-5     B. 6-10     C. 11-15     D. 16-20     E. 21-25     F. >25

32. Number of years of NP experience
   A. 1-5     B. 6-10     C. 11-15     D. 16-20     E. 21-25     F. >25

33. Where is your primary clinical practice site located? (If more than one site,
    please select the site in which you see the most patients)
   B. Urban
   C. Suburban
   D. Rural

34. Which national NP certification(s) do you hold? (Circle all that apply)
   A. FNP     B. Acute NP     C. Women’s Health Care NP     D. PNP     E. Adult Primary Care NP
   F. Family Psychiatric Mental Health NP     G. Adult Psychiatric Mental Health
   H. Neonatal     I. Other __________________

35. In which type of practice do you spend most of your clinical time (i.e.
    what is your major patient population)? Please select only ONE
   A. Adult Primary Care     B. Pediatric Primary Care     C. Women’s Health Care
   D. Geriatrics     E. Family Practice     F. Pediatric Tertiary Care
   I. Psychiatric Outpatient Pediatrics     J. Psychiatric Inpatient Pediatrics
   K. Adult Tertiary Care     L. Psychiatric Inpatient pediatrics
   M. Psychiatric Inpatient Adult     N. Pediatric Specialty Practice (i.e.
G. Family Specialty Practice (i.e. orthopedics, dermatology, surgery, cardiology, etc.)
   please specify _______________
H. Other please specify ________

O. Adult Specialty Practice (i.e. dermatology, surgery, cardiology, etc.)
   please specify _______________

Additional comments – Please feel free to use the other side of this, or any other page:

Thank you for taking the time to complete this survey!
APPENDIX E: SURVEY

The Influence of Pharmaceutical Company Sponsored Educational Programs, Promotions and Gifts on the Self-Reported Prescribing Beliefs and Practices of Certified Nurse Practitioners in Three States

Please answer the following questions based on your experience as a Nurse Practitioner over the last five years, except where otherwise indicated.

- Please circle your responses on the survey
- If you have not practiced and/or have not prescribed medications for patients during the last five years, please indicate so below and return the survey

Again, thank you for your time!

I have not practiced as a nurse practitioner and/or have not prescribed medications for patients during the last five years
Nurse Practitioner Prescribing Practices Survey

1. Do you believe your prescribing practices are influenced by pharmaceutical company sponsored gifts such as pens, note pads, textbooks; promotions such as drug samples for patients; or educational programs at conferences, dinners or your office?

   A. Yes  
   B. No

2. Do you believe it is appropriate to accept promotional products, drug samples, educational information or programming, or gifts from pharmaceutical company representatives?

   Never  1  2  3  Always  4

3. When selecting a prescription drug for your patients, how important are each of the following factors when choosing which drug to prescribe?

   Very Important  1  2  3  Not Important  4

   3a. Patient request for a specific drug  1  2  3  4
   3b. Samples available in the office  1  2  3  4

4. Please rate your opinion of the appropriateness of accepting each of the following pharmaceutical promotional products, gifts and events related to your practice

   Very Appropriate  1  2  3  Very Inappropriate  4

   4a. pens, notepads, coffee mugs, paperclips, small desk clocks  1  2  3  4
   4b. dinner, lunch, snacks or other foods in your clinical practice site while listening to a presentation about pharmaceutical product information  1  2  3  4
   4c. antibiotic and other pocket guides, textbooks, calculators  1  2  3  4
4d. conference registration fees
4e. breakfast lunch or dinner educational meeting at a restaurant or conference
4f. sample drugs for your patients
4g. day trip or event such as theater, concert or sports event which includes an educational presentation which is paid for by a pharmaceutical company
4h. receipt of an honorarium for consultation or a speaking engagement supported by a pharmaceutical company (consultation or meeting presentation)
4i. sample drugs for your personal use
4j. patient education materials
4k. sample drugs for use by your family members

5. I have changed or modified my prescribing practice after attending a pharmaceutical company sponsored educational program or presentation or after receiving promotional items. (if disagree, please skip to question 17)

Agree               Disagree

6. **If you have ever** changed or modified your prescribing practices after attending a pharmaceutical company sponsored event, which of the following factors affected your decision? The drug was:

8a. More effective for the problem
8b. As effective had less side effects
8c. Product had associated patient education materials
8d. A new alternative for my patient (a combination drug a new class of drug, etc.)
8e. Requested by the patient
8f. Samples available in the office  
Yes  No

8g. More palatable (taste) or a new route of administration available  
Yes  No

7. Do you believe other Nurse Practitioners’ prescribing practices are influenced by pharmaceutical company sponsored gifts such as pens, note pads, textbooks; promotions such as drug samples for patients; or educational programs at conferences, dinners or their offices?

A. Yes  B. No

8. Have you ever received any of the following promotional gifts or products from pharmaceutical representatives in you clinical practice site, at an educational dinner or luncheon, grand rounds, local or national conferences or by mail?

8a. pens, notepads, coffee mugs, paperclips, small desk clocks  
Yes  No

8b. dinner, lunch, snacks or other foods in your clinical practice site while listening to a presentation about pharmaceutical product information  
Yes  No

8c. antibiotic and other pocket guides, textbooks, calculators  
Yes  No

8d. breakfast lunch or dinner educational meeting at a restaurant or conference  
Yes  No

8e. sample drugs for your patients  
Yes  No

8f. day trip or event such as theater, concert or sports event which includes an educational presentation which is paid for by a pharmaceutical company  
Yes  No

8g. receipt of an honorarium for consultation or a speaking engagement supported by a pharmaceutical company (consultation or meeting presentation)  
Yes  No

8h. sample drugs for your personal use  
Yes  No

8i. patient education materials  
Yes  No

8j. sample drugs for use by your family members  
Yes  No
9. If you received an item useful to you in your practice such as an educational monograph, product information, patient samples, note pads or pens, from a pharmaceutical representative, how likely would you be to see that pharmaceutical representative again?

Not Very Likely  Very Likely

1  2  3  4

10. Carefully read the statements below and indicate your strength of agreement or disagreement.

Strongly agree

1  2  3  4

Strongly Disagree

10a. Pharmaceutical representatives provide useful information about pharmaceutical products 1 2 3 4

10b. I would continue to meet with pharmaceutical representatives even if they no longer provided drug samples for my practice 1 2 3 4

10c. Pharmaceutical companies provide an important education function 1 2 3 4

10d. Pharmaceutical representatives provide unbiased information about their products 1 2 3 4

10e. Pharmaceutical company sponsored educational programs do not affect my prescribing practices 1 2 3 4

II. Demographic Information

a. On average, how many times a month do you interact with pharmaceutical company representatives while attending: your clinical practice, at educational meetings, continuing education conferences, grand rounds or other events? Please select only ONE.

1. 0
2. 1-4
3. 5-9
4. 10-14
5. more than 14 times per month
b. During the last year, on average, how many times a month have you had a patient request a specific drug because they have seen it advertised on television, billboards, magazines or other media sources or because a friend or relative has suggested it?

1. 0
2. 1-5
3. 6-10
4. 11-15
5. 16-20
6. >20

c. Please rate the following statement based upon your recollection of your initial NP education program:

During my nurse practitioner education program I was given adequate information concerning how a nurse practitioner should interact with pharmaceutical representatives so that I could make informed prescribing decisions

<table>
<thead>
<tr>
<th>Strongly agree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

d. Age

1. 20-35
2. 36-50
3. 51-60
4. >60

e. Gender

1. Female
2. Male

f. Highest degree obtained

1. Diploma
2. Associate Degree
3. Bachelors degree
4. Masters degree
5. Doctorate
6. Post-doctorate
g. State in which you have your primary practice site (please select just one):

1. FL  
2. PA  
3. NY  
4. Other __________________

h. Total number years of nursing experience (RN and NP)

1. 1-5  
2. 6-10  
3. 11-15  
4. 16-20  
5. 21-25  
6. >25

i. Number of years of NP experience

1. 1-5  
2. 6-10  
3. 11-15  
4. 16-20  
5. 21-25  
6. >25

j. Where is your primary clinical practice site located? (If more than one site, please select the site in which you see the most patients)

1. Urban  
2. Suburban  
3. Rural

k. Which national NP certification(s) do you hold? (Circle all that apply)

1. FNP  
2. Acute NP  
3. Women’s Health Care NP  
4. PNP  
5. Geriatric NP  
6. Adult Primary Care NP  
7. Family Psychiatric Mental Health NP  
8. Adult Psychiatric Mental Health NP  
9. Neonatal  
10. Other __________________
L. In which type of practice do you spend most of your clinical time (i.e. what is your major patient population)? Please select only ONE

1. Adult Primary Care
2. Pediatric Primary Care
3. Women’s Health Care
4. Geriatrics Psychiatric
5. Family Practice
6. Pediatric Tertiary Care
7. Family Specialty Practice (i.e. orthopedics, dermatology, surgery, cardiology, etc.)
8. Psychiatric Outpatient Pediatrics
9. Psychiatric Inpatient Pediatrics
10. Adult Tertiary Care
11. Inpatient pediatric
12. Psychiatric Inpatient Adult
13. Pediatric Specialty Practice (i.e. dermatology, surgery, cardiology, etc.)
14. Adult Specialty Practice (i.e. dermatology, surgery, cardiology, etc.)
15. Other please specify ____________

Additional comments – Please feel free to use the other side of this, or any other page:

Thank you for taking the time to complete this survey!
<table>
<thead>
<tr>
<th>Survey</th>
<th>Comments</th>
<th>Practice Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>21</td>
<td>Perhaps guidelines are in order?</td>
<td>Gero-psych</td>
</tr>
<tr>
<td>22</td>
<td>It is probably more the decision of the surgeons of practice I work with that influence which drug reps I come in contact with. i.e. many of them have large accounts with our facility and frequently provide us with educational materials, dinners, etc. I do feel this information is biased (naturally) and this is why I do not let it influence my prescribing. The 2 most important influences I take into account are drug cost to the patient and patient request.</td>
<td>CT surgery</td>
</tr>
<tr>
<td>27</td>
<td>Since starting to practice I have learned a great deal by attending drug company sponsored educational activity. I have found this educational helps invaluable, but often feel expected to prescribe their drug</td>
<td>Adult primary care</td>
</tr>
<tr>
<td>29</td>
<td>I also volunteer at a clinic that relies heavily on samples and with limited resources available sample availability strongly affects what the patient is given (as does cost)</td>
<td>Occupational Health</td>
</tr>
<tr>
<td>36</td>
<td>We don’t accept samples. Our organization does not accept sample meds. We do see reps occasionally for education/lectures but they tend to visit less often because we do not accept samples, because our population is 50% uninsured and many times we choose cheaper alternatives rather than newer drugs. We have a 301b med program.</td>
<td>Family practice</td>
</tr>
<tr>
<td>39</td>
<td>Practices influenced because I am more aware of their products</td>
<td>Cardiology</td>
</tr>
<tr>
<td>41</td>
<td>Pharmaceutical decisions are base don current national guidelines, research studies and (unfortunately) insurance carriers</td>
<td>Cardiology</td>
</tr>
<tr>
<td>51</td>
<td>No samples available in the office As a practice solely treating HIV our meds are continuously changing and research trials are always in progress. Any studies go for 24-48 weeks and</td>
<td>HIV practice</td>
</tr>
</tbody>
</table>
results can change. Cocktails (drugs) and drug interventions can predict medication change.

<p>| 58 | I work in the VA system we do not get samples of drugs | Cardiology |
| 62 | My patients are my primary concern; I do not prescribe medications to please the pharmaceutical representatives that visit me. However, I do feel the information that they provide very helpful. Especially recent studies and data essential to my prescribing practice. Although I believe that pharmaceutical reps are discerning, I believe that pharmaceutical reps are helpful to provide information and samples for my patients, as I prefer to try a patient on samples before they spend their own money on a medication that they may not be able tolerate. | Family practice |
| 63 | Good luck with your research- Pleased to fill out the survey- Excellent insight | Dermatology |
| 64 | I am cautious about info given by sales representatives. Most do not have medical or clinical background and parrot information they have been fed by marketing divisions. I will consider experts in their fields who speak at meetings sponsored by companies/. Luncheons in the office are entertained mostly because the office staff enjoys the sponsored event. The trinkets (coffee mugs) could be forgotten in my opinion. | Asthma and allergy |
| 65 | Good luck with the doctorate. I am interested din finding out why NPs cannot/do not receive honorarium for work completed re: participation or lectures given re: this topic. It seems as though MDs receive payment but we get $0.00 (just curious) | GI/Nutrition |
| 70 | I agree that money used for dinner programs/seminars can be high, however, this is the time slot where I am not seeing patients and am able to digest the information. | Adult primary care |</p>
<table>
<thead>
<tr>
<th>ID</th>
<th>Comment</th>
<th>Specialty</th>
</tr>
</thead>
<tbody>
<tr>
<td>198</td>
<td>As a speaker, I feel that being compensated for my time is justified. I spend a lot of time prepping and preparing for a presentation. Samples are sometimes the only way my patients have of receiving needed meds. I feel fortunate that we can provide meds when our patients can’t afford them.</td>
<td>Family practice</td>
</tr>
<tr>
<td>72</td>
<td>Great survey. Well organized. Maybe you should ask would I go to a presentation that did not include dinner. Answer-maybe.</td>
<td>Dermatology</td>
</tr>
<tr>
<td>73</td>
<td>Samples are important in a dermatology practice to evaluate effectiveness of topical Rx before patient spends a significant amount of $ on something that isn’t effective.</td>
<td>Dermatology</td>
</tr>
<tr>
<td>75</td>
<td>I may be the best source on this. I work nights for a neurosurgery service and rarely see drug reps. Nice idea and good survey!</td>
<td>Neurosurgery</td>
</tr>
<tr>
<td>89</td>
<td>Interesting survey</td>
<td>Cardiology</td>
</tr>
<tr>
<td>92</td>
<td>Many times the rep ahs to see the “doctor” to show how many they have seen. I write 95% of the scripts for the practice!</td>
<td>Women’s health care</td>
</tr>
<tr>
<td>95</td>
<td>Patients don’t request specific drugs-I work with an MA pt. population. Believe me, I work in an underprivileged area and look to use samples for my patients who can’t afford meds I give samples to patients who don’t even have medical assistance Reps are biased. I make my own decisions</td>
<td>Pediatric primary care</td>
</tr>
<tr>
<td>106</td>
<td>I work in a federally designated rural health care center. My prescribing practices are driven by the lowest process. Also, many of my patients are enrolled in indigent programs from the drug companies, and they medications for free</td>
<td>Family practice</td>
</tr>
<tr>
<td>109</td>
<td>It is impossible to say that companies have no influence as the educational materials and product information can sway a provider to try a specific agent. I believe efficacy of the drug and cost to the patient are, more influential over</td>
<td>Psych outpatient</td>
</tr>
<tr>
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<td>Department</td>
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<tr>
<td>116</td>
<td>This appears to be an excellent topic for your doctorate degree. My hypothesis is that NP behavior in prescribing does not differ that much from MDs as for interaction with pharmaceutical representatives is concerned. Good luck</td>
<td>Women’s health care</td>
</tr>
<tr>
<td>130</td>
<td>Thanks for doing research. I feel as NPs we tend to offer what is best for our patients. Not always what is the newest</td>
<td>Woman’s health care</td>
</tr>
<tr>
<td>134</td>
<td>Most of my prescribing practices are dictated by strict protocols. There are products I would like to use but are not permitted. I also must always keep cost in mind for my clients because many are uninsured</td>
<td>Women’s health care</td>
</tr>
<tr>
<td>135</td>
<td>Having drug samples to try a patient on to see if they are going to tolerate the drug is much more cost effective for the patient. Patients actually appreciate the samples.</td>
<td>Endocrinology</td>
</tr>
<tr>
<td>142</td>
<td>Why did you change terminology and reverse order on rating scales...a bit confusing. I accept pens etc. and in the past have found most information useful but I keep in mind the source of the info. Drug reps sponsored activities often provide venue for learning, CEU and networking. There is a place for it.</td>
<td>Women’s health care</td>
</tr>
<tr>
<td>143</td>
<td>Cost effectiveness medication selection is important in the population of clients I see. Therefore, if I know a drug is available at decreased cost to my patient or free and is safe and appropriate for the diagnosis it makes sense to select that med.</td>
<td>Adult primary care</td>
</tr>
<tr>
<td>147</td>
<td>Interesting survey</td>
<td>Family practice</td>
</tr>
<tr>
<td>151</td>
<td>Most of patients I see have no insurance. I rely on samples</td>
<td>Family practice</td>
</tr>
<tr>
<td>155</td>
<td>Good luck</td>
<td>Women’s health care</td>
</tr>
<tr>
<td>156</td>
<td>Although I do feel the pharmaceutical companies spend too much time on superficial giveaways they are the only ones who provide free, accessible treatments.</td>
<td>Adult Outpatiety</td>
</tr>
<tr>
<td>ID</td>
<td>Response</td>
<td>Discipline</td>
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<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>1175</td>
<td>It would be more helpful to make your scales more specific and perhaps have 5 responses</td>
<td>Family practice</td>
</tr>
<tr>
<td>176</td>
<td>Sounds like a good study – can’t wait to get the results</td>
<td>Women’s health care</td>
</tr>
<tr>
<td>183</td>
<td>It’s very nice to get info from other NPs and what research they are doing, I enjoy meeting with reps. Yes, I take their samples and goods, but I still prescribe according to supportive research studies of the products. Example: there are 7 ARBs on the market. I prescribe only 1-3 of that class of drug but I will meet with other reps to be informed of the other ARBs out there in case my patients do question me about them, but I will prescribe them it would be rare unless strong supportive data.</td>
<td>Cardiology</td>
</tr>
<tr>
<td>186</td>
<td>I run a free family practice clinic 1 day a week and depend on drug reps samples to give away</td>
<td>Geriatric LTC</td>
</tr>
<tr>
<td>187</td>
<td>Good luck</td>
<td>Family practice</td>
</tr>
<tr>
<td>190</td>
<td>Question #7 was difficult, near impossible to answer with a clear conscience. Certainly some are, but I also assume most go through the mental/ethical balancing act I do. As a rural practice, many of my patients fall into the “working poor”, uninsured group. I use free samples to treat those who cannot afford or at least to reduce their financial burden. I use samples as a trial for side effects before pt’s purchase the full script. I also get patient signed up for pharm company free med programs. Thanks you for this survey</td>
<td>Family practice</td>
</tr>
<tr>
<td>192</td>
<td>Referring to question 11, I recently in the past year worked minimally due to having my child. While working full time, the number of interactions with a</td>
<td>Neurology</td>
</tr>
<tr>
<td></td>
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</tr>
<tr>
<td>196</td>
<td>I am not influenced by trinkets. I am however influenced by data supported by research regarding the efficacy of pharmaceutical agents.</td>
<td>Cardiology</td>
</tr>
<tr>
<td>197</td>
<td>The likert scale was difficult for some questions as it should have been 1-5</td>
<td>Cardiology</td>
</tr>
<tr>
<td>200</td>
<td>Most NPs see large percentage of their practice with indigent or &quot;working poor” populations. If not for samples, many of these patients would not be able to start treatment due to expense. The sample allows the patient to start treatment immediately and if effective we are able to sign up patient for assistance but it may take up to 6 weeks to be approved.</td>
<td>Adult outpt psych</td>
</tr>
<tr>
<td>208</td>
<td>My practice is hospital based NICU – some of the questions were not applicable to my practice.</td>
<td>Neonatal ICU</td>
</tr>
<tr>
<td>209</td>
<td>I like to have birth control pill samples for instructions and demonstration to the patient, as many insurance policies do not cover contraception for patients. I like having samples for them. I enjoy the updates and articles the reps bring but I try to keep a level head and evaluate for myself. I have to admit a free lunch brought to me on a busy day is nice sometimes</td>
<td>Women's health care</td>
</tr>
<tr>
<td>210</td>
<td>I’d like to say that although some aspects of pharmaceutical marketing may seem improper (to health care providers) this industry is still entitled to conduct business (like any other business or corporation) with marketing, give aways, promotion items, etc. AND my patients appreciate the samples</td>
<td>Gero and adult psych</td>
</tr>
<tr>
<td>214</td>
<td>Question #1 is a wide variety of options. I would say I am not influenced by pens, notepads, dinners in the office, but I am influenced by what samples are available in the office. Question #2 I believe there is a big difference between receiving gifts from reps and getting samples for patients</td>
<td>Women’s health</td>
</tr>
<tr>
<td>217</td>
<td>Sometimes reps present a biased viewpoint pointing only to the positive studies/aspects of their drug.</td>
<td>Family practice</td>
</tr>
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<td></td>
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</tr>
<tr>
<td>202</td>
<td>Can be pushy. Being in family practice there are too many reps to see in a day. Also, difficult to go out without spouse to dinners, education events</td>
<td>Family practice</td>
</tr>
<tr>
<td>221</td>
<td>Good luck, I look forward to receiving your results</td>
<td></td>
</tr>
<tr>
<td>222</td>
<td>Samples are important to our practice as many of our patients can’t afford the needed meds without the samples. If pharmaceutical companies spent less on marketing (pens, clocks, note pads, etc.) and lower the cost of the drugs, samples wouldn’t be as great a need. Non-medical items are left in the office but are not an influence on my prescribing practice.</td>
<td>Urgent care</td>
</tr>
<tr>
<td>225</td>
<td>We are not allowed to accept samples</td>
<td>Pain and palliative care</td>
</tr>
<tr>
<td>228</td>
<td>The drug reps often flash research studies that may or may not be valid as a way to persuade prescribe</td>
<td>Psych</td>
</tr>
<tr>
<td>230</td>
<td>I practice in an urban hospital. My prescriptive practice is influenced by what is available on the hospital formulary, what drugs Medicaid will pay for. If the cost is prohibitive, my patients will not pay. If the pharm company is willing to offer their drugs to the hospital at a reasonable price and if the benefits of that drug is more effective and has less side effect than the ones currently on formulary, then perhaps they will get their drugs on formulary</td>
<td>Women’s health care</td>
</tr>
<tr>
<td>237</td>
<td>Strong emphasis should be placed on benefit of education, should provide CEUs to support the educational forum</td>
<td>Neonatal</td>
</tr>
<tr>
<td>245</td>
<td>I think pharmaceutical companies spend an excessive amount of money and marketing to both professionals and the public. These budgets should be decreased and medications made more affordable to patients. Like anything, if it works and can easily be obtained, it will be used. I enjoy interacting with most reps because they have the ability to answer</td>
<td>Women’s health</td>
</tr>
<tr>
<td>Line</td>
<td>Comment</td>
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<td>------</td>
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</tr>
<tr>
<td>246</td>
<td>Being in neonatal field, some of these questions are not applicable. If I never see another Celebrix mug, I won’t care!</td>
<td></td>
</tr>
<tr>
<td>247</td>
<td>Great survey. #13 - although at school they only touched briefly on the subject, I believe most RNs (especially in management) have been exposed to pharmaceutical reps in a less aggressive way. Good luck</td>
<td></td>
</tr>
<tr>
<td>254</td>
<td>Pharmaceutical information is OK as long as it is given in relation to education. Gifts for the sake of gifts is not OK</td>
<td></td>
</tr>
<tr>
<td>256</td>
<td>Best of luck with your research. I am very interested in your results</td>
<td></td>
</tr>
<tr>
<td>260</td>
<td>In the practices I have been affiliated with, money has the power (not unusual, I know). The huge practices have physicians with reps begging for a nano-second audience. I have typically found the NP/PA “Oh, you’re invited too” when there is an educational event. We will have an? Increasing base in medicine. I am looking forward to the results of this survey. Good or bad. The companies will continue their practices although change is always important. Good luck in your endeavors!</td>
<td></td>
</tr>
<tr>
<td>261</td>
<td>It’s a fine line</td>
<td></td>
</tr>
<tr>
<td>262</td>
<td>Pharm reps almost always never come to my office empty handed. It may be a simple gift like pens or pads, or even candy or maybe an elegant dinner invite for my spouse and me. I have more male reps, where as the men docs see the female reps more often. All dressed to perfection and looking “vogue” Good luck</td>
<td></td>
</tr>
<tr>
<td>263</td>
<td>Samples are great for the uninsured. I strongly oppose the undue influence of the pharm industry in research and care</td>
<td></td>
</tr>
</tbody>
</table>
prescribing. I feel it is highly unethical and biased and skews healthcare towards expensive medications. My patients however must have free samples until we wake up and provide universal health insurance.

264 I find pharmaceutical reps very helpful and informative. It helps keep me up my knowledge of new medications and changes to treatment guidelines. I don’t have a problem with gifts of less than $100.00. If the doctors can do it then it is appropriate for NPs too. Pulmonary

266 I always make a conscious effort to prescribe what seems best for the client, no matter what the relationship with the drug reps. Psychiatry

269 Samples are most useful in my prescribing practice when cost is an issue to my patient. Family practice

292 I could really care less about the JUNK that they (the pharmaceutical companies) give us. Rarely do I find something useful. I like the dosing charts for antibiotics. I find it very helpful to talk to reps. They summarize information in the prescribing guide which I don’t always have time to read and inform me of new indications and new research for a drug. They should give away less junk and provide more educational seminars (I like nice dinners but that is not why I go), decrease advertising so they can offer a drug at a lower cost and have more patient assistance programs. Score tablets so we can them in half to save money! Always include NPs in their invitations. If a company can convince me with the research that their drug is better or cheaper, I will use it. The Junk never influences my decision. Cost and evidenced based research helps me decide what to prescribe. Also, the co-payment on insurance is a big factor. Family practice

296 Samples provided for our clinic have truly been “life savers” for those oncology. Ped heme/onc
patients with chronic pain (Vioxx samples) and nausea (Zofram) and no insurance coverage. So although drug reps may “push their product” we feel the samples for our children are worth a few minutes of hype!

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<tr>
<td>300</td>
<td>Since I am a neonatal NP, patient request for a drug and samples in the office are never factors</td>
<td>Neonatal ICU</td>
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<tr>
<td>310</td>
<td>Neonatal ICU – samples and patient request are not an issue</td>
<td>Neonatal ICU</td>
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<td>307</td>
<td>Drug reps do not visit NICUs very frequently. We do tend to see formula reps more often (I consider these extremely similar)</td>
<td>Neonatal ICU</td>
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<td>312</td>
<td>I think NPs are smart enough to use reps stuff to better serve patient populations, staff, etc, etc. and not be influenced by their used car salesman tactics.</td>
<td>In-house neonatal</td>
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<td>317</td>
<td>Educational programs at conferences and dinners – yes to influence at both. The gifts have no bearing. Drug samples for patients, educational programs at conferences – yes NP practices are influenced to some degree. Don’t have much choice about seeing a rep again, they are in my face when I walk out of a patient’s room. I work 2 times a week and see reps 16-21 times per month. It would be &gt; 21 if I worked full time. The gifts such as pens, notepads, etc..Is not an influence. However, the educational material and studies they provide with re to efficacy, etc…are important. Samples definitely help</td>
<td>Adult primary care</td>
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<td>320</td>
<td>Pharm reps do not routinely call on NPs in central Florida due to the fact prescribing practices are not tracked because we have no DEA#. It is difficult to have a rep meet with me/give me information about a drug – my collaborating MDs get the call because pharmacies track the MDs DEA on my prescriptions.</td>
<td>Geriatric long-term care</td>
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<tr>
<td>Code</td>
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<td>I</td>
<td>I attend dinners for education and to hear cases of use, problem, success by other health care providers. I like to think I have a “thoughtful practice”. The information can only be helpful - how I use it is my choice. I need to be convinced before ever prescribing for my geriatric patients. PS – this is a great topic – good luck!</td>
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<td>322</td>
<td>Pharmaceutical influences have been educational and unbiased in my opinion X 2 years to date Elizabeth – good luck with your survey. I hope your results will show + education, - harm, + samples for needy patients – appropriate therapy, win/win, this ahs been my experience to date.</td>
<td>Cardiology</td>
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<td>325</td>
<td>My clinical practice does not allow drug reps into the office so I have had limited interaction with same</td>
<td>Geriatrics</td>
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<tr>
<td>331</td>
<td>Good luck with your study</td>
<td>Cardiology</td>
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<tr>
<td>332</td>
<td>#1 – this question is loaded. I do rx meds which are readily available as samples for some patients who would otherwise go without #3a – varies with reason for request #3b – again, loaded question #5 – again a loaded, poorly written question. Changed prescribing after educational program – sometimes, after receiving a gift – never #7 – don’t know, purely speculative, not valid</td>
<td>Psych outpatient</td>
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<td>334</td>
<td>Great idea! I think the positive aspect of the drug companies is the free sample so patients without prescription coverage. I find this to be very helpful</td>
<td>Neurology</td>
</tr>
<tr>
<td>336</td>
<td>Great idea!</td>
<td>Adult specialty</td>
</tr>
<tr>
<td>348</td>
<td>Thanks, Good luck to you</td>
<td>Neonatal ICU</td>
</tr>
<tr>
<td>349</td>
<td>I appreciate the help of the pharmaceutical reps and drug companies, but would appreciate even more actions that would lower the cost of drugs to patients</td>
<td>Woman’s health care</td>
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<tr>
<td>351</td>
<td>I have been a paid speaker for 2 companies. I would not speak for a drug in which I do not strongly believe, or with which I did not have adequate experience. I do believe drug reps play an important educational role, however, I do believe their that their information is obviously biased. I take ample opportunity to read medical literature for non-biased review of drugs. Even if the reps did not supply lunch, I would still take the time to briefly talk with them re: new indications, warning, etc. regarding their drugs. In fact, I often speak with them briefly when they stop in the office. I often throw their useless “junk” i.e clocks, etc. away. They do not persuade me with trinkets.</td>
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<tr>
<td>353</td>
<td>I believe samples and educational materials are extremely useful. I strongly believe the money spent on dinners, trips shows, etc. should be put to better use. I find it somewhat unethical however I have been guilty on occasion attending dinners that were given to our entire practice.</td>
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<td>376</td>
<td>I look forward to reading the results of your study. I find in my practice that a patient’s insurance/ability to pay for meds is often the deciding factor in choosing a specific med among those within the same class. Samples have been very beneficial. Also, I have stopped accepting pharm reps “perks” like game tickets, day trips, etc. I see accepting them as a conflict of interest.</td>
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<td>394</td>
<td>Good luck!</td>
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<tr>
<td>398</td>
<td>Free samples for geriatric patients have been helpful in compliance with meds for those who are unable to afford the medications</td>
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VITA

Elizabeth Blunt, is an assistant professor and Director of Graduate Nursing Programs at Drexel University College of Nursing and Health Professions. She graduated from the BSN program at Widener University in 1976, completed an MS in Education at Saint Joseph’s University in 1987 and received an MSN in Adult Primary Care from the University of Pennsylvania in 1995. She completed a Post-Master’s Certificate as a Family Nurse Practitioner from MCPHU in 1999. She has worked primarily in emergency and trauma care and has held positions as a staff nurse, trauma program administrator, nurse manager and director of nursing before bringing her clinical expertise to the faculty role. She is active in both community and professional groups and has been to Eastern Europe multiple times to teach nurses and nurse educators physical assessment. She has multiple professional publications and presentations to her credit.

Elizabeth is certified as an Adult and Family Nurse Practitioner and currently practices at the Eleventh Street Family Health Services and an urban emergency department