THE IMPACT OF COMMERCIAL SUPPORT ON THE PROVISION AND OUTCOMES OF CONTINUING PHARMACY EDUCATION

by

JAYNE LANGFORD SMITH

(Under the Direction of Ronald M. Cervero)

ABSTRACT

There is a rising debate over the growing involvement of the pharmaceutical industry in the development and delivery of continuing education designed to improve a health professional's practice and thus, patient care. Emerging policies and regulations that govern the planning of continuing education for physicians and pharmacists center on the potential conflict of interest when educational and promotional activities are integrated. This quantitative study investigates the impact of commercial support on the provision and outcomes of continuing pharmacy education. A 64-item questionnaire was developed to measure two constructs, *Planning Practices* and *Consequences*. The survey was administered online to accredited providers of continuing pharmacy education and responses from 134 accredited providers were included in the statistical analysis.

The respondents reported that approximately 43% of their continuing pharmacy education programs, or 2,740 programs, received commercial support. Acceptance of commercial support was prevalent among all types of accredited provider organizations and only 14% of respondents reported that their organization received no commercial support for continuing pharmacy education programs. Although the Accreditation Council for Pharmacy Education requires that program providers review all instructional content and materials prior to

program delivery, only 43% of respondents reported that they always conduct such a review for their commercially-supported programs. In addition, 15% of respondents reported that they never conduct such a review prior to delivery of a commercially-supported program. Some accredited providers report that they also violate relevant guidelines and release control to a pharmaceutical company when they allow other questionable and/or unacceptable practices in the development and implementation of their commercially-supported continuing pharmacy education programs and activities. For example, 31% of respondents reported that a program speaker provided preferential treatment of the supporting pharmaceutical company's product and 21% reported that a program speaker omitted discussion of a relevant product sold by a competing pharmaceutical company in at least some of their programs. Commercial support of continuing pharmacy education was also thought to have significant and diverse consequences for provider organizations, pharmacists and patients. Three dimensions of these consequences were revealed through exploratory factor analysis including Cost of Drugs, Quality of Pharmaceutical Care and Financial Dependency.

INDEX WORDS: Commercial support, continuing pharmacy education, continuing professional education, pharmacy, pharmaceutical company, program planning

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DEDICATION

This dissertation is dedicated

to my husband

Kirk M. Smith

to my parents

Hugh and Ernestine Langford

and to my sisters

Judy Spaulding, Joanne Sims and Jeannie Bradford.

Your love, support, understanding and encouragement made this journey possible.

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CHAPTER 1

INTRODUCTION

Background of the Problem

In the United States, the profession of pharmacy and pharmaceutical manufacturer and research-oriented companies "have been inextricably tied for generations. Virtually all of what the industry does involves pharmacists, whose focus is the optimal clinical use of drugs" (Gouveia, 1984, p. 1394). This clinical role of pharmacists, often referred to as "pharmaceutical care," has been emerging and evolving for the past few decades. The American Pharmaceutical Association (n.d., Preamble, ¶ 1) defines pharmaceutical care as "a patient-centered, outcomes oriented pharmacy practice that requires the pharmacist to work in concert with the patient and the patient's other healthcare providers to promote health, to prevent disease, and to assess, monitor, initiate, and modify medication use to assure that drug therapy regimens are safe and effective."

This movement toward pharmaceutical care is being driven internally by economic and professional issues within the profession of pharmacy, and externally by a societal need for improved drug therapy management (Temple, 1996). According to Bectel (1996), pharmacists embracing a pharmaceutical care role can be valuable to the pharmaceutical industry by assuring the provision of appropriate drug therapy and by achieving patient compliance through appropriate drug management. In turn, he states that pharmacists "must look cooperatively to the industry for information on disease management as well as educational support to assist the pharmacist in fulfilling that new clinical role in the evolving, integrated health care system " (p. 113).

Because the clinical role of the pharmacist is becoming an integral part of our health care system, it is important for pharmacists to maintain and improve their professional competence. According to the American Society of Health-System Pharmacists (ASHP), "as roles change, competency requirements change; and as pharmacy practitioners assume the increased responsibilities demanded in these new roles, they must make a corresponding commitment to improve their professional competence" (1990, p. 1855). Continuing pharmacy education (CPE) plays a central role in the maintenance and improvement of a pharmacist's competence; however, this expanded pharmaceutical care role places huge demands on providers of continuing education (Temple, 1996).

In the U.S., there has been a trend toward mandatory CPE requirements for pharmacy relicensure. Florida and Kansas were the first states to initiate mandatory continuing education laws for pharmacists in 1967 (Hodapp, 1988). However, 51 of the 53 U.S. jurisdictions of the National Association of Boards of Pharmacy currently have laws requiring pharmacists to complete a certain number of continuing education units (CEUs) as a requirement for license renewal (American Pharmacists Association and National Association of Boards of Pharmacy, n.d.). The Accreditation Council for Pharmacy Education (ACPE), formerly the American Council of Pharmaceutical Education, is the national agency for accreditation of CPE providers. Most states mandate that pharmacists must complete approximately 15 hours of CPE per year through programs offered by ACPE-accredited providers and/or providers recognized by the state's board of pharmacy (American Pharmacists Association and National Association of Boards of Pharmacy, n.d.).

In How Manufacturers View Pharmacists (2001, \P 2), Cassell states that "pharmaceutical companies tend to look upon pharmacists as a positive force in their mission to get products to

patients." In that regard, continuing education targeted to pharmacists is a strategy that pharmaceutical companies can use to achieve such goals as "building company name awareness and product knowledge to building relationships and selling more products" (Cassell, 2001, Educating Pharmacists, ¶ 1). In fact, whereas pharmacy professional associations and colleges and schools of pharmacy have been the largest groups of ACPE-accredited providers in the past (Anon, 1981, January; Blockstein, 1988; Day, 1991), pharmaceutical industry and educational companies together now lead the list of ACPE-accredited providers (Travlos & Zarembski, 2003). Travlos and Zarembski (2003) report that of the 392 ACPE-accredited CPE providers in 2003, 27% were educational companies and manufacturers, 25% were local, state and national associations, 23% were colleges and schools of pharmacy, and 25% were health systems, publishers, government agencies and others.

In addition to sponsorship of continuing education programs for pharmacists, the pharmaceutical industry has also played a role in providing commercial support to other CPE provider organizations (Gouveia, 1984; Myers, 1990; St. Jean, 1993; Vivian, 2002). This support includes financial assistance for program development, funds designated to pay for a program speaker and/or the provision of a program speaker. There is an obvious potential for conflict of interest when a pharmaceutical company becomes involved with the planning and implementation of a continuing education program, especially when the sponsor of the program is an academic institution (Harrison, 2003; Moynihan, 2003b, 2003c).

Industry and public academic institutions have very different organizational contexts and management philosophies. "Industry is responsible to its stakeholders; its bottom line is financial viability and profits" (Prager & Omenn, 1980, p. 207). For this reason, pharmaceutical manufacturers are involved with educational programs as a means to promote their company and

products to healthcare professionals. In contrast, "academic institutions are in the business of education and training" (Prager & Omenn, 1980, p. 207); however, in public academic institutions, the adult and continuing education mission is typically marginal to the overall organizational mission (Courtney, 1993). This marginality within a parent organization can often result in insufficient resource allocation for continuing education activities, thus leading program planners to accept or even actively seek commercial support for their programs.

In recognition of the potential conflict of interest when integrating educational and promotional activities, ACPE and professional organizations of both the profession of pharmacy and pharmaceutical industry have issued guidelines and policies for the development of educational activities. ACPE's role is to ensure the delivery of educational experiences in accordance with professional standards as described in *Criteria for Quality and Interpretive Guidelines for Approval of Providers of Continuing Pharmaceutical Education* (n.d.-b). Criterion 17 of these guidelines specifically addresses the issue of non-commercialism. This criterion allows for financial support from external sources; however, the approved program provider must retain full control over all aspects of a program and must rigorously assure that all educational programs and materials are non-promotional in nature. ACPE's guidelines also require full disclosure of information to audiences regarding financial support from companies and speaker relationships with companies.

Pharmacy practice and pharmaceutical manufacturer professional organizations also support the sponsor of a CPE program retaining control of program content and quality. For example, The American Society of Health-System Pharmacists (ASHP) has an official statement on continuing education that contains guidelines for development of CPE activities (1990). These guidelines state that CPE programs must be planned and conducted in accordance with

ACPE standards. ASHP's *Guidelines on Pharmacists' Relationships with Industry* (1992) give guidance for continuing education activities when commercial support is involved. These guidelines state that "providers of continuing education that accept industry funding for programs should develop and enforce policies to maintain complete control of program content" (Continuing Education, ¶ 1). In an effort to avoid conflicts of interest or appearances of impropriety, these guidelines also reflect ACPE's requirement of full disclosure of financial support and speaker relationships with companies.

The Pharmaceutical Manufacturer's Association (PhRMA), a professional organization of pharmaceutical manufacturing and research-oriented companies, recently released its *Code on Interactions with Healthcare Professionals* (2002). This voluntary code states that financial support from companies is permissible if it contributes to the improvement of patient care; however, a company should give funding directly to the conference sponsor, and the sponsor should retain control over the program including content, faculty, and educational methods and materials.

In addition to the above guidelines, the United States Office of the Inspector General of Health and Human Services has recently issued a draft compliance guideline for pharmaceutical manufacturers (U.S. Office of the Inspector General of Health and Human Services, 2002).

Although still in draft form, these guidelines adopt and incorporate PhRMA's voluntary *Code on Interactions with Healthcare Professionals*. According to Vivian (2002), since these compliance guidelines specifically state that pharmacy practice will be addressed in a future guideline, it is wise to consider the implications for the profession of pharmacy at this time. In a discussion on the possible implications of these emerging federal compliance guidelines, Vivian states:

Perhaps the biggest impact on the industry and pharmacy relationship will pertain to activities associated with marketing prescription drugs....a great deal of attention is given to drawing lines between educational activities that can be funded by the industry versus promotional marketing activities that purport to be of an educational purpose but serve no direct patient benefit. (p. 98)

Within this context of a multifaceted relationship between pharmacy and pharmaceutical manufacturers, and a concurrent expectation that program providers maintain control over program quality and content, it is evident that CPE program planners must recognize the political and ethical dimensions surrounding acceptance of commercial support for CPE programs. Cervero and Wilson's (1994) theoretical framework for program planning can be a useful guide for planners in such complex situations. Cervero and Wilson (1994) contend that program planning cannot be a neutral activity, that "between the individual actions that program planners undertake and the political and economic structures that provide the backdrop for those actions lie the practical situations in which planners must work" (p. 118). Responsible planners must have not only technical knowledge and skills, but political and ethical knowledge and skills to negotiate the varied interests of those affected by an educational program (Cervero & Wilson, 1994). Although the pharmacy literature acknowledges the relationship between pharmaceutical manufacturers and continuing pharmacy education, no studies could be identified that investigate the impact of commercial support on continuing pharmacy education. Planners of CPE programs will be better equipped to ensure a politically and ethically responsible planning process if they have a better understanding of the impact of commercial support on their practice, their organization, their learners and their affected public.

Statement of the Problem

There is a long-standing relationship between the profession of pharmacy and the pharmaceutical industry in the U.S.; however, the emerging and evolving clinical role of the pharmacist on the healthcare team is moving this relationship to a new level. Pharmaceutical manufacturing companies recognize that pharmacists are gaining power and influence in product selection and promotion; therefore, it is in the interest of these companies to improve relationships with pharmacists (Cassell, 2001).

Continuing education targeted to pharmacists is a strategy pharmaceutical companies can use to achieve such goals as building brand awareness, product knowledge and relationships as well as increasing sales (Cassell, 2001). In addition to sponsoring continuing pharmacy education programs, pharmaceutical manufacturers also provide commercial support to other CPE program providers. This support, including financial and programming assistance, is an additional opportunity for company and product promotion. Non-commercial providers of CPE are often compelled to accept or even seek commercial support for their programs due to CPE's marginal status and low resource allocation.

In recognition of the potential conflict of interest involved in the integration of promotional and educational activities, the Accreditation Council for Pharmacy Education (ACPE), professional organizations, and the U.S. government have developed policies to guide CPE program planning when a provider organization accepts commercial support from a pharmaceutical manufacturer. At the core of these policies is an expectation that the CPE provider of record retain full control over program quality and content. Although individual program planners are central to ensuring a responsible planning process when commercial support for CPE programs is provided, no studies have examined how the provision of

commercial support for CPE impacts planning practice and the resulting consequences for the provider organization, the learners, and affected public.

Purpose and Research Questions

The purpose of this study was to understand the impact of commercial support on the provision and outcomes of continuing pharmacy education. The study addressed the following research questions:

- 1. What is the impact of commercial support on continuing pharmacy education planning practice?
- 2. What are the consequences of commercial support of continuing pharmacy education for the provider organization, pharmacists, and patients?

This study examined the above questions through a national survey of ACPE-accredited continuing pharmacy education providers.

Significance of the Study

Cervero and Wilson (1994) state the following about adult education program planning: Planners must be ethically sensitive to the fundamental link between the people whose interests are represented and the central features of the program that is constructed, as well as the political relationships that are reconstructed. Ultimately, planners have to take a stand about who will represent which interests in making judgments about the purposes, audience, content, and format of the program. Because planners always have to decide who will represent which interests, they need to attend to the ways in which power relationships among people strengthen certain interests and silence others. Thus, a necessary part of planners' ethical knowledge is awareness of the commitment to a substantively democratic planning process of the people involved.Finally planners

must be clear in their own hearts and minds about their own expressed and real interests with regard to constructing an educational program. (p. 164)

In this regard, Cervero and Wilson (1994) view planning practice as an "ethically, politically and structurally sensitive practical human action" (p. 171). Many studies have substantiated their program planning theory through individualized accounts of planning practice; however, this study provides an understanding of the perceptions of a specific population of program planners regarding a common situation of conflicting personal and organizational interests. This study builds on past research by taking a broad look at a politically and ethically complex planning situation. By viewing this common planning situation through the lens of Cervero and Wilson's planning theory, CPE program planners might gain a better understanding of how inclusion of additional personal and organizational interests within the planning process not only affects their own practice, but the consequences for all relevant parties.

ACPE charges the CPE program sponsor with the task of retaining full control over all aspects of a program and rigorously assuring that all aspects of educational programs are non-promotional in nature (American Council on Pharmaceutical Education, n.d.-b). In turn, there is also an expectation that pharmaceutical companies, when providing commercial support to CPE programs, allow the program sponsor to retain complete control over all aspects of the program. This study identified common practices and consequences of commercial support of CPE programs, and also draws attention to the fact that individual program planners are central to achieving a responsible planning process.

The results of this study should prove beneficial for both individuals and organizations involved in CPE planning activities including program planners, provider organizations, pharmaceutical manufacturing companies and pharmaceutical company representatives. These

individuals and organizations will benefit from the identification of the consequences of commercial support of CPE on the key stakeholders of these programs – the provider organization, the learners, and most importantly, the affected public (i.e., the patients of the pharmacists who attend these programs). In addition, ACPE and other policy-making organizations for CPE should benefit through a better understanding of the impact of commercial support on CPE approved for use in fulfillment of legal and regulatory requirements for professional pharmacy practice.

Definition of Key Terms

The following terms are defined to clarify the purpose, research questions and discussion in this study:

<u>Commercial support</u> – Any monetary funding or in-kind contribution from a pharmaceutical company to an accredited continuing pharmacy education provider that is specifically designated for the provision of a continuing pharmacy education program.

<u>Consequences</u> - Outcomes that are a direct result of commercial support of continuing pharmacy education that affect the provider organization, pharmacists, and/or patients.

<u>Impact</u> – The effect of commercial support on the development, implementation and consequences of continuing pharmacy education programs and activities.

CHAPTER 2

REVIEW OF THE LITERATURE

The purpose of this study was to understand the impact of commercial support on the provision and outcomes of continuing pharmacy education. Specifically, the study examines the impact of commercial support on continuing pharmacy education planning practice and the consequences for the provider organization, pharmacists, and patients. In order to provide the background for this study, three major sections of literature were reviewed: continuing pharmacy education, commercial support of continuing education in the health professions, and studies of Cervero and Wilson's program planning theory. The first section of this chapter reviews continuing pharmacy education including relevant literature within the profession of pharmacy and continuing professional education. The second section reviews commercial support of continuing education in the health professions including continuing pharmacy education and continuing medical education literature. The third section reviews Cervero and Wilson's program planning theory, including health-related studies.

Continuing Pharmacy Education

This section provides an overview of continuing pharmacy education (CPE). To provide the context for CPE, this review is organized into 4 subsections including pharmacy workforce, pharmacy practice, legal and regulatory framework of CPE, and economic framework of CPE.

Pharmacy Workforce

The current workforce composition and expected future workforce trends are of key importance to CPE providers because these pharmacy professionals are the target audience of

CPE programs. Due to a critical shortage of pharmacists in the United States, there have been a number of significant studies on the current pharmacy workforce, projected estimates of the future pharmacy workforce and projected need for pharmacists in recent years. In December 1999, the U. S. Congress mandated a study to determine if there was indeed a shortage of licensed pharmacists, and if so, to determine the extent of the shortage (Health Resources and Services Administration, 2000). The Pharmacy Manpower Project (PMP), a coalition of pharmacy and pharmaceutical industry regulatory and professional associations, commissioned both a national pharmacist workforce survey (Pedersen, Doucette, Gaither, Mott, & Schommer, 2000) and a conference of experts in the profession to project the need for pharmacy services over the next twenty years (Knapp, 2002). In addition, the Midwest Pharmacy Workforce Research Consortium released a trend analysis of pharmacist's participation in the workforce from 1990-2000 (Mott, Doucette, Gaither, Pedersen, & Schommer, 2002).

These studies confirm that a critical shortage of pharmacists currently exists in the U.S. and that this shortage is expected to persist over the next few decades. According to the pharmacy workforce study mandated by Congress (Health Resources and Services Administration, 2000, p. i):

The evidence clearly indicates the emergence of a shortage of pharmacists over the past two years. This shortage is considered a dynamic shortage since it appears to be due to a rapid increase in the demand for pharmacists coupled with a constrained ability to increase the supply of pharmacists. The factors causing the current shortage are of a nature not likely to abate in the near future without fundamental changes in pharmacy practice and education.

Although this study identified an increase in the overall supply of pharmacists over the last decade, the demand for pharmacists and pharmacy services during this time is unprecedented (Health Resources and Services Administration, 2000). In fact, this demand for pharmacists and other health care professionals will likely continue to increase as a result of an increasing demand for health care "due to the aging of the population, improved access to health care and technological advances in treating diseases" (Mott et al., 2002, p. 223).

Pharmacists were the third largest health professional group in 2000, with an estimated 196,000 practicing pharmacists in the U.S.; however, the estimated number of practicing pharmacists is expected to grow to only 224,500 by 2010. This expected growth is less than the total growth of pharmacists over the past decade (Health Resources and Services Administration, 2000) and is of great concern due to the projected need for pharmacists in the future. The PMP conference report (Knapp, 2002) projects that by the year 2020, the U.S. could have a shortfall of 157,000 pharmacists.

The considerable imbalance in supply and demand for pharmacists "has led to drastic increases in wages, as companies are competing for workers using salary and sign-on bonuses as recruitment incentives" (Pedersen et al., 2000, p. 1). In fact, Mott, et. al. (2002) estimate that hourly wage rates for pharmacists have increased a drastic 59.4% between 1990 and 2000.

The workforce trends in relation to full-time versus part-time employment and pharmacists not in active practice are also important given the shortage of pharmacists. In the year 2000, only 73.3% of all licensed pharmacists were working full-time at an average of 44.2 hours per week and 14.9% were working part-time in pharmacy at an average of 19 hours per week (Pedersen et al., 2000). Of these full-time pharmacists, 12.3% also held part-time jobs for an average of 8.7 hours per week. Almost 12% of licensed pharmacists were not working in

pharmacy. Between 1990 and 2000, there was a small increase (0.9%) in the proportion of licensed pharmacists in active practice and a small decrease (1.4%) in the proportion of licensed pharmacists working outside of the profession (Mott et al., 2002).

Another trend in pharmacy in the U.S. has been an increasing number of women entering the profession. Although female pharmacists accounted for 13% of the workforce in 1970, they accounted for 46% of the workforce in 2000 (Health Resources and Services Administration, 2000,). Between 1990 and 2000, there was also a slight decrease (2.7%) in the proportion of practicing full-time male pharmacists (Mott et al., 2002).

Growth in the overall proportion of practicing pharmacists can be partially attributed to the growing proportion of females in active practice (Mott et al., 2002); however, the increase in women entering the profession has also contributed to the shortage of pharmacists because more women elect to work part-time (Pedersen et al., 2000). It was estimated that more females (21%) were employed part-time compared to males (9.9%) in 2000 (Pedersen et al., 2000). On the other hand, there was also an increase between 1990 and 2000 in the proportion of females working full-time and a decrease in the proportion working part-time (Mott et al., 2002). One factor that may be contributing to this growing proportion of full-time female pharmacists is the substantial hourly wage rate. Mott, et. al. (2002, p. 230) concluded that "gender role-reversal may be more common in families where one spouse is a pharmacist" due to the sizeable wages of pharmacists. The increasing proportion of female pharmacists is likely to continue as evidenced by the current pharmacy academic statistics. The American Association of Colleges of Pharmacy (2003) reports that as of fall 2002, 67% of the 38,902 first professional degree students were women. In addition, 65.7% of the 7,573 first professional degrees awarded in 2001-02 were to females.

Mott, et. al. (2002) also report an increase in the ethnic diversity of pharmacists between ages 41 and 60; however, the overall ethnic diversity of active pharmacists is nominal. The *Final Report of the National Workforce Survey: 2000* (Pedersen et al., 2000) indicates that only 12.7% of active pharmacists are non-white including 2.1% black, 7.5% Asian, and 3.1% of other ethnic origins. In fall 2002, 14% of the first professional degree students were underrepresented minorities (American Association of Colleges of Pharmacy, 2003) which does not indicate that a significant change in the overall ethnic diversity of pharmacists can be expected in the near future.

Pharmacy Practice

The discussion of pharmacy practice includes a description of practice settings and professional roles of pharmacists. An understanding of educational needs based on differing practice settings and professional roles is important to ensure an appropriate mix and range of educational offerings for pharmacists.

There are many types of pharmacy practice settings in which pharmacists have differing roles and job functions. The largest pharmacy practice setting is community pharmacy including chain and independent drug stores (Pedersen et al., 2000). Pharmacists in this practice setting, often called retail pharmacists, typically have a primary role of dispensing medications. The 2000 national workforce survey (Pedersen et al., 2000) found that an estimated 55.4% of practicing pharmacists were working in a community setting; however, AACP (1996) reports that the demand for dispensing pharmacists is decreasing. Hospitals and health systems are a growing area for pharmacy practice. An estimated 24.8% of full-time pharmacists currently practice in a hospital setting (Pedersen et al., 2000). Many hospital pharmacists have direct impact on patient care and are generally referred to as clinical pharmacists. Clinical pharmacists

typically have various pharmacotherapy and disease management responsibilities. Other practice settings include clinics, HMO pharmacies, long term care, home health care, mental health facilities and prisons (Pedersen et al., 2000).

According to Knapp (2002), current and future roles of pharmacists include order fulfillment, management of simple and complex medicine use in ambulatory patients, acute care services such as medication safety systems and drug policy issues, and non-patient care pharmacy services. These roles of pharmacists have been advancing and expanding due to many factors both external and internal to the profession of pharmacy. In the Pharmacy ManPower Project conference report, Knapp (2002, p. 2) states that the expansion of these roles "will depend heavily upon changes in methods of payment, improvements in electronic communication (which can also improve productivity), changes in the regulatory environment, support from other health professions and health system leaders, and the willingness of pharmacists themselves to accept broader challenge." These changes uniquely position the profession of pharmacy "to influence the use of medications, the most frequently employed and preferred of all medical interventions save perhaps consultation and advice" (Knapp, 2002, p. 5).

The pharmaceutical care role "emphasizes pharmacists establishing an ongoing relationship with the patient and other care givers of the patient to help assure optimal outcomes in the patient's drug therapy" (Chalmers, 1992, p. 402). The increase in need for pharmaceutical care has resulted in "substantially expanded roles and responsibilities of pharmacists in both retail and institutional settings" (Health Resources and Services Administration, 2000, p. i).

Technological trends and issues are also influencing changes in the profession that can result in a pharmacist's need for continuing education. Towle (2000, p. 210) describes these new technologies as one force that is shaping health care:

New health technologies include diagnostic and screening techniques, medical and therapeutic interventions, and techniques for drug delivery, surgical interventions, information technology, and telecommunications...The greatest change in health services over the next 10 years is likely to be as a result of computers and telecommunications technology. These implications will require substantial changes in manpower skill mix and have major training implications for medical, nursing, and technical staff.

As for the profession of pharmacy specifically, Felkey and Fox (2001, p. 529), state that "the Internet is profoundly changing the practice and business of pharmacy, and the pace at which these changes are occurring is accelerating as more Americans go online to access medical information and purchase health care products." New technologies are already making pharmacists with access more efficient in practice. The availability of pharmacy content via health-related articles and electronic databases can give pharmacists easy access to up-to-date patient care, pharmacotherapy, and drug information. Pharmacy web-sites and email communication can also enhance patient information and counseling. (Felkey & Fox, 2001)

It is also believed that pharmacists can use information technology, automation and robotics to improve order fulfillment productivity (Felkey & Fox, 2001; Knapp, 2002). This improved productivity, thought to be as much as five times greater than without the technology (Knapp, 2002), could allow pharmacists more time for patient counseling and pharmaceutical care. Other emerging technologies include *e-prescribing* which allows physicians to send electronic prescription orders directly to the pharmacy, *telepharmacy* which offers pharmaceutical care services and management from a distance, and *electronic medical records* in which a patient's medical records are available via the Internet to authorized providers (Felkey & Fox, 2001).

The changes in professional roles, particularly in the area of pharmaceutical care, have prompted new professional demands and educational requirements for pharmacists and an increased need for education is one of the critical issues currently facing the profession of pharmacy (Knapp, 2002). In a discussion on preparing for the future roles of pharmacists, the American Colleges of Clinical Pharmacy (2000, p. 992) address the ensuing educational needs for pharmacy students and practicing pharmacists:

A number of steps should be considered as pharmacy prepares to shift toward a profession-wide, patient-centered practice model. More effective collaboration between pharmacy educators and the profession will be necessary to improve experiential education, develop new patient-centered practice models, and increase student professionalization. Pharmacy practice systems must be revised to support a level of patient care that genuinely impacts health outcomes...A broad-based, inclusive planning process involving all pharmacy organizations and associations will be necessary to address the professions vast retraining needs.

Legal and Regulatory Context of CPE

Accreditation in the United States is based on a history of decentralized systems where legal authority resides with the 50 states, and "these states, in turn, have delegated the authority for accreditation to primarily nongovernmental agencies" (Hodapp, 1988, p. 372). The Accreditation Council for Pharmacy Education (ACPE) is the national accrediting agency for both pharmacy professional degree programs and providers of CPE in the U.S. Over the past 25 years, the number of ACPE-accredited continuing education providers has grown from about 72 to 392 (Travlos & Zarembski, 2003). These providers include educational companies and manufacturers (27%); local, state and national associations (25%); colleges and schools of

pharmacy (23%); and health systems, publishers, government agencies and others (25%). According to Vlasses (2001), 44% of the new applications received by ACPE between January 2000 and October 2001 (n=43) were from educational companies and manufacturers. In addition, 52% of the discontinued providers for this same period (n=39) were educational companies and manufacturers. Other discontinued providers included local, state and national associations (11%), and colleges and schools of pharmacy (2%).

The increase in accredited CPE provider organizations is a reflection of a trend towards legal and regulatory requirements for all professional practice. According to Cervero (2001, p. 23), "one of the major changes of the past 20 years has been the incorporation of continuing education into accountability systems for professional practice" as evidenced by the increased use of mandatory continuing education as a basis for professional relicensure by the states.

Mandatory continuing education for pharmacy relicensure in the U.S. has steadily increased over the past 35 years (American Pharmacists Association and National Association of Boards of Pharmacy, n.d.; Hodapp, 1988). CPE programs used in fulfillment of a pharmacist's relicensure requirements must typically be offered by a CPE provider accredited by ACPE or approved by a state board of pharmacy (American Pharmacists Association and National Association of Boards of Pharmacy, n.d.). Currently only one of the 53 U.S. jurisdictions of the National Association of Boards of Pharmacy does not have laws in place that require pharmacists, as a requirement for license renewal, to complete a certain number of continuing education units offered by approved and/or accredited providers (Travlos & Zarembski, 2003).

Economic Context of CPE

There is much evidence of economic issues and concerns for all providers of continuing professional education. These program providers are routinely asked "to balance good education

principles against the increasingly entrepreneurial demands of their organizations and institutions, forcing them to adopt cost-effective strategies for designing, developing, and delivering continuing professional education" (Queeney, 2000, p. 380). In addition, many continuing education providers are departmental units within larger organizations where the adult and continuing education mission is considered marginal to the overall organizational mission (Courtney, 1993). This entrepreneurial orientation has also been evident in continuing pharmacy education (CPE) as indicated in this reflective question posed by Chalmers (1992, p. 405) to deans and those in CPE leadership positions in colleges of pharmacy: "Is CPE a business that is accorded space and equipment with administrative blessing because it makes enough money to pay for its costs and them some?"

Due to the complexity of issues, including possible marginality within a parent organization, many continuing professional education providers find they cannot afford to operate programs independently, thus seek to merge their strengths and resources with other organizations (Queeney, 2000). Cervero (2001) discusses collaboration and corporatization as two trends in continuing professional education that are directly related to the economic demands of the provider organization. Regarding collaboration, Cervero states (2001, p. 21):

Long-lasting educational trends often come not from the work of educators, but from larger political, economic and cultural movements that push educational institutions in certain ways. One movement that has accelerated in the past two decades is that public universities are under great pressure to play a larger role in the 'economic development' of their state or region. Clearly, continuing education is part of the economic development strategy and so universities and businesses are actively collaborating in

structuring continuing education programmes. This collaboration is being driven by economic development needs.

Cervero also suggests that for-profit providers are increasing their collaborative efforts with universities and professional schools. A benefit of these collaborative relationships is that each organization can offer complementary resources for the design, development and/or delivery of content (Cervero, 2001; Queeney, 2000).

Corporatization is another trend in continuing professional education due to economic and financial issues of the provider organization. Cervero (2001) provides several examples of corporatization of continuing education in non-commercial settings. For example, he notes how professional schools often use profits from their continuing education units to support the core university functions of research and teaching. In another example, Cervero notes how professional associations have a history of diverting continuing education surplus income to support other member services such as lobbying. These forms of corporatization illustrate how the competing organizational goals of education and surplus revenue add to the complexity of the economic issues within the practice of continuing professional education.

In conclusion, the critical shortage and increasing demand for pharmacists are expected to continue over the next few decades. Unprecedented changes in the health care environment are resulting in growing numbers and changing types of pharmacy practice settings and professional roles. There is also an array of new information and automation technologies changing the practice of pharmacy and requiring new skills and competencies on behalf of the pharmacist. There are almost 400 accredited providers of CPE. Educational companies and pharmaceutical manufacturers, both commercial organizations, comprise the largest category of

CPE providers. In addition, there is a large amount of turn-over of this type of provider organization as indicated by the number of new and discontinued commercial providers.

Diminishing financial support is increasing entrepreneurial demands for all types of continuing education provider organizations. Whereas these organizations have historically had a core educational focus, they must now operate with an increasing business orientation as a survival tactic.

Commercial Support of Continuing Education in the Health Professions

A major issue in the provision of continuing education for pharmacists and physicians is the influence of commercial support on continuing education programs. This section of the literature review will address the history and context for commercial support, provide a description of relevant policies of government, accrediting bodies, and professional associations of pharmacy and industry, and provide an analysis of the costs and benefits of commercial support for industry and continuing education providers.

The issues surrounding commercial support of educational activities for health professionals have historically been more pervasive in continuing medical education (CME). The pharmaceutical industry's interest in influencing physicians is evident given physician's capacity to prescribe drugs; however, as pharmacists assume an expanded clinical role, they too have emerged as a focus of the marketing and promotional efforts of pharmaceutical companies. Because this study focuses on the influence of commercial support in continuing pharmacy education (CPE), my discussion will concentrate within this area. However, the context of the relationship between industry and CME is extremely relevant and is used as an indicator and predictor of the trends and issues of commercial support for CPE.

History & Context

Cervero (2001, p. 26) identifies a key issue of continuing professional education as "the struggle between the learning agenda and the political and economic agendas of continuing education," or in other words, "who benefits from continuing professional education." He states that "this issue recognizes the reality that continuing education is about many things in addition to professionals' learning" (p. 26). In addition to improving learning and practice, organizations and institutions might view their sponsorship or co-sponsorship of continuing professional education as beneficial for other reasons. For example, an academic institution might use surplus income generated by continuing education programs to fund other initiatives such as faculty support (Cervero, 2001) or as a way to keep in contact with alumni as part of a larger organizational development effort.

The relationship between the pharmaceutical industry and continuing education for health professionals is strife with competing agendas. According to Farrar (2002, p. 74), "for years, medical education activities have been a sure way for pharma marketers to deliver key messages to the medical community about scientific discoveries, new treatments, and products fostering medical advancement." Although industry sponsorship of CME plays a role in an "overriding mutual interest to ensure that patients receive the most up-to-date and appropriate care" (Holmer, 2001, p. 2012), marketing via educational activities is also an important strategy used by pharmaceutical manufacturers to promote their company and products to physicians. However, continuing education is not the only strategy used by industry to inform physicians and other healthcare professionals about its products. The pharmaceutical industry also "publishes scientific studies in peer-reviewed journals, advertises in medical journals, and employs sales representatives who visit physicians in their offices" (Holmer, 2001, p. 2012).

A review of the pharmacy literature over the past few decades reveals a growing awareness of the issues and concerns regarding commercial support of CPE. Leading into the 1980's, there was an indication that industry's involvement in the continuing education of pharmacists, as the largest provider of educational materials, was considered sound and logical (Street, 1979). According to Street, although industry's expenditure on these materials was sizable, and typically at no cost to the pharmacist, it was considered logical because of industry's extensive technical knowledge based on basic drug research and product development. Although industry was considered the largest educational provider for pharmacists at the time, there was an emergence of non-commercial providers as states began to mandate continuing education for relicensure (Anon, 1981). These non-commercial providers of continuing education included colleges of pharmacy and state associations.

In an article on the relationship between hospital pharmacy and the pharmaceutical industry, Gouveia (1984) noted that the relationship between industry and pharmacy was beginning to grow complex. The industry had traditionally marketed drugs primarily to physicians, viewing pharmacists mostly as a distributor of drugs; however, the relationship between industry and pharmacists was beginning to move beyond a personal level. According to Gouveia (1984), this relationship was becoming murky due to a number of factors including the increasing patient care role of the pharmacist, the dramatic growth of and competition within the pharmaceutical industry, and an increasing dependency on industry for financial support of the hospital pharmacy's professional activities including continuing education programs.

Over the next decade, the pharmacy literature indicates a growing awareness that commercial support of continuing education for pharmacists may lead to biased content. For example, it was estimated that the pharmaceutical industry contributed substantially, as much as

75%, to the educational programs of affiliated state societies (St. Jean, 1993). St. Jean stated that these societies needed to "determine effective ways of soliciting funding, deal with the possibility that anticipated donations may not materialize, and ensure that industry-funded educational programs do not appear biased toward their sponsors" (p. 864). St. Jean also noted that the American Society of Hospital Pharmacy and other national healthcare organizations were beginning to address the issue of commercial support for educational activities. Although little data on commercial support for CPE in academic institutions was available, the American Association of Colleges of Pharmacy (1993) did note that the level of support was substantial and voiced the following concerns:

...the role of the pharmacists in exerting an ever-increasing influence in the drug-use process could be compromised through bias introduced into manufacturer-supported programs...even if content is controlled by practitioners and educators, manufacturers that support mid-career education and training generally support only those programs that address areas in which they have products. (p. 17)

The 1990's also saw the emergence of government awareness of the influence of commercial support on educational activities for health professionals. In 1997, the Food and Drug Administration (FDA) published guidelines addressing industry-supported scientific and educational activities. These guidelines were developed to provide guidance for industry-supported continuing education for physicians and other health professionals, and to address the FDA's concern for incorporating promotional and educational activities; however, the year after the guidelines were released, they were ruled too broad and thus violated the free speech of industry (Zappala, 1998). Shortly after, the FDA lost an appeal of the ruling (Anon, 1999).

The emerging and evolving relationship between industry and the educational activities of pharmacists can be explained in large part by the changes in our health care environment and the resulting change in the role of the pharmacist. According to Bectel (1996, p. 112):

The economic structure of health care, technological advances, "who" or "what" is to exercise control over health care delivery (the political reality), and the actual delivery of health care services to the patient are all factors undergoing wrenching changes in the U.S. of the 1990's.

Within this context of a progressively changing health care environment, pharmacists are proving they can be a significant and unique member of a multidisciplinary health care team. The pharmacist's role on the health care team, with influence on physicians and personal access to patients, makes them "valuable to the pharmaceutical industry by assuring the provision of appropriate drug therapy and by achieving patient compliance through appropriate drug management" (Bectel, 1996, p. 113). In this regard, continuing education targeted to pharmacists is a significant strategy pharmaceutical companies can use to market their products. There is a strong indication that these companies are using CPE as a marketing strategy as evidenced by the fact that pharmaceutical manufacturers, along with educational companies, currently lead the list of accredited CPE providers (Travlos & Zarembski, 2003).

As commercial organizations, these companies exist in a competitive marketplace.

According to Harrison (2003, pp. 198-199), the concerns related to promotional influence on continuing education "arise from differences between professionalism and commercialism."

He explains that commercial norms are based on transactions where the buyers and sellers generally hold equal power, whereas professional norms for medicine are based on a system where the health professional has expertise that the patients do not have. Harrison (2003)

recognizes that commercial interests can be reflected either directly or indirectly within CME programs. Although current guidelines and standards focus on minimizing bias in individual programs, he voices concern about the cumulative effects and unintended consequences of commercial funding:

The overall curriculum of CME offerings is increasingly biased toward topics that will benefit commercial interests. Companies are engaged in a commercial transaction, providing physicians with access to knowledge that will benefit the company. In accepting commercial funds, CME providers, faculty, participants and the profession must act to ensure that subsidies for this knowledge do not distract busy physicians from other knowledge important to patients. (Harrison, 2003, p. 207)

Policies

Accreditation in the United States is "a self-regulating process of peer review, rather than a government-regulating process of legislated review" and is part of an interconnected credentialing system that "represents how we examine professional training programs to ensure quality in the delivery of education" (Bobby, 1997, pp. 37-38). The Accreditation Council for Pharmacy Education (ACPE) was established in 1932 as the accrediting body of pharmacy professional degree programs and added accreditation of CPE providers in 1975 (Travlos & Zarembski, 2003).

ACPE's role in CPE is to ensure the delivery of educational experiences in accordance with professional standards as described in *Criteria for Quality and Interpretive Guidelines for Approval of Providers of Continuing Pharmaceutical Education* (n.d.-b). These guidelines consist of 26 criteria in such areas as administration, organization, personnel, and fiscal responsibilities, as well program development, delivery and evaluation. In recognition of the

potential conflict of interest when integrating educational and promotional activities, this document also has guidelines and policies for the development of educational activities when commercial support is involved. Criterion 17 specifically addresses the issue of non-commercialism. This criterion allows for financial support from external sources; however, the approved program provider must retain full control over all aspects of a program and must rigorously assure that all educational programs and materials are non-promotional in nature. In addition, any significant relationship between the funding organization and program faculty must be disclosed. ACPE's Criterions 3, 4, and 5 also address the issue of financial support received for CPE programs including co-sponsorship with accredited and non-accredited ACPE providers. In all cases, the accredited-provider must retain full quality control and relationships must be fully disclosed. In addition to a continuous self-assessment process by provider organizations, ACPE completes a comprehensive review of providers every six years to ensure adherence to their standards (Traylos & Zarembski, 2003).

Professional organizations of both the profession of pharmacy and pharmaceutical industry have also issued guidelines and policies for the development of educational activities. Common among the policies of these professional organizations is the provision that the sponsor of a continuing professional education program retain control of program content and quality. These policies also specifically address commercial support of continuing education programs. For example, The American Society of Health-System Pharmacists (ASHP) has an official statement on continuing education that contains guidelines for development of CPE activities (1990). These guidelines state that CPE programs must be planned and conducted in accordance with ACPE standards. ASHP's *Guidelines on Pharmacists' Relationships with Industry* (1992) give guidance for continuing education activities when industry support is involved. These

guidelines state that "providers of continuing education that accept industry funding for programs should develop and enforce policies to maintain complete control of program content" (Continuing Education, ¶ 1). In an effort to avoid conflicts of interest or appearances of impropriety, these guidelines also require full disclosure of information to audiences regarding financial support from companies and speaker relationships with companies.

The Pharmaceutical Manufacturer's Association (PhRMA), a professional organization of pharmaceutical manufacturing and research-oriented companies, recently released its *Code on Interactions with Healthcare Professionals* (2002). This voluntary code states that financial support from companies is permissible if it contributes to the improvement of patient care; however, a company should give funding directly to the conference sponsor, and the sponsor should retain control over the program including content, faculty, educational methods and materials, and venue. Pharmaceutical companies are not to provide financial support directly to healthcare professionals attending continuing education programs

In addition to the above guidelines, the U. S. Office of the Inspector General of Health and Human Services (OIG) is "stepping up efforts to detect and prevent fraud and abuse in the health care industry, creating growing concern among health care providers that they may become the subject of an investigation" (Spooner & Peterson, 2002, p. 1874). To accomplish this effort, OIG has recently issued guidelines for physicians and the pharmaceutical industry. The first compliance document to be finalized was *OIG Compliance Program for Individual and Small Group Physician Practices* (2000). Shortly after the release of this compliance program for physicians, OIG issued draft compliance guidelines for pharmaceutical manufacturers (2002). Although still in draft form, these guidelines adopt and incorporate PhRMA's voluntary *Code on Interactions with Healthcare Professionals*. According to Vivian (2002), since the compliance

guidelines for pharmaceutical manufacturers specifically state that pharmacy practice will be addressed in a future guideline, it is wise to consider the implications for the profession of pharmacy at this time. In a discussion on the possible implications of these emerging federal compliance guidelines, Vivian (2002, p. 98) states:

Perhaps the biggest impact on the industry and pharmacy relationship will pertain to activities associated with marketing prescription drugs....a great deal of attention is given to drawing lines between educational activities that can be funded by the industry versus promotional marketing activities that purport to be of an educational purpose but serve no direct patient benefit.

As a result of these emerging policies and federal guidelines regarding the integration of promotional and educational activities, continuing education practitioners should consider that a change in the provision of commercial support is likely in the near future.

Cost-Benefit Analysis

An examination of the issues of commercial support for continuing education would not be complete without an understanding of why pharmaceutical companies provide commercial support and why continuing education providers accept this funding. This concluding section will examine the political and economic context of commercial support with respect to the costs and benefits for both continuing education providers and pharmaceutical industry. The CPE literature did not reveal research for commercial support related to continuing education; however, the CME literature was rich with data and information that establishes the extent of commercial funding for continuing education activities.

Pharmaceutical companies. Pharmaceutical companies develop many new products to benefit patients, and their support of continuing education can have a positive impact on patient

care. As stated by Holmer (2001, p. 2014), "industry-supported CME is one valuable way that information about important scientific developments will be conveyed to the medical profession for the benefit of the patients we are both dedicated to serving." Although commercial support of continuing education can be beneficial to improved patient care, "it must be recognized that, for pharmaceutical and device companies, support of independent educational activities, as well as promotional educational activities, is a part of the marketing mix" (Schaffer, 2000, p. 122). This is evident in that "support for CME comes from the marketing budget in most companies, and that budget must produce sales" (Relman, 2001, p. 2009). By providing commercial support for the continuing education of health professionals, pharmaceutical companies reap such benefits as influencing prescribing patterns and promoting individual products (Relman, 2001).

If pharmaceutical company support of educational activities for health professionals was not guided by the corporate missions of profit and growth, why else would they provide millions to CME alone (Accreditation Council for Continuing Medical Education, 2002) each year? As evidenced by a trend in significantly increasing levels of commercial support (Harrison, 2002), pharmaceutical companies demonstrate that the monetary cost of supporting continuing education for health professionals is well worth the promotional benefit.

Continuing education providers. Although the acceptance of support from the pharmaceutical industry is not an absolute indication that CPE units are delivering biased programs, it does raise the question about how continuing education should be funded (Kues, 2003). In academic institutions and other organizations relying on government funding, appropriated funds for continuing education units are diminishing (DelSignore, 2003; Harrison, 2002; Schaffer, 2000). Harrison (2002) reports a startling eight-year trend in decreasing medical

school funding stating that "40% of medical schools provide no direct central funding to the CME unit, up from 25%" (p. 4). In a later article, he explains that this type of "substantially increased commercial funding has masked decreased direct and indirect funding" from traditional sources (Harrison, 2003, p. 198). As a result of this diminishing internal support, continuing education units must assume an increased responsibility for expenses. Appropriated funds are typically allocated for administrative support such as salaries, facilities and office supplies (Schaffer, 2000); however, if administrative funding is less than 100%, any administrative expenses, in addition to educational program expenses, must be covered by other sources of revenue. In addition to a decrease of internal funding, increases in administrative and program expenses are of concern to continuing education administrators. For example, it is estimated that the fees paid to guest faculty have doubled and the number of staff in the continuing education unit has increased by 50% over the past eight years (Harrison, 2002).

This concern for generating revenue is not limited to covering the actual administrative and educational program expenses of a continuing education unit. When administrative and other program funds are provided, the parent organization often expects a return on their investment. According to Schaffer (2000. p. 121), "the CME office is often viewed as one that should be a profit center for the institution, the academic department, or, at the very least, the faculty program director." In these situations, continuing education units are striving to generate surplus revenue in addition to covering their increasing expenses (Courtney, 1993; Harrison, 2003; Schaffer, 2000).

Aside from commercial support, there would seem to be other options for increasing continuing education income including increased program registration fees or grants. However, these alternative funding sources may not be feasible options in the current climate (Kues, 2003).

For example, although increased registration fees appear to be a logical way to increase income, there are many considerations when choosing this option. It is commonly assumed that physicians, and oftentimes pharmacists, are seldom expected to pay the actual cost of programming. According to Schaffer (2000, p. 121), "we seemed to have developed a culture in which physicians expect to obtain continuing education at minimal or no financial cost" due in large part to the infusion of commercial support. If not attending commercially-supported live continuing education programs, physicians and pharmacists have many options for free or minimally priced commercially-supported continuing education via the Internet and trade journals (Tipton, 2003). Although these health professionals can afford to pay for their continuing education, the current culture does not support a drastic across-the-board increase in program registration fees without the risk of low or no registration for programs (Harrison, 2003; Moynihan, 2003c).

Within this political and economic climate of decreasing appropriations, an expectation of surplus revenue and limited sources for additional income, it is understandable that responsible and ethical continuing education practitioners would accept or even actively seek commercial support for their programs (DelSignore, 2003). In fact, given the current guidelines and regulations, the provision of commercial support to continuing education providers is one of the few acceptable practices available for pharmaceutical companies to market directly to medical professionals (Harrison, 2003).

Reports of CME activities verify that acceptance of commercial support is indeed widespread and growing. According to the Accreditation Council for Continuing Medical Education's 2001 annual report data (2002), commercial support including exhibits and advertising was almost \$729 million and covers well over half of all CME expenses. Within

medical school CME units, this translates into a five-fold increase in commercial support over the last eight years, or typically more than a half million dollars per year (Harrison, 2002). Given the emerging policies on commercial support, however, it might be expected that this trend in substantial levels of commercial support for continuing education activities will either stabilize or diminish in the future.

In summary, although commercial providers are capable of delivering quality educational programs, there is potential for conflict of interest when integrating promotional and educational activities. Growing concerns about the extent of this issue are reflected in the policies that guide the relationships between the pharmaceutical industry and CPE providers, as well policies and regulations that address appropriate behaviors between the pharmaceutical industry and medical professionals. Emerging debate is focusing not only on the influence of commercial support on the topics and content of individual programs, but on the cumulative effect of commercialism on continuing professional education that is designed to improve patient care.

Cervero and Wilson Planning Theory

Cervero and Wilson's program planning theory (1994) forms the theoretical basis for this study. As such, this section will provide a description of their planning theory with special attention given to studies in the health professions.

In *Planning Responsibly for Adult Education: A Guide to Negotiating Power and Interests* (1994), Cervero and Wilson introduce a different approach to program planning theory in adult education. Where previous theories in program planning deal mostly with the technical aspects of planning, they do not account for the relationships of power that are central to planning activity. However, Cervero and Wilson (1994, p. 4) claim that "planning programs is a social activity in which people negotiate personal and organizational interests." The authors

present three case studies to demonstrate how "planning is always conducted within a complex set of personal, organizational, and social relationships of power among people who may have similar, different, or conflicting sets of interests regarding the program" (p. 4). Cervero and Wilson (1994, p. 28) also claim that viewing planning practice as a social activity "inextricably links planners' actions to the complex world of power relationships and interests." In other words, adult educators' actions in constructing programs "are structured by the power relationships and interests of all the people who have a stake in the program" (p. 28).

Within this theoretical framework, Cervero and Wilson (1994) define power in the planning process as the capacity to act and as a necessary characteristic of all relationships among people. The power of a planner is carried out through actions and restricted by institutional and social contexts. Within these contexts, interests and power relationships are not static, but are continually negotiated. Cervero and Wilson (1994) contend that to plan responsibly, adult educators must be able to understand the situations they face and distinguish between the forms of power they might use in order to select appropriate strategies for action. These power relationships can be enabling or constraining, symmetrical or asymmetrical, and may or may not involve conflicting interests among the stakeholders. The planners' values and choice of strategies are central to responsible planning because both shape the educational program as well as support or transform the relationships of power.

In a model adapted from Forester (1989), Cervero and Wilson (1994) delineate four ways that relationships of power and legitimate interests can structure a planning situation and offer practical strategies for responsible planning. They state that power relationships "may be *socially systematic* – they are tied to existing organizational designs or political structures – and others may be relatively *ad hoc* – they derive from temporary organizational conditions or

interpersonal relationships" (Cervero & Wilson, 1994, p. 129). In addition, legitimate interests can be the same (consensual) or different (conflicting). To achieve a substantively democratic planning process, Cervero and Wilson (1994) suggest that planners should choose an appropriate strategy of action given the power relationships and interests of a specific planning situation.

According to Cervero and Wilson (1994, p. 130), although this framework can help planners focus attention on "what really matters as they seek a democratic planning process," many planning situations can be complex and the contexts can be difficult to read. In these complex situations, power and interests may lie on a continuum requiring planners to draw on their specific context and personal experiences to make a best guess for the most appropriate strategy or combination of strategies (Cervero & Wilson, 1994). Thus, Cervero and Wilson contend that in addition to technical knowledge and skills, responsible planners must also have political and ethical knowledge and skills for constructing adult education programs. *Studies of Cervero and Wilson Theory in the Health Professions*.

There have been numerous studies of Cervero and Wilson's program planning theory.

Many of these studies are situated in the health professions in various practice settings. Several studies of Cervero and Wilson's planning theory address the need for differentiated HIV/AIDS prevention and education programs. A case study by Archie-Booker, Cervero and Langone (1999) examined a community-based AIDS education provider to determine if its HIV education programs were culturally relevant for African-American women. These women represented a large portion of the agency's infected target group and their needs differed from the agency's other constituencies. This study determined that the agency recognized the need to provide differentiated educational programs because many of their programs focused on the needs of their gay male audience; however, the agency was not responsive to the needs of African-

American women. This study also identified three social and organizational factors that influenced the cultural relevance of the educational programs for African-American women: organizational image and funding, internal interpretation of the educational mission, and organizational structures. The authors concluded that "power relations manifested themselves concretely and specifically in this case through the three factors in the social and organizational context (the what), which produced undifferentiated educational programs for African-American women by defining these learners as generic entities (the how)" (Archie-Booker et al., 1999, pp. 173-174).

Sessions and Cervero (2001) also examined the planning of HIV prevention programs, but within the context of serving the educational needs of uninfected gay men. The authors describe the experiences of an HIV-negative gay man who, after the AIDS-related death of his life partner, was offered the position as director of gay outreach for a major southeastern AIDS service organization. He finds that the prevention curriculum unintentionally excludes HIV-negative men from its programming, focusing rather on the needs of HIV-positive men.

Sessions, et. al. (2001) note that although there are social and political factors and various interests driving this occurrence, it is obvious that the program planning efforts of the organization are disenfranchising an audience that they should be serving. The researchers conclude that stakeholder interests are driving the HIV education program planning effort and that personal, professional and societal obstacles must be overcome before any changes can be made to this system (Sessions & Cervero, 2001).

In another HIV/AIDS-related study, Carter (1996) examines a health promotion coalition's planning of a mini-grant program. The grants were to be awarded to community organizations for development of educational programs on HIV. Carter's case-study analysis

(1996, p. 29) asks the question "how do the interests of the planners affect the activities and outcomes of the empowerment planning process?" She observed that different political and ethical issues were often central to program planning such as the kind of organizations that could be grant recipients and the wording and format of the application form. Carter concluded that the planners "negotiated around the issues that came up as they conceptualized and constructed the program…and out of these issues comes the concrete program design" (p. 34). She recommends that in addition to the technical aspects of planning, empowerment planning practitioners should pay attention to the dynamic factors in the planning environment and ensure that community interests are represented in the planning process.

Several studies of Cervero and Wilson's planning theory have examined program planning practice in academic settings. In *Renegotiating Institutional Power Relationships to Better Serve Nursing Students*, Hendricks (1996) discusses the power relationships and interests in a college nursing program. She notes that most nursing education authors describe the planning process as a series of steps; however, she compares the planning environment to a calm surface of a lake with a dynamic ecosystem underneath. She states that "when considering program planning for nursing students, I realized that those things on the surface – educational topics and objectives, timing and details of programs, and even teaching strategies – are less important than the interplay of structural and personal interests and power relationships underneath" (p. 37). To clarify her perspective, she relates her experiences in planning a program for new nursing students. The planning takes place within a grant-funded program that was marginal to the nursing school. This program had little organizational power or authority, and uncertain longevity. There was no common physical space for the program office and tension existed among the four staff members. Hendricks (1996) worked to improve

communication and instill a team-oriented, collaborative approach to planning, resulting in a moderately successful program for new nursing students. She concludes that "experience and reflection on the nature of program planning under the surface facilitates recognition of the dynamic nature of the negotiation of power and interests in educational program planning, even in the quietest of landscapes" (Hendricks, 1996, p. 46).

Maclean (1996) also conducted a study within an academic setting, examining a major medical school's program planning for continuing medical education (CME). Through a series of interviews, the author examines political and ethical issues and interests of different stakeholders in developing CME programs. Program planners and administrators viewed their programs as fulfilling a variety of needs and interests including an immeasurable goal of generating patient referrals, and thus income, for the university hospital. Maclean (1996) finds that the importance of referrals, although not an explicit goal of CME, can satisfy both a real institutional interest (revenue) and an expressed interest (potential to improve physician's practice); however, the expectation that CME generate referrals also presents an ethical dilemma for the continuing education unit whose primary mission is adult education.

Based on the same case study, Maclean (1997) describes how these program planners approached planning practice. He provides an overview of the participants, their varying levels of power and how they develop programs. While technical similarities existed in the program planning models and guidelines used by these planners, Maclean identified contextual and political differences in each planner's approach to planning. In summary, Maclean (1997, p. 13) states that "the study recognizes that power and the political context have a direct affect on the actions of the program planners, even if they are not always cognizant of those influences." He

also suggests that "further studies should look at what planners actually do rather than what they ought to do" (p. 13).

Umble, Cervero, and Langone (2001) examine the usefulness of distinguishing between different types of negotiations in planning a public health continuing education course. The context for this case study was a federal immunization program that was presented both live and via satellite. According to Umble, et. al. (2001), this study provides a better understanding of effective strategies of negotiation as seen through the lens of Cervero and Wilson's theory. Specifically, the authors examined meta-negotiations (e.g., power relationships, norms, standards, funding, personnel) and substantive negotiations (e.g., content, audience, format) in program planning. Unique to this case study was that "frames were established not by courserelated meta-negotiations, but rather by historic processes and organizational relationships" resulting in "universal consensus among stakeholders that the conceptual frame was appropriate" (p. 142). Findings indicate that many meta-negotiations and substantive negotiations occurred simultaneously, and that the power relationships were not static. According to Umble, et. al. (2001), the research showed how program planners are constrained by power relationships and by material and conceptual frames. These power relationships and frames shape both the course and the substantive negotiations, thus the course created may not represent the interests of all stakeholders. The authors suggest "further research could describe in more depth the negotiation strategies that planners employ to deal with different types of power relationships and frames they encounter" (p. 144).

In summary, these studies of Cervero and Wilson's planning theory in health-related settings conclude that program planning involves the planner's awareness and attention to the

power relationships, stakeholder interests, and political and ethical dilemmas in order to ensure a responsible and democratic planning process.

Summary

This literature review has identified many significant trends and issues related to commercial support of CPE. First, the current legal and regulatory context includes mandatory continuing education for relicensure and pharmaceutical manufacturers as accredited providers of CPE. This along with the current economic context of CPE including low resource allocation and increasing entrepreneurial demands are among the issues that have created a climate where CPE providers often seek and accept commercial support for their programs. Second, there is an obvious potential for conflict of interest when promotional and educational activities are integrated. The literature reflects a growing debate regarding this conflict of interest. This debate centers not only on the effect of commercial support on individual CPE programs, but on the cumulative effect of commercialism of CPE on pharmacists, on their profession, and on the patients they serve. Third, program planning is a process that involves negotiation of interests, power relationships and ethical and political dilemmas. Commercial support is an important dimension of the relationships of power that are central to planning CPE programs. All of these findings reveal a need for research on the impact of commercial support of CPE on planning practice and the consequences for relevant stakeholders.

CHAPTER 3

METHODOLOGY

The purpose of this chapter is to describe the methodological procedures that were designed to answer the following research questions:

- 1. What is the impact of commercial support on continuing pharmacy education planning practice?
- 2. What are the consequences of commercial support of continuing pharmacy education for the provider organization, pharmacists, and patients?

This chapter is organized into five sections: (a) measurement framework, (b) instrumentation, (c) study population and sample, (d) data collection, and (e) data analysis.

Measurement Framework

While reviewing continuing pharmacy education (CPE) and related literature, it became apparent to me that commercial support for CPE was a phenomenon that needed to be studied. The literature revealed a rising debate over the growing involvement of the pharmaceutical industry in the development and delivery of continuing education designed to improve a health professional's practice and thus, patient care. Emerging policies and regulations that govern the planning of continuing education for physicians and pharmacists center on the potential conflict of interest when educational and promotional activities are integrated. Although much attention is being cast on this issue, commercial support of CPE in many ways is still an unknown terrain. Over many months of writing, reading, thinking, listening and discussing, I experimented with different aspects of this broad phenomenon to see if specific themes would surface. Ultimately, there were two major and distinct concepts that seemed worthy of investigation: the impact of

commercial support on planning CPE programs, and the consequences of commercial support of CPE for relevant stakeholders.

My first step was to clarify the constructs for the study that would ultimately be measured by indicators items on a survey instrument. Concept clarification for the instrument development process involved defining the two constructs to be measured. The first construct, *Impact of Commercial Support on Planning Continuing Pharmacy Education Programs*, is hereafter referred to as *Planning Practices*. The second construct, *Consequences of Commercial Support of Continuing Pharmacy Education*, is hereafter referred to as *Consequences*. Table 1 provides a complete definition of the two constructs. For the purposes of this study, commercial support is defined as any monetary funding or in-kind contribution from a pharmaceutical company to an accredited CPE program provider that is specifically designated for the provision of a CPE program.

Table 1

Definition of Constructs for Measures

Name	Definition
Planning Practices	Specific program planning practices utilized when commercial support is received for the provision of CPE programs and activities.
Consequences	Outcomes that are a direct impact of commercial support of CPE that affect the provider organization, pharmacists and patients.

Instrumentation

A multi-faceted, researcher-designed instrument was developed for the purpose of measuring the two distinct constructs: *Planning Practices* and *Consequences*. Instrument administration was online as a self-completion survey. The questionnaire was designed for accredited CPE providers to report on their knowledge of commercial support of CPE programs. The following sections describe the five-step instrumentation process including (a) development and refinement of item pools, (b) assessment of saturation, (c) construction of response scales, (d) addition of background items, and (e) expert critique of the questionnaire and other study documents. The final version of the instrument is available in Appendix A.

Development and Refinement of Item Pool

Over a seven month period, I developed and refined item pools for the separate measures of planning practices and consequences of commercial support of CPE. I ensured content validity for both measures through a rigorous process of item generation as described in detail below.

Development of the *Planning Practices* measure. I began the process by working to develop and refine the item pool for measuring *Planning Practices* as summarized in Table 2. I generated the item pool for the measure of *Planning Practices* through a careful review of the literature, interviews with practitioners, and a brainstorming session with an expert panel of CPE professionals. During the literature review and interview process, I generated a list of 68 construct indicators in no particular order (Appendix B). I was not concerned with revision of items or deletion of redundant items during the initial compilation of construct indicators.

Table 2

Item Pool Development and Refinement Process for the Planning Practices Measure

Steps for Instrument Development	Principal Activities
Item Pool Development	Literature review
	Interviews with practitioners
	Brainstorming session with expert panel
Item Pool Refinement	Review for redundancy
	Review for inappropriate items
	Revision of wording
	Review by Adult Education graduate students
	Review by Study Methodologist
	Relocation of items from measure of consequences
Expert Critique	Revision of items
	Revision of scale
	Re-wording of directions
	Elimination of inappropriate item

The next step of development and refinement of the measure of *Planning Practices* was a brainstorming session with four CPE experts. The expert panel included a director of CPE at a college of pharmacy, a former medical liaison with a major pharmaceutical company, a CPE program speaker, and a retired hospital pharmacy director. I gave these experts the task of having an open discussion on pharmaceutical company involvement in CPE programs and

activities. The expert panelists also provided feedback on the wording and format of a proposed version of the questionnaire including instructions, a 6-point Likert scale and a few sample items (Appendix C).

After completion of the literature review and brainstorming session, I grouped the construct indicators by common program planning categories to assist in the identification of redundant and inappropriate items (Appendix D). I retained the original numbering sequence for this stage of item refinement. Based on the literature and primary data from the expert panel, I eliminated semantic equivalents, retained the most inclusive items, and standardized grammar. Upon further examination, I eliminated items from the item pool that were inappropriate for the study. This refinement process resulted in 23 total items that were included in an initial draft of the planning practices questionnaire including a 6-point Likert scale ranging from "Never" to "Always" (Appendix E). I reviewed this draft questionnaire with a panel of adult education graduate students enrolled in a survey development course and with the study methodologist. Based on feedback from these reviews, I made minor changes to the instructions and guiding question. In addition, I reduced the Likert scale to 4 points with the addition of specific response categories, rather than a range from "Never" to "Always".

The second draft of the questionnaire, used for an expert review, included brief instructions and 23 items presented in a Likert-type format (Appendix F). The guiding question was: "How frequently do the following practices occur in the provision of continuing pharmacy education?" The questionnaire was self-administered to four pharmacy professionals with experience in CPE program planning including an academic dean in a college of pharmacy, a retired pharmaceutical company employee, a college of pharmacy professor, and a director of a college of pharmacy continuing education department. Following completion of the

questionnaire, I interviewed the experts individually using a standard set of questions to guide the discussions (Appendix G). As a result of feedback and suggestions from the expert critique, I eliminated one item and made minor revisions to the instrument.

Development of the *Consequences* measure. I began the process by working to develop and refine the item pool for the measure of *Consequences* as summarized in Table 3. I carefully reviewed the literature and generated 137 potential indicators of *Consequences* (Appendix H). As I generated the items, it was apparent that the indicators represented a broad and overlapping range of themes that would be difficult to refine. After item generation, I had several discussions with the dissertation advisor and methodologist to determine a logical categorization that would simplify refinement of the item pool. Over a period of several months, I sorted and refined the items using three different grouping strategies.

Table 3

Item Pool Development and Refinement Process for Consequences Measure

Steps for Instrument Development	Principal Activities	
Item Pool Development	Literature review	
Item Pool Refinement	Review for redundancy	
	Review for inappropriate items	
	Revision of wording	
	Review with Study Methodologist	
	Relocation of items to measure of planning practices	

The first grouping of the item pool used categories related to such topics as patient care, financial and educational practices (Appendix I). During this grouping, I did not revise or eliminate items. After review of the grouped items with the study methodologist revealed that I could appropriately place many items in more than one category, I conducted a second grouping with subcategories (Appendix J). Subcategories included such topics as selection and recommendation of drugs, drug information, provider costs, provider funding, non-educational expenses, costs to participants, program content, and bias. After this grouping was complete, I sub-divided any items determined to contain multiple indicators which resulted in 163 total items in the pool. After a thorough review of items, I eliminated eleven inappropriate items.

It was again evident to me that I could place items in more than one category, thus I removed the groupings and standardized item grammar. During this process, I eliminated seven redundant and/or inappropriate items resulting in 145 items in the item pool. Following discussion with the dissertation advisor, I attempted a third grouping strategy (Appendix K). I based the categories on relevant stakeholders of CPE including the provider, learner, the learner's practice site, and patients. After grouping of the item pool, I further standardized grammar and removed semantic differences and inappropriate items resulting in 52 total items. An item-by-item review again revealed overlap in the groupings, thus I removed the categories. After I made another review of items and eliminated redundancies and inappropriate items, 29 potential items remained in the item pool.

Assessment of Saturation

In a dissertation designed to map unknown terrain, it is very important to fully cover the constructs. Consequently, I sought to determine whether I had reached the level of saturation for each of the constructs. The evidence I used to determine saturation had been reached is

anecdotal in nature, but still convincing. I relied on the literature of pharmacy and related health professions to construct lists of indicators of *Planning Practices* and *Consequences*. I relied on experts in the field to describe their experiences and perceptions of commercial support of CPE. I reflected on the insight of health education accrediting bodies, administrators and practitioners of CPE who presented their many perspectives on this issue at a continuing pharmacy education providers conference. I worked alone, as well as in conjunction with my dissertation advisor and methodologist, to refine the planning practices item pool from 68 to 24 items and the consequences item pool from 137 to 29 items. Finally, towards the end of the instrumentation process, I continued to review newly published literature and was unable to identify novel indicators of the two constructs. As a result, it is my conclusion that I adequately mapped the landscape of *Planning Practices* and *Consequences*.

Construction of Response Scales

The next step in the instrument development process was to devise the optimal response scales for the two measures. Because no prior research studies had identified *Planning Practices*, there was a need to distinguish the specific planning practices that occur and frequency of occurrence when a provider receives commercial support for a CPE program.

Thus, for the measure of *Planning Practices*, I chose a scale to capture the respondent's opinion of the relative frequency of the construct indicators. The scale utilizes a range of percentages of programs believed to use the listed planning practices. For the measure of *Consequences*, I did not want to specify an expected direction of the listed items in the response scale wording. In addition, I wanted the respondents to have the option to select that commercial support had no affect on the listed items. For these reasons, I decided that the most appropriate scale would measure a respondent's opinion of the directional effect of each of the listed items. This type of

scale would not point the respondents towards an expected response, thus removing any suggestion of researcher bias from the individual items. For each measure, I chose to use a consistent response format in an effort to make the mental task of completion easier for the respondents and to allow uniformity of scoring for data analysis.

I, along with the dissertation advisor and methodogist, discussed numerous formats for both measures. After much consideration, we determined that the following scales were most appropriate for this study: The *Planning Practices* measure utilized a six-point scale including "0%," "1-25%," "26-50%," "51-75%," "76-99%," and "100%"; The *Consequences* measure utilized a three-point scale including "Decreases due to commercial support," "Not Affected by commercial support," and "Increases due to commercial support." An example of the response scales as they appear in the final instrument are illustrated in Tables 4 and 5.

Table 4

Measure of Planning Practices Response Scale

org	Think about all of the continuing pharmacy education programs offered by your organization as an ACPE-accredited provider over the last two years.						
For the programs that received commercial support, in what percentage do you think the							
foll	following practices occurred?						
		0%	1-	26-	51-	76-	100%
			25%	50%	75%	99%	
1.	A pharmaceutical company						
	representative assists with						
	establishment of program objectives						
2.	A pharmaceutical company						
	representative recommends the						
	program topic(s)						

Table 5

Measure of Consequences Response Scale

Think in a general sense about continuing pharmacy education programs offered by ALL ACPE-accredited providers. In your opinion, what is the effect of commercial support of continuing pharmacy				
education on the following?				
	C	Decreases due to commercial support	Not affected by commercial support	Increases due to commercial support
1.	Overall revenue of continuing pharmacy			
	education providers			
2.	Institutional funding of continuing			
	pharmacy education providers			

Addition of Background Items

The final instrument contained 8 items for the purpose of collecting professional and organizational information from the study participants. These questions included volume of CPE programs, size of the CPE unit, and educational background of the provider. These variables were chosen to describe the survey participants and to serve as predictor variables in the analysis of differences in responses based on professional and organizational dimensions.

Expert Critique of Study Documents and Questionnaire

I asked four experts in continuing education for the health professions to participate in a final critique of the items and structure of the online questionnaire, and to test administration procedures. The participants included a continuing pharmacy education director, a continuing medical education consultant with over 20 years experience in the pharmaceutical industry, and representatives from two continuing health education accrediting bodies. I faxed these experts a

copy of critique instructions, pre-notification and request for participation emails, and all online documents including the questionnaire (Appendix L). I immediately followed up with an email link to the online questionnaire and documentation. The critique group members were located in different states, so I asked them to review the materials independently. I followed up within a few days with scheduled phone interviews using the standard set of guiding questions provided in the fax cover letter.

Everyone in the expert critique group stated that they felt the instrument was valid, easy to complete and had a professional appearance. The only major change to the questionnaire was in regards to the planning practices section. Based on the critiques, the scope of the guiding question for this section was narrowed from the provider's knowledge of CPE in general to practices within the provider's own practice site within the last two years. I had considered this referent early in the instrument development process, but changed the scope to CPE in general due to the sensitivity of the subject area and fear that providers might feel threatened and thus unwilling to self-report on their own practice. Justification for this change included that an estimated 75% of providers would probably not be aware of planning practices outside of their own organization. In addition, two years was used as a referent because new ACPE policies regarding commercial support were released approximately two years ago. Items regarding the provider's annual volume of continuing education programming, types of programs and percentage of programs receiving commercial support were added to the front of the questionnaire to set the context and to serve as a quantifier for the planning practices section. I also removed the instructions and background question regarding a respondent's knowledge of CPE as a program faculty and/or participant as a result of this change in the practices section.

In addition, I made minor changes to the correspondence and several items on the questionnaire, added one item to both the practices and consequences section, and deleted one item from the consequences section. I also added a link from the survey entry page to a list of study references. My affiliation with the UGA College of Pharmacy was added to all correspondence and online documents because the critique group felt my continuing pharmacy education credentials were important to disclose and could enhance response rate. I reviewed all changes based on the expert critiques with a dissertation committee member and with the study methodologist, and then finalized the instrument which contained a total of 64 items. The final version of the instrument is available in Appendix A.

Study Population and Sample

The population for this study was program planners working in accredited CPE provider organizations in the U.S. Because no list of this population exists, a convenience sample consisting of a list of contact persons of record for each of the continuing education provider organizations accredited by the Accreditation Council for Pharmacy Education (ACPE) was used for this study. ACPE delivered their continuing education provider email list for this research project several weeks prior to data collection in order to ensure that the most current version of the email address list was utilized. After removal of one duplicate address, the list included 386 unique email addresses.

Data Collection

The data collection process was a confidential, self-administered, web-based survey following the online design principles suggested by Dillman (2000). According to Dillman (2000), web-based surveys have many advantages such as a more refined appearance, easy access, and dynamic interaction. Dillman also states that adequate coverage is typically not an

issue for most businesses, universities, large organizations, and professional organizations.

Because it was assumed that the intended respondents would complete the questionnaire from their professional practice site, coverage was not a concern for this study.

The survey software offered an option to provide a unique hyperlink to each person on the email listsery in order to track responses and send personalized email requests for participation, reminders and thank you messages. However, because of the sensitive nature of the research topic and the request for respondents to be an informant for their organization, this feature was not utilized. It was anticipated that respondents would be more candid about their organization's planning practices and their own opinions about commercial support of CPE if tracking was not utilized. Although respondents were not tracked, online surveys are considered confidential rather than anonymous because Internet communications can be insecure and there is a limit to the level of confidentiality that can be guaranteed.

As suggested by Dillman (2000), a multiple contact strategy was used for this study. Contacts included four unique email notifications within a four week period (Dillman, 2000). The first communication was an advance notice of the study (Appendix M). Within a few days, the study request for participation (Appendix N) containing a hyperlink to the survey entry page was sent to the listsery. A follow-up request for participation (Appendix O) was sent two weeks later and the final request for participation (Appendix P) was sent approximately 10 days after the follow-up request. The follow-up and final requests for participation thanked those who had already responded and appealed to those who had not yet responded. All email communications contained researcher contact information, a request to either notify the researcher or forward the email if there was someone in the organization who could better respond to the survey, and instructions for removal from the study email list.

Each request for participation contained a hyperlink to the online implied consent form (Appendix A) which was located on the UGA College of Pharmacy webserver. The implied consent form linked to the survey entry page which contained a welcome message and general information about the study such as total number of items, study references, and a direct link to the online survey. Both the implied consent form and survey entry page contained a link to a pdf version of the survey for fax or mail submission. A short password was provided in each request for participation email to ensure only legitimate individuals could access the online survey (Dillman, 2000).

I chose the survey development and administration website SurveyMonkey

(http://www.surveymonkey.com/) for the online questionnaire for several reasons. Most importantly, the intended respondents had successfully completed questionnaires administered by ACPE through this website. D. Travlos, Associate Director of ACPE, reported that a recent survey of their CPE provider contact persons had a response rate of over 50% of the approximately 400 providers (personal communication, December 5, 2003). This web-based survey software also offered multiple access, design, administration, and collection features that were appropriate for this study. These features included ability to restrict access via a password and the ability to control how responses were collected. In addition, results could be downloaded in a format compatible with the software used for statistical analysis.

Dillman's (2000) visual design principles for online surveys were used for the questionnaire including appropriate use of color to enhance flow of questions, complete instructions, and efficient response and navigation features. In addition, entry into the online questionnaire via the Implied Consent Form was designed to ensure that respondents were aware that the study was administered and IRB-approved by the University of Georgia.

The online questionnaire was presented as a series of pages that were easily viewed in their entirety on a majority of computer monitors. Instructions and information about the number of questions on each page and total number of questions on the survey were prominently placed at the top of each page (i.e., Questions X-Y of Z). If a respondent exited the survey before completion, the software would save responses and the respondent was returned to the point of exit if the survey was re-entered from the same computer. When respondents submitted or exited the survey, a thank you webpage was displayed (Appendix A). This thank you page also contained instructions on how to return to the survey at a later time, how to request a copy of the study results, and how to ask questions about the study.

Response rate. ACPE's email address list of continuing education providers contained 386 unique email addresses, only one address per organization. A consideration during the early planning stages was whether or not data could be manipulated by commercial interests.

However, due to the tensions surrounding the current debate on commercial support of continuing education for the health professions and the request that respondents be an informant on their organization's program planning practices, a decision was made that the survey respondents would not be tracked by their email address. Because tracking was not utilized, it was possible for multiple people from one organization to log onto the survey, posing a threat to the external validity of the survey results. Although it was impossible to prevent this occurrence, I dealt with this issue by coding two separate groups for data collection. One listsery contained 215 email addresses, 55.7% of the ACPE list, that could be assumed to be non-commercial providers based on their email address extensions (e.g., .edu, .gov, .mil). The second listsery contained 171 email addresses, 44.3% of ACPE providers, that could not be identified as either commercial or non-commercial based soley on their email address extensions (e.g., .com, .net). I

then created two identical instances of all survey webpages and .pdf documents and provided a separate URL and password to each listsery. This process assisted in tracking the rate of return for non-commercial vs. undetermined organization type of respondents.

Following all email requests for participation, 134 useable surveys were received, a raw response rate of 34.72%. However, five providers (one non-commercial, four non-determined) requested removal of their email address from the study listserv prior to provision of the URL and password for the survey. In addition, 20 email delivery failures (six non-commercial, fourteen non-determined) were received. Removal of these 25 addresses from the study list resulted in an adjusted response rate of 37.12%. Of the useable surveys, 60.45% (n=81) were from the non-commercial provider listserv, 32.84% (n=44) were received from the listserv of providers whose affiliation could not be determined, and 6.72% (n=9) were received via fax or U.S. mail submission. Comparison of the return rate with the total number of email addresses per listserv indicated little chance of manipulation of survey results based on the type of CPE provider organization.

Respondent characteristics. An assumption of this research is that only one person for each of the provider organizations responded to the survey. The respondent provided data from two perspectives: 1) An informant for their organization's CPE planning practices; and 2) Their own professional reaction to the impact of commercial support of CPE. A majority of respondents listed pharmacy or pharmacy in combination with other disciplines as their educational background. A majority of respondents were also licensed pharmacists and had practiced in the area of CPE between 3-10 years, with over 30% in CPE practice for more than 10 years. A summary of the description of respondents is presented in Table 6.

Table 6

Description of Study Respondents

63 17	48.5% 13.1%
17	
17	
	13.1%
	5.4%
	6.1%
	4.6%
	1.5%
	1.5%
	.8%
7	5.4%
78	60%
52	40%
24	18.3%
39	29.8%
27	20.6%
19	14.5%
8	6.1%
7	5.3%
7	5.3%
	78 52 24 39 27 19 8 7

The organizations represented in this study are described in Table 7. As reported by respondents, 26.1% worked in a school or college of pharmacy and 20.9% in an educational company. In order to determine if the respondent organizations were representative of the ACPE-accredited continuing education provider organizations, I acquired a list of provider organization names and types from ACPE. This list, slightly different from the study email list, contained 398 continuing education provider organizations, twelve more organizations than were

included on the study email list. A comparison of the organizations of study respondents and ACPE's list of accredited continuing education providers is also presented in Table 7.

Table 7

Comparison of Respondent and ACPE Continuing Education Provider Organizations

Type of Organization	Respondents (n=134)	ACPE (n=398)
School or College	29.1% (n=39) ^a	21.4% (n=85)
Educational Company	20.9% (n=27)	22.1% (n=88)
Local or State Association	12.7% (n=17)	12.8% (n=51)
Hospital	7.5% (n=10)	10.6% (n=42)
National Association	7.5% (n=10)	5.6% (n=22)
Healthcare Network	4.5% (n=6)	2.5% (n=10)
Publisher	3.7% (n=5)	2.3% (n=9)
Government Agency	3% (n=4)	2.8% (n=11)
Pharmaceutical Company	2.2% (n=3)	3.8% (n=15)
Other	8.9% (n=13)	16.3% (n=65)

^aFor this survey, the number of respondents for "School or College" was obtained by adding those who were from both pharmacy and medical schools and colleges. Of the respondents, 26.1% (n=35) reported they worked in a school or college of pharmacy and 3% of respondents (n=4) reported they worked in a school or college of medicine.

Because the response rate was 37%, approximately 63% of the CPE providers are not represented in this study. Because of this limited response rate, there are no claims of statistical

inference for the data; however, the research proceeded based on the fact that we had a large and diverse enough number of organizations represented to allow for logical inference. The respondent organizations resembled the diversity of the ACPE-accredited organizations, although response from academic institutions was somewhat higher and response from hospitals was somewhat lower than represented on the ACPE list.

The study respondents reported that their organizations employed a mean of 6.7 (median=2.0) full time faculty and/or staff dedicated to continuing pharmacy education (CPE). Two respondents, both employed by educational companies, reported at least 100 full-time employees dedicated to CPE. A complete description of the number of full-time equivalent (FTE) employees by type of provider organization is presented in Table 8. As shown in the table, the standard deviation exceeds the mean for the total FTEs per organization. To better understand the distribution, Figure 1 presents a graph of this data.

Data Preparation

The surveys received via mail or fax were entered into a separate instance of the online survey. The raw responses for all three instances of the online survey were then downloaded into three Excel spreadsheets. An additional column was added to identify each the three groups, then the three spreadsheets were merged into a common spreadsheet for data cleaning. The text-based responses were exported to a Microsoft Word document for separate analysis.

The first step in data cleaning was to standardize entries for open-ended questions in which the respondents typed their response. These items included the total number of CPE programs offered each year, the number of full-time faculty and staff in their organization dedicated to CPE, and the number of years of CPE practice. To standardize responses where the respondent specified over a certain number, a 10% correction was added to the item (e.g., 'over

20' was changed to '22', '>25' was changed to '27.5'). Using this system, five responses to the annual number of programs and three responses for years of practice were changed. In addition, the midpoint was used for any respondent who specified a range (e.g., '15-20' was changed to '17.5', '25-30%' was changed to '27.5%'). Using this system, eight responses for number of programs, one response for percentage of commercial support, and one response for number of full-time CPE faculty and staff were changed.

I then reviewed the submissions to determine if all were complete and appropriate to include in the study. After review, I deleted 3 submissions that had responses for organizational/background items, but did not have responses for any of the *Planning Practices* and Consequences items. In addition, I noted that a series of 11 incomplete surveys were submitted from the same computer IP address within 20 minutes on the same day. Given the survey settings, this should not have been possible, but the occurrence was apparently caused by an unknown computer error. The pattern of responses indicated that the respondent was able to respond to only one page of items per attempt and was then able to open a new instance of the survey. After review of the .pdf submissions, I identified a complete submission that closely matched these responses (e.g., organizational and program information was identical, and other responses followed the same patterns), therefore I deleted the series of 11 online submissions. This data cleaning process resulted in 134 useable surveys which I saved as a new 'cleaned' SPSS file. The number of full-time faculty and staff at each organization variable was recoded in SPSS by rounding all values to whole numbers (e.g., '.2' was recoded to '0', '.5' was recoded to '1'). Finally, computation of variables was conducted to determine the total number of CPE programs that received commercial support (i.e., percentage of programs receiving commercial support multiplied by the number of programs offered annually for each respondent).

Table 8

Description of Full-Time CPE Faculty and Staff by Organization Type (n=131)

Type of Organization	n	Mean	Median	SD	Minimum	Maximum
School or College of Pharmacy	34	2.7	2.0	4.2	0	25
Educational Company	27	19.1	6.0	29.4	0	110
Local or State Association	16	1.6	1.5	1.4	0	5
Hospital	10	3.7	1.5	4.8	0	12
National Association	9	5.1	3.0	5.3	0	18
Healthcare Network	6	2.2	1.0	1.8	1	5
Publisher	5	13.4	6.0	17.7	4	45
School or College of Medicine	4	5.2	5	4.0	1	10
Government Agency	4	2.5	3.0	1.0	1	3
Pharmaceutical Company	3	2.3	2.0	1.5	1	4
Other	13	3.3	3.0	3.1	1	12
TOTAL	131	6.7	2.0	15.4	0	110

I conducted an additional data cleaning process before subjecting the data to exploratory factor analysis for research question two. Before beginning this process I saved a new instance of the cleaned SPSS file. I then scanned the consequences data to locate submissions with only one or two missing items. I located 15 respondents who skipped only one item and six respondents who skipped only two items. I then impleted the mean value of the group for these

skipped items. This process resulted in 126 useable surveys for factor analysis, or 4.34 complete surveys per *Consequences* item.

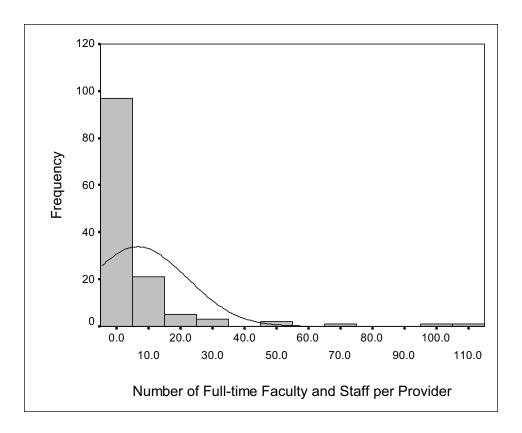


Figure 1. Number of full-time faculty and staff per provider organization

Data Analysis

Data analysis was conducted using SPSS 11.5.1 statistical software package. Appropriate statistical analyses were selected to answer the two research questions. I completed a two step process to answer research question one. I first converted each response to the numerical midpoint (i.e., 0%=0, 1-25%=12.5, 26-50%=38, 51-75%=63, 76-99%=87.5, 100%=100) and

calculated the mean for each item. I then rank-ordered the items by item mean. Second, I calculated the frequency distribution for the responses.

For research question two, I first analyzed the data in an attempt to prioritize the overall consequences. I converted each response to a numerical code (i.e., decrease due to commercial support=-1, not affected by commercial support=0, increase due to commercial support=1), calculated the means, rank-ordered the items, and calculated the frequencies.

For this research question, I also attempted to discover the conceptual dimensions of the consequences by subjecting the data to exploratory factor analysis. Exploratory factor analysis allowed me to determine that the consequences grouped together based on observed variation of impact. To accomplish the optimal grouping of items, I generated solutions for two through six factors using SPSS. I then examined solutions for conceptual clarity. I also examined alpha and determined that the measures had acceptable reliabilities (Nunnally & Bernstein, 1994).

Limitations

Due to the limited response rate (37%), the results are not generalized to the population and only logical inference is utilized. Because tracking was not employed, I was unable to conduct a follow-up survey with non-respondents to determine if they were different from the respondents. Although this potential for non-response error is a limitation of the study, I speculate that non-respondents, as a whole, could likely represent organizations that receive higher percentages of commercial support and would have reported higher percentages on the planning practices section of the instrument. This speculation is based on anecdotal evidence that some respondents were cautious to participate in a study that might reveal that they allow questionable and unacceptable practices in their organization and/or might threaten the allowance of commercial support of CPE programs and activities.

CHAPTER 4

RESEARCH FINDINGS

The purpose of this study was to understand the impact of commercial support on the provision and outcomes of continuing pharmacy education. This chapter presents the results of the statistical analysis described in the preceding chapter. First, a complete description of the continuing pharmacy education (CPE) programs represented in this study will be presented. Next, the findings will be presented separately in relation to the two research questions:

- 1. What is the impact of commercial support on continuing pharmacy education planning practice?
- 2. What are the consequences of commercial support of continuing pharmacy education for the provider organization, pharmacists, and patients?

Description of Programs

All 134 respondents worked in ACPE-accredited CPE provider organizations. Taken together, these 134 CPE providers offer a total of 6,394 programs annually. As reported by these providers, an estimated 2,740 programs, or approximately 43%, received commercial support. A complete summary of programs by the type of provider organization is presented in Table 9, and the delivery format of the programs is presented in Table 10. Of the provider organizations with the greatest number of respondents (n≥10), local and state associations reported commercial support for 73% of their CPE programs, national associations for 50%, schools and colleges of pharmacy for 48%, hospitals for 31%, and educational companies for 24%. Also, 19 providers

from various types of provider organizations reported that they receive no commercial support for their CPE programs.

Table 9

Number of Programs Offered Each Year and Number Receiving Commercial Support

]	Number of	Programs	
	Number			Total Rece	_
Type of Provider	of	Total Offered E	Each Year	Commercial	Support
Organization	Providers	Mean (SD)	Sum	Mean (SD)	Sum
School/College Pharmacy	35	45.2 (47.1)	1583	21.7 (23.94)	761
Educational Company	27	76.4 (164.5)	2064	18.5 (28.2)	499
Local or State Assn	17	63.4 (58.9)	1079	46.2 (41.9)	786
Hospital	10	18.9 (9.7)	189	5.8 (5.9)	58
National Association	10	64.9 (79.0)	649	32.5 (44.6)	325
Healthcare Network	6	22.7 (11.7)	136	2.7 (1.9)	16
Publisher	5	26.9 (22.3)	134	11.1 (8.1)	55
School/College Medicine	4	17.6 (12.2)	71	9.6 (6.1)	39
Government Agency	4	13.1 (9.0)	53	1.9 (1.4)	8
Pharmaceutical Co.	3	13.0 (18.2)	39	13.0 (18.2)	39
Other	13	30.6 (31.3)	397	11.8 (20.6)	154
ALL PROVIDERS	134	47.7 (85.3) median=20	6394	20.4 (29.2) median=9.2	2740

As shown in Table 9, the standard deviation exceeds the mean both for the number of programs per year and the number of programs receiving commercial support per provider organization. To better understand the distribution of programs, Figures 2 and 3 present graphs

of this data. The two extreme cases in Figure 2 (i.e., 600 and 660 programs per year) were both reported by educational companies. Figure 3 also reveals two extreme cases. A local or state association reported 140 programs per year that receive commercial support, and a state association reported 150 programs per year that receive commercial support.

Table 10

Description of Program Delivery Formats (n=134)

_	Percentage of	Programs
Delivery Format	Mean	SD
Face-to-Face	73.1	31.6
Homestudy	17.7	25.1
Asynchronous Online	6.8	17.7
Synchronous Online	2.4	10.1

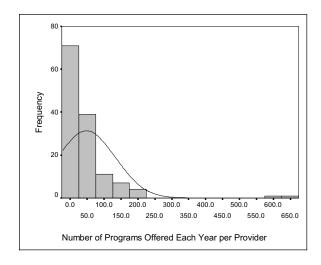


Figure 2. Number of programs per year per provider organization

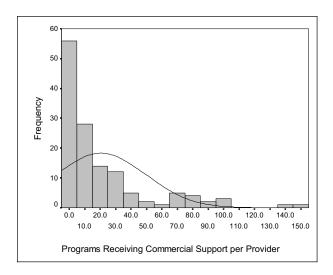


Figure 3. Number of programs per provider per year receiving commercial support

Impact of Commercial Support on Planning Practice

The first research question asked "What is the impact of commercial support on continuing pharmacy education planning practice?" The mean percentage of the 25 indicators of *Planning Practices* ranged from 1.9% to 60.6% of the programs receiving commercial support. Five of the items demonstrated a mean percentage above 30%. Twelve of the items demonstrated a mean percentage below 10%. A complete rank-order listing of the *Planning Practices* items by mean percentage is available in Appendix Q.

To better understand the results of the impact of commercial support on the individual *Planning Practices* items, the results are reported in three separate tables according to appropriateness of the activity. Although the categorization is subjective, ACPE's Criteria for Quality and Interpretive Guidelines (n.d.-b) (ACPE Critieria), ACPE Memorandum #00-023 regarding noncommercialism and fair and equitable balance within offerings (Travlos & Vlasses, 2000) (ACPE Memo #00-023), and the PhRMA Code on Interactions with Healthcare

Professionals (2002) (PhRMA Code) were used as guides for developing the categories.

Although the PhRMA Code is voluntary, it is relevant in determining appropriateness of

Planning Practices items because it is accepted by ACPE as a tool in guiding interactions
between the pharmaceutical and research companies and CPE providers (Accreditation Council
for Pharmacy Education, 2003).

Table 11 presents 12 *Planning Practices* items that are considered acceptable. Only one of these items is expected by ACPE when a pharmaceutical company or any other commercial interests are represented in the planning of a CPE program. ACPE Criterion 17, Guideline 17.3 on non-commercialism states that "providers are expected to be rigorous in their efforts to assure that all educational programs and associated materials are free from promotional influence and/or content." As presented in Table 11, only 57 respondents reported review of all instructional materials and program content prior to delivery for all their programs receiving commercial support. Thirty five respondents reported review of all instructional materials and content for 0-50% of their programs, with 20 of these respondents reporting that they never reviewed instructional material or content for their programs receiving commercial support.

The remaining eleven items shown in Table 11 are considered acceptable practice. There are no specific criteria prohibiting these practices regarding a pharmaceutical company's involvement in the program planning process; however, the ACPE-accredited provider is always expected to maintain control of all aspects of program planning and ensure that promotional activities are not an integral part of the educational program and program materials. The mean percentage of programs represented in this category ranged from 9.6% to 40.6%.

Acceptable Planning Practices Ranked by Mean Percentage of Programs

Table 11

						Frequencies	encies		
			I			26-	51-	-92	
Rank	Item	Mean %	Median %	%0	1-25%	20%	75%	%66	100%
_	The program provider reviewed all instructional materials and program content prior to delivery ^a (item 13)	67.4 (42.1)	100	20		4	9	12	57
7	A program speaker had an existing relationship with a pharmaceutical company (item 4)	40.6 (31.9)	38.0	_	43	21	19	15	
κ	A pharmaceutical company designated funding in their grant to pay for program speaker fees (item 5)	40.0 (38.5)	38.0	32	23	17	10	16	16
4	A pharmaceutical company sponsored a refreshment break and/or meal function as part of a program (item 20)	36.0 (34.3)	12.5	23	37	15	16	4	∞
S	A pharmaceutical company representative recommended the program speaker (item 6)	28.7 (30.8)	12.5	25	45	21	_	10	9
9	A pharmaceutical company representative recommended the program topic(s) (item 2)	24.4 (26.8)	12.5	31	40	26	7	9	в

^aThis was the only planning practice item on the instrument expected by the Accreditation Council for Pharmacy Education.

Table 11 (continued)

						Frequencies	encies		
			I			26-	51-	-92	
Rank	Item	Mean %	Median %	%0	1-25%	20%	75%	%66	100%
7	A pharmaceutical company had promotional literature available outside of the classroom (item 22)	22.7 (27.5)	12.5	37	40	19	7	∞	7
∞	A pharmaceutical company offered items of minimal value to participants that could primarily be associated with practice (item 24)	22.3 (28.6)	12.5	34	8	11	٢	L -	4
6	A pharmaceutical company banner or sign was displayed outside of the classroom (item 23)	17.4 (27.7)	6.25	99	32	10	4	_	К
10	A pharmaceutical company provided instructional materials to a program speaker (item14)	15.1 (23.5)	12.5	84	44	10	W	W	m
=	A pharmaceutical company representative assisted with establishment of program objectives (item 1)	11.3 (21.9)	0	89	29	10	-	6	ϵ
12	A pharmaceutical company representative reviewed content for medical accuracy (item 10)	9.6 (23.6)	0	08	21	4	0	8	4

The two most common practices in this category of acceptable practices (Table 11) were for the program speaker to have an existing relationship with a pharmaceutical company and for a pharmaceutical company to designate funding in their grant to pay for the program speaker fees. Although there is no guideline preventing relationships between the speaker and the funding organization, ACPE does expect that any significant relationship be fully disclosed (American Council on Pharmaceutical Education, n.d.-b). Other acceptable planning practices represented in this category include a pharmaceutical company sponsoring a refreshment break and/or meal function, and recommending the program speaker and/or topic.

According to the ACPE Criteria, ACPE Memorandum #00-023, and the PhRMA Code, seven of the planning practices are considered questionable and should be avoided. As shown in Table 12, the mean percentage of programs represented in this category ranged from 3.0% to 37.1%. ACPE Memorandum #00-023 specifically addresses several of these practices including the provider's responsibility for selection of faculty. This memo also asks providers to avoid the following: 1) Involvement of the supporting company in audience selection decisions; 2) Promotional activities in the meeting room; and 3) Advertisements for the supporting company's products within materials disseminated to participants. If the approved program sponsor or cosponsor is a pharmaceutical company, it is is understood that it may be impossible to avoid some or all of these practices. Regardless of the type of provider organization, all programming decisions and actions should benefit the patient and/or healthcare professional and should not be promotional in nature (American Council on Pharmaceutical Education, n.d.-a; Pharmaceutical Research and Manufacturers of America, 2002).

Questionable Planning Practices Ranked by Mean Percentage of Programs

Table 12

						Frequencies	encies		
			I			26-	51-	-92	
Rank	Item	Mean %	Median %	%0	1-25%	%05	75%	%66	100%
_	A pharmaceutical company representative was present in the classroom during a program (item 18)	37.1 (30.2)	38	10	42	22	19	41	3
6	A pharmaceutical company offered to support a program based on the participant profile (item 8)	29.2 (33.6)	12.5	39	29	16	13	L	6
ю	A presentation was targeted to a specific audience of interest to the supporting company (item 12)	22.7 (30.10	12.5	46	32	10	13	9	4
4	A pharmaceutical company representative selected the program topic(s) (item 3)	10.1 (22.1)	0	92	23	S	ω	ю	7
V	A pharmaceutical company representative selected and/or invited the program speaker(s) (item 7)	9.4 (21.3)	0	77	24	9	0	\$	_
9	A presentation was scripted by a pharmaceutical company (item 11)	6.7 (20.8)	0	06	14	7	0	1	4
	A pharmaceutical company representative assisted with program evaluation (item 9)	3.0 (11.5)	0	66	10	8	0	0	-

As shown in Table 13, six of the items are considered unacceptable practice. The mean percentage of programs represented in this category ranged from 2.2% to 10.7%. The highest ranking item in this category was that a pharmaceutical company offered items of minimal value to participants that could be considered of personal benefit for 10.7% of the programs receiving commercial support. Although ACPE Criteria does not directly address this issue, the PhRMA Code states that items of minimal value for personal benefit should not be offered. Other unacceptable practices that occurred in 2.2% to 6.2% of programs represented in this study include preferential treatment of a supporting company's product, a company's sponsorship of entertainment and/or recreational activity, omitted discussion of a relevant product sold by a competing company, and promotional literature and/or a company banner or logo displayed in the classroom.

Consequences of Commercial Support

The second research question asked "What are the consequences of commercial support of continuing pharmacy education for the provider organization, pharmacists, and patients?" The items in this section asked the respondents to rate a variety of impact items on a 3-point scale with '-1' for 'decreased due to commercial support', '0' for 'not affected by commercial support' and '1' for 'increased due to commercial support'. The scale on the survey instrument only listed the text version of these items (i.e., numbers -1, 0, and 1 were not listed on the instrument).

The first step in answering this research question was to calculate the mean values for the 29 indicators of *Consequences*. The mean values ranged from -.62 to .82. A complete rank order listing of *Consequences* by mean value can be found in Appendix R. For interpretive purposes, the intensity of an item's mean value is considered more significant than the direction of the mean value. For example, item 8 (program registration fees for participants) displayed a

Unacceptable Planning Practices Ranked by Mean Percentage of Programs

Table 13

						Frequencies	encies		
			1			26-	51-	-92	
Rank	Item	Mean %	Mean % Median %	%0	1-25%	20%	75%	%66	100%
1	A pharmaceutical company offered items of minimal value to participants that could be considered of personal benefit (item 25)	10.7 (21.2)	0	71	27	∞	κ	2	7
7	A program speaker provided preferential treatment of the supporting pharmaceutical company's product(s) (item 15)	6.2 (12.0)	0	70	38	ω	0	0	1
κ	A pharmaceutical company sponsored entertainment and/or a recreational activity in conjunction with a program (item 21)	5.5 (17.9)	0	92	16	0	_	ю	-
4	A program speaker omitted discussion of a relevant product sold by a competing pharmaceutical co (item 16)	4.0 (10.1)	0	84	26	-	0	П	0
S	A pharmaceutical company had promotional literature available in the classroom during a program (item 17)	3.1 (11.2)	0	76	13	-	П	-	0
9	A pharmaceutical company banner or logo was displayed in the classroom (item 19)	2.2 (9.0)	0	66	13	0	0	-	0

mean value of -.62, whereas item 6 (faculty honoraria and fees) displayed a mean value of .62. It can be interpreted that commercial support has the same level of impact on these two items; however, program registration fees decreased due to commercial support and faculty honoraria and fees increased due to commercial support.

As shown in Table 14, twenty one of the *Consequences* items increased due to commercial support (i.e., revealed a mean value above .20). Of these items, six demonstrated a mean value at or above .70. The top four items on the rank-order listing, demonstrating a mean value at or above .72, relate to increased educational effectiveness of CPE due to commercial support including a pharmacist's awareness and access to information, use of expert faculty, and the overall number of CPE programs offered. Three items, displaying a mean value between .62 and .70, related to a CPE provider's financial dependency on commercial support.

Only two of the *Consequences* items decreased due to commercial support (i.e., revealed a mean value beyond -.20). As presented in Table 15, both of these items demonstrated a mean value beyond -.50 and relate to a pharmacist's financial dependency on industry due to commercial support including a decrease in program registration fees and the decreased willingness of pharmacists to incur the full cost of a CPE program.

Commercial support is thought to have little to no impact on *Consequences* items with a mean value closer to zero (i.e., revealed a mean value between -.20 and .20). As shown in Table 16, six of the consequence items demonstrated a mean value between .19 and -.19. The item with a mean value closest to zero, or the item thought to be least affected by commercial support, was the overall variety of program topics.

Table 14

Consequences Items that Increased Due to Commercial Support Ranked by Mean Value

				Frequencies	
			Decreases	Not	Increases
			due to	Affected by	due to
			commercial	commercial	commercial
		Mean	support	support	support
Rank	Item	(SD)	(-1)	(0)	(1)
1	A pharmacist's awareness of the	.82	0	23	106
	availability of new drugs	(.38)			
	(item 18)				
2	Overall number of CPE	.81	4	17	109
	programs offered (item 15)	(.47)			
3	Use of nationally and	.78	3	23	104
	internationally renowned experts	(.47)			
	as program faculty (item 7)	(* *)			
4	A pharmacist's access to disease		1	33	93
4	<u> </u>	.72	1	33	93
	management information	(.47)			
	(item 19)				
5.5	a. Use of newer drugs (item 27)	.70	0	38	89
(tie)	a. Ose of newer drugs (item 27)	(.46)	U	30	0)
(110)		(.10)			
	b. Overall revenue of CPE	.70	7	25	99
	provider organizations (item 1)	(.56)			
		` ,			
7	A pharmacist's knowledge of	.68	4	33	90
	advances in pharmacy care	(.53)			
	(item 22)	(.55)			
			_	• •	0.4
8	A CPE provider's financial	.66	2	39	84
	dependency on industry (item 3)	(.51)			
9	Faculty honoraria and fees	.62	7	36	87
7	(item 6)	(.59)	,	30	0 /
	(item 0)	(.39)			
10	A pharmacist's recommendation	.53	1	57	68
	to patients about drugs featured	(.52)	-		
	in a CPE program (item 23)	()			

Table 14 (continued)

11	Program topics that reflect the self-interest of a pharm company (item 13)	0.52 (.59)	6	49	73
12	Perception of bias on the part of program participants (item 14)	0.49 (.57)	5	56	69
13	Non-educational expenses for a CPE program (item 5)	0.48 (.70)	15	37	78
14	Quality of pharmacy care (item 24)	0.45 (.57)	5	60	62
15	Cost of prescription drugs (item 20)	0.44 (.51)	1	69	56
16	Formulary Requests for the supporting company's drug(s) (item 25)	0.41 (.49)	0	74	52
17	Use of more expensive drugs (item 26)	0.38 (.49)	0	77	48
18	A pharmacist's recommendation to physicians about drugs featured in a CPE program (item 16)	0.34 (.54)	4	76	47
19	Cost of OTC drugs (item 21)	0.33 (.49)	1	82	42
20	A CPE provider's allegiance to a supporting pharm company (item 4)	0.32 (.51)	3	83	44
21	Use of brand name rather than generic drugs (item 29)	0.26 (.52)	5	84	38

Table 15

Consequences Items that Decreased Due to Commercial Support Ranked by Mean Value

				Frequencies	
			Decreases	Not	Increases
			due to	Affected by	due to
			commercial	commercial	commercial
		Mean	support	support	support
Rank	Item	(SD)	(-1)	(0)	(1)
1	Program registration fees for	62	94	23	13
	participants (item 8)	(.67)			
2	Willingness of pharmacists to incur the full cost of a CPE program (item 9)	54 (.57)	75	50	5

Table 16

Consequences Items Not Affected by Commercial Support Ranked by Mean Value

				Frequencies	
			Decreases due to commercial	Not Affected by commercial	Increases due to commercial
		Mean	support	support	support
Rank	Item	(SD)	(-1)	(0)	(1)
1	Overall quality of a CPE program (item 10)	0.19 (.62)	15	75	39
2	Brand loyalty on behalf of the pharmacist (item 17)	0.18 (.42)	2	101	25
3	Institutional funding for CPE providers (item 2)	0.14 (.75)	28	53	46
4	Overall variety of program topics offered (item 12)	-0.01 (.74)	36	59	35
5	A CPE provider's control of program quality (item 11)	-0.13 (.38)	19	108	2
6	Use of older but still effective drugs (item 28)	-0.19 (.62)	38	74	14

Exploratory Factor Analysis

The next step in answering the second research question was to subject the data to exploratory factor analysis. Given the limited sample size, I was reluctant to attempt to derive many factors from the data set; therefore, I decided to examine solutions ranging from a two-factor solution to a six-factor solution. Table 17 shows the amount of variance explained by each option. The complete eigenvalue chart is shown in Appendix S.

Table 17

Amount of Variance Explained by Each Factor Solution

Number of		Initial eigenvalues	
Factors	Total	Percent of Variance	Cumulative
1	4.85	16.71	16.71
2	3.67	12.65	29.36
3	2.37	8.15	37.50
4	1.80	6.20	43.70
5	1.62	5.59	49.29
6	1.30	4.47	53.76

I reviewed each of the factor solutions for conceptual clarity, starting with the 6-factor solution and working down to the 2-factor solution. Initially, I used a loading factor of .45 to sort the items. I placed all items with a loading below .45 in a category labeled 'non-loading items'.

After a thorough examination of each solution, starting with the 6-factor solution, it appeared that the 3-factor solution was conceptually the most meaningful. I then dropped the loading to .40 or above to determine if any of the non-loading items would load conceptually into an appropriate category. This process resulted in two additional relevant items placed within Factor I and one additional relevant item placed within Factor III.

I named the three factors based on items with the highest loading values and with a theme that broadly covered the factor items. The factors were named Cost of Drugs, Quality of Pharmaceutical Care, and Financial Dependency. Next, I calculated scale scores for each of the three factors by summing those items with a loading of .40 or above on the respective factors. After calculating each of the scale scores, coefficient alpha was also calculated for each of the factors. All three of the scales exhibited adequate reliability for research purposes (Nunnally & Bernstein, 1994). The distribution and reliability of these scale scores are presented in Table 18.

Table 18

Distribution and Reliability of Scale Scores

				Mean	
	Number	Scale	Scale	Item	
Factor	of Items	Mean	SD	Mean	Alpha
I: Cost of Drugs	10	4.1	2.9	.41	.78
II: Quality of Pharmaceutical Care	8	2.5	2.8	.31	.78
III: Financial Dependency	7	4.4	2.3	.63	.74

Factor I: Cost of Drugs. The first factor included ten items that loaded above .40. These items relate to the cost of drugs for the patient and health care provider (Table 19). The items represent use and recommendation of both brand name and newer drugs which are typically more expensive than generic and older drugs. In addition, items represent formulary requests and recommendation of a supporting company's drugs, which are typically brand name and/or newer drugs, thus more expensive than generic and older drugs.

Table 19

Factor I: Cost of Drugs

Item	Loading	Item Mean
Cost of prescription drugs (item 20)	0.71	.43
Use of more expensive drugs (item 26)	0.69	.39
Use of brand name rather than generic drugs (item 29)	0.65	.27
Cost of OTC drugs (item 21)	0.62	.33
Use of newer drugs (item 27)	0.61	.70
Formulary requests for the supporting company's drug(s) (item 25)	0.56	.42
Perception of bias on the part of program participants (item 14)	0.51	.50
A pharmacist's recommendation to patients about drugs featured in a CPE program (item 23)	0.48	.54
Brand loyalty on behalf of the pharmacist (item 17)	0.42	.19
A pharmacist's recommendation to physicians about drugs featured in a CPE program (item 16)	0.41	.34

Factor II: Quality of Pharmaceutical Care. The second factor included eight items that loaded above .40 (Table 20). These items represent the quality of pharmaceutical care. Items include a pharmacist's knowledge of advances in pharmacy care, access to disease management information, and quality and variety of CPE programs.

Table 20

Factor II: Quality of Pharmaceutical Care

Itam	Loadina	Item
Item A pharmacist's knowledge of advances in pharmacy care (item 22)	Loading 0.75	
11 pharmacises into wreage of act anteres in pharmacy care (noin 22)	0.75	.00
Quality of pharmacy care (item 24)	0.71	.45
Overall quality of a CPE program (item 10)	0.66	.20
Overall quality of a CFE program (nem 10)	0.00	.20
A pharmacist's access to disease mgmt info (item 19)	0.65	.73
	0.60	0.2
Overall variety of program topics offered (item 12)	0.60	02
Use of older but still effective drugs (item 28)	0.49	20
A CPE provider's control of program quality (item 11)	0.48	15
A pharmacist's awareness of the availability of new drugs (item 18)	0.46	.82

Factor III: Financial Dependency. The third factor included seven items that loaded above .40 (Table 21) and demonstrated the highest mean item mean of the three factors (Table 18). The items represent both the CPE provider's and participant's financial dependency on industry. Items include a provider's financial dependency on industry, overall revenue of provider organizations, overall number of programs offered, use of expert faculty, and faculty honoraria and fees.

Table 21

Factor III: Financial Dependency

Item	Loading	Item Mean
A CPE provider's financial dependency on industry (item 3)	0.73	.66
Overall revenue of CPE provider organizations (item 1)	0.73	.71
Overall number of CPE programs offered (item 15)	0.60	.81
Use of nationally and internationally renowned experts as program faculty (item 7)	0.59	.78
Program topics that reflect the self-interest of a pharmaceutical company (item 13)	0.59	.53
Faculty honoraria and fees (item 6)	0.47	.62
A CPE provider's allegiance to a supporting pharmaceutical company (item 4)	0.41	.33

Non-loading items. Four items did not exceed a .40 loading on any factor (Table 22).

Although items 2 and 8 cross-loaded on Factor I, all items shown in Table 22 loaded the highest on Factor III. Although these items represent loadings below .40 for Factor III, conceptual interpretation indicates that they could all be logically placed in Factor III: Financial Dependency.

Greatest Impact of Commercial Support

At the end of the survey, the respondents were asked to respond to the question "Overall, what do you think has been the greatest impact of commercial support for continuing pharmacy education?" Ninety eight respondents provided 146 items of impact in response to this question. Three respondents provided information not applicable to greatest impact, thus their remarks

were moved to the section for additional comments. Although a majority of respondents (61%, n=60) listed only one item of impact, 25 listed two items of impact, six listed three items of impact, two listed four items of impact, and two listed five items of impact. Several responses were not included in the results because I could not interpret the intended direction of the listed impact (i.e., whether commercial support increased, decreased, or did not have an effect). These responses included one comment stating "quality of programs," two comments stating "quantity of programs," and one comment stating "program topics."

Table 22

Non-loading Items

T.	Factor III	Item
Item	Loading	Mean
Willingness of pharmacists to incur the full cost of a CPE program (item 9)	-0.38	55
Program registration fees for participants (item 8)	-0.34	63
Non-educational expenses for a CPE program (item 5)	0.29	.49
Institutional funding for CPE providers (item 2)	0.25	.16

I subjected the remaining comments to quantitative content analysis in which I studied the discrete categories represented. A rank order listing, as well as illustrative examples of all comments, is shown in Appendix T. Overall, the areas of greatest impact were thought to be increased quantity and quality of CPE programs, followed by decreased program registration fees and increased use of expert faculty.

Respondents listed two areas of greatest impact related to Factor I: Cost of Drugs. As shown in Table 23, these areas include the use of CPE as a marketing strategy by pharmaceutical companies and the fact that CPE participants are more willing to report bias due to commercial support.

Table 23

Greatest Impact Responses Related to Factor I: Cost of Drugs

		Number of
Rank	Item and Examples of Responses	Responses
1	CPE used as a marketing strategy by pharmaceutical companies resulting in biased programming	9
	"The greatest impact of commercial support has been pharmaceutical marketing in the guise of CE."	
	"Commercial support of programs is not totally altruistic: having a large number of pharmacists, nurses or others in one place at one time makes their communication/marketing efforts more efficient."	
	" for the overall provider industry I think the impact has been on the topics and content presented. Companies providing support expect to get their message out there about their products."	
2	CPE program participants more willing to report bias	1

As shown in Table 24, respondents listed six areas of greatest impact related to Factor II: Quality of Pharmaceutical Care. The highest ranked areas of response in this category include increased quality of CPE programs and a pharmacist's increased access to new information due to commercial support.

Table 24

Greatest Impact Responses Related to Factor II: Quality of Pharmaceutical Care

		Number of
Rank	Item and Examples of Responses	Responses
1	Increased quality of CPE programs	18
	"The ability of providers to offer high-quality continuing education."	
	"Commercial support plays a key role in making quality educational programs available to many pharmacists."	
	"Since the changes occurred to the PHRMA code and the involvement of OID, I have seen an increase in the quality of the programs because of the hands-off approach the big pharmaceutical companies are taking. Smaller pharmaceuticals must not have gotten the memo!"	
2	Increased access to new information (e.g., drugs, disease management)	10
	"Provides pharmacists with updates on management of specific diseases and drug classes."	
	"More available information on new drugs, clinical trials, future disease treatments."	
	"Greater awareness of new drugs resulting in better patient care."	
3.5 (tie)	A. Increased variety of CPE program topics	8
(iic)	"Without commercial support it is difficult to offer a broad range of topics with excellent speakers due to costs."	
	"More funding and resources are made available to provide a broad range of new topics."	
	B. Decreased variety of CPE program topics	8
	"With the PhRMA changes, we are finding it more difficult to provide a variety of program topics and speakers.	
	"It has hampered some of our responsiveness to the needs of pharmacists. For instance, there are fewer programs on skill development than on drugs. We tend to see the same topics done over and over again."	

Table 24 (continued)

5.5 (tie)	A. Improved access to CPE programs (e.g., alternative delivery methods)	4
, ,	"Encouraging and supporting different types of programming and alternative methods of program delivery especially the increase use of online or web-based programming."	
	B. Decreased quality of CPE programs	4
	"Quality has suffered due to commercial pressures."	
	"Less credibility of the information (real or imagined)."	

Respondents listed ten areas of greatest impact of commercial support of CPE related to Factor III: Financial Dependency. As shown in Table 25, the highest ranked areas of response in this category include increased quantity of CPE programs, decreased program registration fees, and increased use of expert faculty.

Only one area of response regarding greatest impact of commercial support of CPE could not be logically placed within one of the three Factors. Three respondents listed increased policies and regulations regarding the provision of CPE as the area of greatest impact. Their comments included "more hoops to jump through, more excuses to say no to support." and "the Office of Inspector General and Pharma guidelines."

Table 25

Greatest Impact Responses Related to Factor III: Financial Dependency

		Number
		of
Rank	Item and Examples of Responses	Responses
1	Increased quantity of CPE programs	22
	"Commercial support has been very important in increasing the amount of programs available."	
	"The ability for continuing education providers to present more educational programs with more pharmacists participating."	
2	Decreased CPE program registration costs for pharmacists	16
	"Commercial support has kept the cost of CE down for pharmacists."	
	"Lowering the costs of CE programs for pharmacists."	
3	Increased use of expert faculty for CPE programs	12
	"Increase in national thought leaders as faculty."	
	"If done appropriately, the commercial support of CE is able to provide quality faculty."	
4.5 (tie)	A. Culture of expectation for free or reduced cost of CPE for pharmacists resulting in less value on CPE	11
	"The abundance of commercial support in some venues appears to have had the overall effect of detracting from the educational goals of pharmacy education as a whole. It seems that most pharmacists base their CE choices on which programs are offered free of charge or at the nicest restaurants rather than on the topic and educational goals of the program being offered."	\
	"Pharmacists in general are now unwilling to pay for their own CE. They think all CE should be free and have no idea how much money comes in from Pharma to support their CE. It is a gift from Pharma but they don't acknowledge it."	
	"I think pharmacists do NOT want to pay a dime for CE because they are able to get so many commercials for free."	

		Number
- 1		of
Rank	Item and Examples of Responses	Responses
	"Pharmacists place less value on the CE and see it all too often as a method	11
	for the drug companies to sell product rather than teach CE. The	
	availability of free CE with a meal has diminished the response to quality	
	CE that is paid for by the pharmacist."	
	B. A CPE provider's financial dependency on industry	
	"It has encouraged the dependency of the pharmacy profession on financial support from pharmaceutical manufacturer's thereby diminishing the profession's control over its own future.	
	"This limits CE providers to reliance on drug companies for financial support."	
	"We'd be out of business if it wasn't for commercial support. My primary role is to manage the conflicts that commercial support raises.	
	"Allows the institution to withdraw its support of a CE unit forcing it to be totally self-supporting."	
6	A non-commercial CPE provider's increased competition with commercial CPE providers	5
	"The biggest threat are the marketing firms that are becoming ACPE providers. Their survival depends on funding from industry. When they were intermediaries between providers and industry they could be controlled. Our recent experience with them indicates that they are influenced by their need to turn a profit."	
	"drug companies now support commercial organizations which promote free CE which cuts into our own CE & may put us out of business if it continues."	

Table 25 (continued)

Doule	Itam and Evenuelas of Damanas	Number of
_Rank	Item and Examples of Responses	Responses
7	Increased cost of CPE faculty honoraria and fees	2
	"As a by-product of commercial support, the cost of securing quality faculty has risen."	
8.5 (tie)	A. Increase in non-educational expenses	1
(1)	B. Decreased quantity of CPE programs	1

Additional Comments by Respondents

The final question on the survey asked respondents for any additional comments. Thirty nine respondents provided 47 unique comments. These comments included reactions and/or observations about the research topic and study. Although a majority of respondents (82%, n=32) listed only one comment, six listed two unique comments, and one listed three unique comments.

I subjected the comments to quantitative content analysis in which I studied the discrete categories represented. Through this analysis, eight themes emerged. Approximately 30% (n=15) of the comments related to ACPE, ACPE guidelines and the responsibility of the program provider to maintain control of program quality and content. Approximately 23% (n=11) were reactions and comments about the research study and/or instrument. Of these, seven were describing difficulty or explanations regarding their responses to the survey and four were acknowledging their appreciation for the study and/or the need for more research of commercial support of CPE. Approximately 20% of respondent's comments (n=9) related to the financial

dependency of providers and/or program participants on commercial support. Other themes included concerns regarding bias of content and commercialism of CPE (n=4), effects of PhRMA code and other regulations on commercial support (n=3), improved quality of CPE due to commercial support (n=3), and the importance of full disclosure of any commercial support or relationships with industry (n=2).

Summary

This chapter presented the findings of the research study. First, a description of the CPE programs offered by the provider organizations of the study respondents was presented. This description provided detailed information on the number of programs offered each year and the number of programs receiving commercial support by the type of provider organization. Second, the results related to the impact of commercial support on planning practice were presented based on the appropriateness of the individual planning activities. The three categories included *Acceptable Planning Practices*, *Questionable Planning Practices*, and *Unacceptable Planning Practices*. Third, the findings related to the consequences of commercial support were presented. The *Consequences* items were categorized based on direction of impact (i.e., increased, decreased, or not affected by commercial support). Exploratory factor analysis on the *Consequences* data resulted in the identification of three factors of commercial support of CPE. The three factors identified were *Cost of Drugs*, *Quality of Pharmaceutical Care* and *Financial Dependency*. This factor solution was supported by the study respondent's reply to an openended question about the greatest impact of commercial support of CPE.

CHAPTER 5

DISCUSSION OF FINDINGS

The purpose of this chapter is to present a summary of the study and discussion of the research findings, and to consider significant implications for research and practice related to commercial support of continuing pharmacy education (CPE).

Overview of the Study

This study gathered data from accredited providers of CPE. The purpose of the study was to understand the impact of commercial support on the provision and outcomes of continuing pharmacy education. The research questions guiding this study were: (1) What is the impact of commercial support on continuing pharmacy education planning practice? (2) What are the consequences of commercial support of continuing pharmacy education for the provider organization, pharmacists, and patients?

I developed a survey instrument to address these research questions. The item pool for the survey was generated directly from relevant literature and directed discussions and review of the items with key stakeholders. The instrument included 25 items designed to measure the frequency of specific program planning practices used in the provision of commercially supported CPE programs (*Planning Practices*). The instrument contained 29 items to measure the directional effect of specific outcomes resulting from commercially supported CPE programs that affect the provider organization, pharmacists and patients (*Consequences*) and one openended question on the greatest impact of commercial support. The instrument also contained five items designed to describe CPE organizational and program characteristics of the study

respondents, and three items designed to describe educational and professional background of the study respondents.

The questionnaire was administered online to the contact person of record for the 387 CPE provider organizations accredited by the Accreditation Council for Pharmacy Education (ACPE). The adjusted response rate was 37% with 134 completed surveys. Although this response rate did not allow for statistical inference, logical inference was allowed because the types of provider organizations represented in this study resembled ACPE's accredited provider list.

To address the first research question, the item means were calculated. The items were then rank-ordered by item mean and categorized based on appropriateness of the specified planning practice. To address the second research question, the item means were calculated. The items were then rank-ordered by item mean and categorized based on direction and level of impact. Exploratory factor analysis on the *Consequences* data revealed a three-factor solution that captured 37.5% of variance observed in the 29 variables. The factors for the dimensions of commercial support of CPE were as follows: *Factor I: Cost of Drugs; Factor II: Quality of Pharmaceutical Care*; and *Factor III: Financial Dependency*.

Summary of Principal Findings

This study represents 6,394 programs offered by ACPE-accredited CPE providers.

Respondents reported that 2,740 of these programs, or approximately 43%, received commercial support. In addition, 19 of the 134 respondents reported that their organizations received no commercial support for their CPE programs. Following are significant findings for each of the two research questions.

Principal findings for research question 1. Of the 25 items designed to measure the Planning Practices construct, 12 items were considered acceptable, 7 items were considered questionable, and 6 items were considered unacceptable. Of the acceptable planning practices, the highest ranking item was for the program provider to review all instructional materials and content prior to delivery. Although ACPE expects this type of review, 20 respondents reported that their CPE provider organization never reviews instructional materials and program content. Fifteen additional respondents reported their organization performed a review in only 1-50% of their CPE programs. A number of providers did report that some of the unacceptable practices do occur in their organization. For example, although the PhRMA Code on Interactions with Healthcare Professionals (2002) expressly states that a pharmaceutical company should not offer items to healthcare professions intended for personal benefit, 15 respondents reported that this practice occurs in 51-100% of their programs. The *PhRMA Code* also states that a pharmaceutical company's provision of entertainment and/or recreational activities in connection with an educational program is inconsistent with the code; however, 5 respondents reported that they have allowed this practice in conjunction with 51-100% of their CPE programs.

Principal findings for research question 2. Of the 29 items designed to measure the Consequences construct, 21 items were thought to increase due to commercial support. These items relate to a pharmacist's awareness of new drugs and access to drug information, the number of CPE programs offered, use and cost of drugs, and a CPE provider's financial dependency on industry. Two of the Consequences items were thought to decrease due to commercial support. These items include program registration fees for participants and a pharmacist's willingness to incur the full cost of a CPE program. Six Consequences items were not thought to be affected by commercial support. These items include overall program quality

and a provider's control of program quality, overall variety of program topics, brand loyalty, institutional funding for CPE providers, and use of older but still effective drugs.

This study also established three factors in the provision of commercial support of CPE programs: Factor I: Cost of Drugs; Factor II: Quality of Pharmaceutical Care; and Factor III: Financial Dependency. In addition to the statistical analysis, the relevancy of these factors was supported by responses to the open-ended question regarding the greatest impact of commercial support of CPE. Of 18 categories of the greatest impact of commercial support of CPE, only one category (i.e., increased policies and regulations) could not be logically placed within one of the three factors.

Conclusions and Discussion

The conclusions of this study are a result of a thorough review of relevant literature, dialogue with pharmacists, pharmaceutical company representatives and CPE professionals, and the results of this national study of ACPE-accredited CPE providers.

The extent of commercial support of continuing pharmacy education is substantive. The Accreditation Council for Continuing Medical Education (ACCME) releases annual data on the extent of commercial support of continuing medical education (CME). ACCME's 2003 annual report (Accreditation Council for Continuing Medical Education, 2004a) revealed that over half of all CME income is received from firms that manufacture products regulated by the FDA. A recent survey of accredited CME providers at colleges and schools of medicine (Harrison, 2004) reported that these academic CME providers receive commercial support for 70% of their CME activities. Although this documentation and data of commercial support of CME is available, little information is available on the extent of commercial support of CPE activities. This lack of data is confirmed by the American Association of Colleges of Pharmacy (AACP). An AACP

position paper on postgraduate professional education and training (AACP Commission to Implement Change in Pharmaceutical Education, 2002) states:

Recent FDA and Congressional investigations have caused the professions and the pharmaceutical industry to reexamine the latter's role in supporting programs. While little data are available on the level of pharmaceutical industry support of mid-career education and training in pharmacy, the Commission believes, based on its own observations, that it is substantial.

This study provides the first empirical evidence that a substantial number of CPE programs offered by both commercial and non-commercial accredited providers do in fact receive commercial support. Of the study respondents, only 14% reported that their organizations did not receive commercial support for their CPE programs. Therefore, a large majority of respondents (86%) reported that their organizations accept commercial support for CPE programs. These providers estimate that an average of 43% of their CPE programs each year (approximately 2,740 programs) received commercial support.

The acceptance of commercial support is prevalent among all types of accredited CPE provider organizations. Every category of provider organization represented in this study reported receipt of commercial support. Although a few types of provider organizations, such as healthcare networks, reported receiving commercial support for less than 40% of their programs, most other types of organizations reported that commercial support was received for over 40% of their programs. For example, among the non-commercial providers, local and state associations reported taking commercial support for an average of 73% of their programs, national associations for 50% of their programs, schools and colleges of pharmacy for 48% of their programs, and schools and colleges of medicine for 55% of their programs.

The respondents in this study closely resemble the diversity of the almost 400 accredited CPE provider organizations. Because this study group is representative of the population of interest, a logical assumption is that the reported number of programs receiving commercial support in this study is reasonably descriptive of providers who did not respond to the survey. As discussed in the limitations section in Chapter 3, it is also possible that non-respondents received commercial support for a higher percentage of CPE programs. This empirical data, supported by guidelines being promulgated by accrediting and regulatory bodies (Accreditation Council for Continuing Medical Education, 2004b; U.S. Office of the Inspector General of Health and Human Services, 2000, 2003) leads to the conclusion that commercial support of individual CPE programs is indeed substantive, is prevalent among all types of accredited provider organizations, and is a critical and urgent issue for the profession of pharmacy.

Commercial support has a broad impact on the development and implementation of continuing pharmacy education. According to Harrison (2003), one of the few acceptable practices remaining for pharmaceutical companies to market directly to health care professionals is to provide support for continuing education activities. These types of continuing professional education programs are incorporated into the accountability systems for professional practice (Cervero, 2001). In the U.S., mandatory continuing education for pharmacists offered by approved and/or accredited providers is the basis for professional relicensure by all but one of the U.S. jurisdictions of the National Association of Boards of Pharmacy (American Pharmacists Association and National Association of Boards of Pharmacy, n.d.; Hodapp, 1988; Travlos & Zarembski, 2003).

In order to be an accredited provider of continuing pharmacy education (CPE), the Accreditation Council for Pharmacy Education (ACPE) requires a comprehensive review every

six years as well as continuous self-assessment (Travlos & Zarembski, 2003) to ensure each provider's adherence to ACPE's *Criteria for Quality and Interpretive Guidelines for Approval of Providers of Continuing Pharmaceutical Education* (n.d.-b). Although these ACPE guidelines allow for financial support from outside organizations, each accredited CPE provider is required to retain full control over all aspects of an educational program and to rigorously assure that all programs and materials are non-promotional in nature.

The Pharmaceutical Manufacturer's Association's (PhRMA) voluntary Code on Interactions with Healthcare Professionals (2002) also considers the provision of financial support for CPE as acceptable practice if the continuing education activity contributes to the improvement of patient care and if the program sponsor retains control over all aspects of the program including content, faculty, and educational methods and materials. In recent years, the U.S. Office of the Inspector General of Health and Human Services (OIG) has increased efforts to prevent fraud and abuse in the health care industry by issuing a series of compliance guidelines (Spooner & Peterson, 2002). OIG compliance guidelines have been implemented for physician practices and pharmaceutical manufacturers (U.S. Office of the Inspector General of Health and Human Services, 2000, 2003), and pharmacy practice is expected to be addressed in a future guideline (Vivian, 2002). The OIG guideline for pharmaceutical manufacturers incorporates PhRMA's Code on Interactions with Healthcare Professionals as a benchmark for these companies to judge their compliance. In a discussion of these emerging federal guidelines, Vivian (2002) states that they specifically address concerns regarding educational activities that can be funded by industry versus promotional activities that allege to serve an educational purpose but do not result in direct benefit to patients.

Although standards and guidelines issued by these accrediting and regulatory bodies expects independence of the CPE provider, literature reviewed for this study suggests that pharmaceutical companies have a direct and significant influence on planning CPE programs by becoming involved in all aspects of planning practice (Brett, Burr, & Moloo, 2003; DelSignore, 2003; Haines & Dumo, 2002; Harrison, 2003; Hensley, 2003; Holmer, 2001; Katz, Goldfinger, & Fletcher, 2002; Moynihan, 2003a, 2003b, 2003c; Relman, 2001; Relman & Angell, 2002; Schaffer, 2000; Tipton, 2003; Vivian, 2002). Even with the abundance of recent literature, mostly on commercial support of CME, there is still much speculation and anecdotal accounts of how pharmaceutical companies become involved and the extent of their involvement in the development and implementation of educational programs and activities for health care professionals. This study provides the first empirical evidence that the provision of commercial support to accredited CPE providers does have a broad impact on CPE planning practice. In addition, this study provides the first empirical evidence that accredited CPE providers allow questionable and unacceptable practices in the development and delivery of their programs.

Under the current guidelines and standards, some of the planning practices covered in this study are considered acceptable; however, there are many questionable and unacceptable practices that accredited providers are permitting in the provision of CPE. Many of these practices are considered questionable and/or unacceptable according to ACPE, PhRMA and/or OIG because they result in promotional benefit for the supporting company. ACPE Guideline 17.1 on non-commercialism (n.d.-b) states that "accredited providers will be held responsible for the administration, content, quality, and integrity of all continuing pharmaceutical education activities" and Guideline 17.3 states that "providers are expected to be rigorous in their efforts to assure that all educational programs and associated materials are free from promotional influence

and/or content." The PhRMA Code (2002) states that "responsibility for and control over the selection of content, faculty, educational materials, and venue belongs to the organizers of the conferences or meetings in accordance with their guidelines." Some accredited providers participating in this study report that they violate these guidelines and release control of an educational program to a pharmaceutical company when they allow specific questionable and/or unacceptable practices. For example, some providers report they allow a pharmaceutical company representative to select the program topic, select and/or invite a program speaker, and use a presentation scripted by a pharmaceutical company. In addition, some accredited providers report that pharmaceutical companies market directly through educational programs by offering to support a program based on the participant profile and by targeting a presentation to an audience of particular interest to the company. Some providers also report that they allow pharmaceutical companies to influence participants through non-educational activities that are expressly prohibited by ACPE (n.d.-b) and/or the *PhRMA Code* (2002) such as the provision of items of personal benefit to participants, sponsorship of entertainment and/or recreational activities in conjunction with a program, and allowing a speaker to provide preferential treatment of the supporting company's product. Through such practices, pharmaceutical companies are allowed to have promotional influence on CPE activities and programs that should be designed expressly for the enhancement of a pharmacist's professional competence and for the benefit of patients (American Council on Pharmaceutical Education, n.d.-a; Pharmaceutical Research and Manufacturers of America, 2002).

Commercial support in the provision of continuing pharmacy education results in significant and diverse consequences for relevant stakeholders. Relevant literature on continuing education designed to improve a health professional's practice indicates much

anecdotal opinion and debate on the consequences of commercial support of educational programs for health-care professionals (Angell, 2000; Brett et al., 2003; Canadian Medical Association, 2004; Croasdale, 2004; Crowninshield, 2003; Davis, 2004; DelSignore, 2003; Farrar, 2002; Finestone, 2001; Harrison, 2003; Hensley, 2002, 2003; Holmer, 2001; Holmer et al., 2000; Katz et al., 2002; Kues, 2003; Liebman, 1998; Marlow, 2004; Martin, 2004; Mazmanian, 2003; Moynihan, 2003a, 2003b, 2003c; Relman, 2001; Relman & Angell, 2002; Sarmiento, 2003; Schaffer, 2000; Tipton, 2003; Vedantam, 2002). This debate largely centers on the consequences of integrating promotional and educational practices in continuing education activities that receive support from pharmaceutical companies and the financial dependency of healthcare professionals and continuing education providers on this type of support. Harrison (2003, p. 198), professor and director of CME at University of Michigan Medical School, voices much concern of the cumulative effects of commercial support of CME that "shift CME toward a commercial exchange that benefits funders rather than a professional service addressing all the needs of patients". Regarding this cumulative effect of commercial support he states:

A remarkable aspect of these cumulative changes on the CME system is that no one planned them. The increased commercial funding likely resulted from factors generally increasing all pharmaceutical marketing activities...Longer-term changes in the overall CME system are unintended consequences, resulting from many thousands of offers and acceptances of increased commercial funding for CME over many years. (Harrison, 2003, p. 204)

In support of this ongoing debate, this study presents the first empirical evidence that the provision of CPE does have numerous significant consequences for program providers, pharmacists, and their patients. These consequences are revealed through the three multifaceted

dimensions of commercial support of CPE identified in this study: *Quality of Pharmaceutical Care, Cost of Drugs, and Financial Dependency*.

The intended goal of CPE is to improve a pharmacist's professional competence, and thus, to improve patient care. Pharmaceutical Research and Manufacturers of America (PhRMA) maintains that industry support of continuing education activities assists heathcare professionals in fulfilling and improving patient care. In 1996, Bectel, PhRMA Vice President, stated that pharmacists "must look cooperatively to the industry for information on disease management as well as educational support" (p. 113). Holmer (2001, p. 2012), also a PhRMA affiliate, stated that the pharmaceutical industry's "leading role" in CME "serves the overriding mutual interest to ensure that patients receive the most up-to-date and appropriate patient care." The accredited providers participating in this study were of the opinion that CPE programs receiving commercial support are effective in improving the quality of pharmaceutical care in part by improving a pharmacists knowledge of advances in pharmacy care and access to disease management information; however, since this educational outcome is the intended goal of CPE, it is likely that similar results would be obtained in a comparative analysis with CPE programs that did not receive commercial support.

Although these providers feel that commercial support assists them in attaining their fundamental educational goal of improving pharmaceutical care, it is important to remember that continuing professional education "is about many things in addition to a professionals' learning" (Cervero, 2001, p. 26). In this regard, this study reveals that there are additional and significant consequences of commercial support of CPE beyond improving the quality of pharmaceutical care.

Holmer (2001) acknowledges that pharmaceutical company involvement in CME may generate sales. Specifically, he states "the extent that physicians become more knowledgeable about the benefits of their products, they may also generate increased sales" (Holmer, 2001, p. 2012). In addition to learning more about the benefits of specific products through CPE programs, this study revealed that accredited CPE providers and pharmaceutical company representatives participate in specific practices that violate the required separation of promotional and educational practices and activities. Due to the belief that these types of marketing practices are widespread in CME, Relman (2001), professor emeritus at Harvard Medical School, offers strong opposition to pharmaceutical company support of CME activities. Relman (2001, p. 2009) states that "CME is now so closely linked with the marketing of pharmaceuticals that its integrity and credibility are being questioned. The problem is not new, but it has recently grown to alarming proportions."

Considering that pharmaceutical companies must operate with a business orientation where the fundamental goal is financial viability and profits (Prager & Omen, 1980), it is understandable that companies that offer their support to a CPE program provider would expect to either directly or indirectly market their products and services to the program participants (Angell, 2000; Cassell, 2001; Crowninshield, 2003; DelSignore, 2003; Farrar, 2002; Grossi, 2002; Haines & Dumo, 2002; Harrison, 2003; Hensley, 2003; Marlow, 2004; Relman, 2001; Schaffer, 2000; Wilson, 2003). From this perspective, an important dimension of commercial support that is unrelated to the educational goals of continuing education, but still has a direct impact on patients, is the increased cost and use of drugs (Angell, 2000; Canadian Medical Association, 2004; Harrison, 2003; Relman & Angell, 2002; Vivian, 2002). The accredited CPE providers participating in this study are of the opinion that commercial support of CPE is

increasing the cost of both prescription and over-the-counter drugs, and is increasing the use of newer and more expensive drugs.

Another significant consequence of commercial support that has been widely speculated about in the literature and is not connected to the educational goals of continuing education is the financial dependency of program providers and participants on this support (Abbasi & Smith, 2003; Brett et al., 2003; Croasdale, 2004; DelSignore, 2003; Harrison, 2002, 2003; Hensley, 2002; Holmer, 2001; Katz et al., 2002; Kues, 2003; Moynihan, 2003b, 2003c; Relman, 2001; Relman & Angell, 2002; Sarmiento, 2003; Schaffer, 2000; Steward, 2003; Tipton, 2003). This financial dependency has resulted in a culture of expectation for both of these key stakeholders where program participants expect to obtain continuing education at minimal or no cost, and program providers accept commercial support so they can cover increased expenses, offer their programs at a reduced rate, and/or generate additional revenue. The findings of this study provide evidence that reduced registration fees and a decreased willingness of pharmacists to incur the full cost of CPE programs has created this financial dependency on the pharmaceutical industry. This study also provides evidence that accredited CPE providers are dependent on industry to assist them in covering increased administrative, educational and non-educational expenses. This financial dependency of providers was revealed through an overall increase in revenue, increased use of expert faculty, increased fees paid to faculty, and an increase in noneducational expenses.

The findings of this national study of accredited CPE providers, supported by the current debate on and attention to commercial support by healthcare professionals, professional associations, and accrediting and regulatory bodies, lead to the final conclusion of this study:

Commercial support in the provision of continuing pharmacy education results in significant and

diverse consequences for relevant stakeholders. These multidimensional and extremely complex consequences include quality of pharmaceutical care, cost and use of drugs, and financial dependency on industry support. Whether intended or unintended, anticipated or unanticipated, or considered positive or negative for relevant stakeholders, these consequences suggest that commercial interests are directly and indirectly impacting pharmacy professional practice and patient care through pharmaceutical company involvement in and influence on CPE programs and activities.

Implications for Practice

On a global scale, this study has important implications for the profession of pharmacy. It is the responsibility of each professional regulatory system in the U.S. to set accreditation, practice, and ethical standards and to advocate for change to maintain the relevance of the profession in society (Bobby, 1997); thus, the education of pharmacists should be the sole responsibility of the profession. This study revealed that commercial influence on CPE programs has significant consequences that go beyond the educational goals of CPE programs. These consequences, including the cost and use of drugs and financial dependency of program providers and participants on industry support, are extremely significant and should not only be addressed by the Accreditation Council for Pharmacy Education (ACPE), but also by pharmacy regulatory and professional organizations. All organizations that have a relevant stake in the quality of pharmacy practice need to engage in formal and informal dialogue regarding the profession's ultimate responsibility to society to deliver the most appropriate and unbiased pharmaceutical care. This dialogue should also consider that a substantial decrease in commercial funding could threaten the viability of the overall system of accredited CPE. As the accredited CPE system is in place to ensure a pharmacist's professional competence, a plan

should be devised regarding how to move away from current practice into a new model that removes pharmacy's financial dependency on industry.

This study also has immediate implications for the Accreditation Council for Pharmacy Education and providers of CPE. The ethical guidelines for accredited CPE providers are defined by ACPE's *Criteria for Quality and Interpretive Guidelines for Approval of Providers of Continuing Education* (n.d.-b). These guidelines are designed to ultimately protect public and professional interests; however, the criterion on non-commercialism is broad and does not provide a CPE program planner with the tools necessary to deal with asymmetrical power relationships and conflict of interests surrounding receipt of commercial support for CPE programs. This study provided empirical evidence through self-report that some accredited providers allow activities and practices that are in clear violation of ACPE and other relevant guidelines. It is unclear whether these providers understand that their actions may be in violation of the required separation of promotion and education.

According to Peter Vlasses, ACPE Executive Director, ACPE is currently reviewing their criterion and guidelines regarding non-commercialism due to the recent release of the new ACCME standards for commercial support (personal communication, October 6, 2004). ACPE should ensure that any new guidelines are unambiguous and clearly define appropriate interactions with pharmaceutical companies and other commercial entities. The findings of this study related to the extent, current practices, and consequences of commercial support should assist ACPE in strengthening and clarifying their standards so that program providers have a clear understanding of what is considered unacceptable practice and why it is imperative to remove commercial influence on CPE programs and activities.

Implications for Research

As this was the first empirical study on the practices and consequences in the provision of commercial support of continuing pharmacy education (CPE), further studies are needed to extend this research. First, there are numerous areas for future investigation within the profession of pharmacy. There is a need for research on the actual dollar amounts of commercial support of CPE and on the number of program participants attending commercially supported CPE programs. There is also a need to study this issue from the perspective of the pharmacy professional including the effect of commercial support on pharmacy practice and pharmaceutical care. Future research should also seek a comparative analysis of the outcomes of commercially-supported CPE programs versus CPE programs that do not receive commercial support. In addition, comparative analyses of different types of commercially-supported programs (e.g., one grantor versus multiple grantors, restricted versus unrestricted grants) would assist in a better understanding of the impact and consequences of specific types of commercial support.

Second, future research should seek to replicate this study with accredited continuing education for other types of healthcare professionals. Although the instrument would require modifications for each field of healthcare, this type of research would provide the opportunity for comparative analysis among the healthcare professions and would further clarify the practices and dimensions of commercial support of continuing education programs for healthcare professionals. There is also a need to better understand how this issue is managed in other countries that might have either similar or different systems for accredited continuing education for healthcare professionals and/or funding structures for healthcare.

Third, there is also a need for qualitative research in the areas identified by this study.

The use of case studies would be particularly beneficial in determining how pharmaceutical company representatives interact with accredited program providers and how their involvement impacts both the program planning process and the delivery of the continuing education program. Qualitative research would be useful in a better understanding of the impact on individual programs as well as the cumulative effect of commercial support from the perspective of the program participants.

Finally, as the accrediting and regulatory bodies introduce new standards and guidelines for commercial support of continuing education for healthcare professionals, future research should investigate the impact of new policies and procedures and any resulting changes on the practice of continuing education for healthcare professionals.

Concluding Note

This research study generated many supporting comments and requests for study results from the sample group. It was apparent that these accredited providers of continuing pharmacy education (CPE) have been directly impacted, both positively and negatively, by the provision of commercial support for their CPE programs and activities. It was also apparent from their responses to the survey instrument, as well as their unsolicited comments sent directly to me, that these accredited providers understand the magnitude of the issues surrounding commercial influence on CPE. The success of this study is due to their willingness to self-report on an extremely sensitive area of their organization's practice. It is my hope that their participation and preceding study findings and conclusions are beneficial to the Accreditation Council for Pharmacy Education, as well as to other accrediting and regulatory bodies, in ensuring the integrity and independence of accredited continuing education for healthcare professionals.

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APPENDICES

APPENDIX A FINAL VERSION OF STUDY INSTRUMENT



Implied Consent Form

This is notification of implied consent for the research study titled *Provision of Commercial Support for Continuing Pharmacy Education: Practices and Consequences.* The purpose of this research is to understand the impact of commercial support on the provision and outcomes of continuing pharmacy education. Please know that this research activity is being conducted by the below individuals and may be published.

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Your participation is voluntary. You may withdraw at any time without penalty, or skip any questions that you feel uncomfortable answering. It should take approximately 15-20 minutes to complete the online questionnaire. All of your responses will be confidential and will not be associated with your name, email address or any other identifying information.

Please note the following: Internet communications are insecure and there is a limit to the confidentiality that can be guaranteed due to the technology itself. However, once the completed survey is received by the researchers, standard confidentiality procedures will be followed. In addition, only summary data will be reported.

Given that communication via the Internet is more risky in regards to privacy, if you prefer, you can open a pdf version of the survey instrument, complete by hand, and then submit via FAX or US mail to:

Commercial Support of Continuing Pharmacy Education Questionnaire (pdf) UGA Department of Adult Education c/o Dr. Ronald M. Cervero and Jayne L. Smith River's Crossing - 4th Floor Athens, GA 30602 FAX: (706)542-4024

If you have any questions, do not hesitate to ask now or at a later date. You may contact Jayne L. Smith, Study Director at (706)542-5288 or jsmith@mail.rx.uga.edu.

Additional questions or problems regarding your rights as a research participant should be addressed to Chris A Joseph, Ph.D., Human Subjects Office, University of Georgia, 612 Boyd Graduate Studies Research Center, Athens, Georgia 30602-7411; Telephone (706) 542-3199; E-Mail Address <u>IRB@uga.edu</u>



Thank you in advance for taking the time to complete this survey!

Commercial support plays a central role in the provision of continuing pharmacy education and your expertise as an ACPE-accredited provider will help us in a better understanding of the many dimensions of this important issue.

- Your participation is voluntary and the results will be kept confidential.
- * There are a total of 64 items on the questionnaire and it should take approximately 15-20 minutes to complete.
- If you have any questions or problems, please contact the Survey Director, Jayne L. Smith, at <u>jsmith@mail.rx.uga.edu</u> or call (706)542-5288.

Please, only one submission per continuing pharmacy education provider organization accredited by the Accreditation Council for Pharmacy Education (ACPE).

COMMERCIAL SUPPORT OF CONTINUING PHARMACY EDUCATION QUESTIONNAIRE

Please, only one submission per ACPE-accredited continuing education provider.

This survey requires a password.

The password is provided in the email request for participation. If you need assistance, please contact the study director.

Password:	Submit
Password:	Submit



Items 1-4 of 64

Items 1-4: Provider Organization Information

1. Which best describes your ACPE-p	rovider organization?
Educational Company	
Government Agency	
Health Care Network	
Local or State Association	
Pharmaceutical Manufacturer or Rese.	arch-Based Company
National Association	
→ Publisher	
School or College of Medicine	
School or College of Pharmacy	
Other (please specify)	
	any continuing pharmacy education programs does your CPE-accredited provider?
organization offer each year as an AC 3. On average, approximately what p	
organization offer <u>each year</u> as an AC 3. On average, approximately <u>what p</u> following formats?	CPE-accredited provider?
organization offer <u>each year</u> as an AC 3. On average, approximately <u>what p</u> following formats?	CPE-accredited provider?
3. On average, approximately what p following formats? (Must sum to 100%)	CPE-accredited provider?
3. On average, approximately what p following formats? (Must sum to 100%) Face-to-Face	CPE-accredited provider?
3. On average, approximately what p following formats? (Must sum to 100%) Face-to-Face Synchronous Online	CPE-accredited provider?



Items 5-12 of 64

<u>For Items 5-29:</u> Think about all of the continuing pharmacy education programs offered by your organization as an ACPE-accredited provider over the last two years.

For the programs that received commercial support, in what percentage do you think the following practices occurred?

	0%	1- 25%	26- 50%	51- 75%	76- 99%	100%
A pharmaceutical company representative assisted with establishment of program objectives	J)))))
A pharmaceutical company representative recommended the program topic(s)					U	
 A pharmaceutical company representative selected the program topic(s)))))))
8. A program speaker had an existing relationship (e.g. consultant, speaker, researcher, major stockholder) with a pharmaceutical company						J
A pharmaceutical company designated funding in their grant to pay for program speaker fees	J	J)	J	J)
10. A pharmaceutical company representative <i>recommended</i> the program speaker			0	J		
 A pharmaceutical company representative selected and/or invited the program speaker(s)))	J)))
12. A pharmaceutical company offered to support a program based on the participant profile (e.g. practice sites/workplace of pharmacists expected to attend)						J



Items 13-21 of 64

<u>For Items 5-29:</u> Think about all of the continuing pharmacy education programs offered by your organization as an ACPE-accredited provider over the last two years.

For the programs that received commercial support, in what percentage do you think the following practices occurred?

	0%	1-25%	26-50%	51-75%	76-99%	100%
13. A pharmaceutical company representative assisted with program evaluation))))))
 A pharmaceutical company representative reviewed content for medical accuracy 						
15. A presentation was scripted by a pharmaceutical company))))))
16. A presentation was targeted to a specific audience of interest to the supporting company						
17. The program provider reviewed all instructional materials and program content prior to delivery))))))
18. A pharmaceutical company provided instructional materials to a program speaker (e.g. slides, handouts)						
19. A program speaker provided preferential treatment of the supporting pharmaceutical company's product(s))))))	J
20. A program speaker omitted discussion of a relevant product sold by a competing pharmaceutical company						
21. A pharmaceutical company had promotional literature (e.g. brochures, pamphlets) available in the classroom during a program)	J	J	J))



Items 22-29 of 64

<u>For Items 5-29:</u> Think about all of the continuing pharmacy education programs offered by your organization as an ACPE-accredited provider over the last two years.

For the programs that received commercial support, in what percentage do you think the following practices occurred?

	0%	1-25%	26-50%	51-75%	76-99%	100%
22. A pharmaceutical company representative was present in the classroom during a program)	J))))
A pharmaceutical company banner or logo was displayed in the classroom						
24. A pharmaceutical company sponsored a refreshment break and/or meal function as part of a program	J))))	J
25. A pharmaceutical company sponsored entertainment and/or a recreational activity in conjunction with a program						
26. A pharmaceutical company had promotional literature (e.g. brochures, pamphlets) available outside of the classroom)))	J	J)
27. A pharmaceutical company banner or sign was displayed outside of the classroom				0	9	
28. A pharmaceutical company offered items of minimal value to participants that could be primarily associated with practice (e.g. notepad, pen, mousepad, calendar))	J)))	J
29. A pharmaceutical company offered items of minimal value to participants that could be considered of personal benefit (e.g. coffee mug, golf balls, candy)	U					



Items 30-43 of 64

<u>For Items 30-58:</u> Think in a general sense about continuing pharmacy education programs offered by ALL ACPE-accredited providers.

In your opinion, what is the effect of commercial support of continuing pharmacy education on the following?

	Decreases due to commercial support	Not Affected by commercial support	Increases due to commercial support
30. Overall revenue of continuing pharmacy education provider organizations)))
31. Institutional funding for pharmacy continuing education providers			
32. A continuing pharmacy education provider's financial dependency on industry)))
33. A continuing pharmacy education provider's allegiance to a supporting pharmaceutical company			
34. Non-educational expenses (e.g. breaks, meals, facilities) for a continuing pharmacy education program)))
35. Faculty honoraria and fees (i.e. amount paid to continuing pharmacy education faculty)			
36. Use of nationally and internationally renowned experts as program faculty)))
37. Program registration fees for participants			0
38. Willingness of pharmacists to incur the full cost of a continuing pharmacy education program)))
39. Overall <i>quality</i> of a continuing pharmacy education program			
40. A continuing pharmacy education provider's control of program quality	J))
41. Overall variety of program topics offered		0	
42. Program topics that reflect the self-interest of a pharmaceutical company)))
43. Perception of bias on the part of program participants			



Items 44-58 of 64

<u>For Items 30-58:</u> Think in a general sense about continuing pharmacy education programs offered by ALL ACPE-accredited providers.

In your opinion, what is the effect of commercial support of continuing pharmacy education on the following?

	Decreases due to commercial support	Not Affected by commercial support	Increases due to commercial support
44. Overall <i>number</i> of continuing pharmacy education programs offered))	J
45. A pharmacist's recommendation to <i>physicians</i> about drugs featured in a continuing pharmacy education program	0	0	
46. Brand loyalty on behalf of the pharmacist))
47. A pharmacist's awareness of the availability of new drugs	0		
48. A pharmacist's access to disease management information)))
49. Cost of prescription drugs	0		
50. Cost of OTC drugs))
51. A pharmacist's knowledge of advances in pharmacy care			
52. A pharmacist's recommendation to <i>patients</i> about drugs featured in a continuing pharmacy education program)	J)
53. Quality of pharmacy care	0		
54. Formulary requests for the supporting company's drug(s)))	J
55. Use of more expensive drugs	0		
56. Use of newer drugs)	J)
57. Use of older, but still effective drugs	0		
58. Use of brand name rather than generic drugs))	© Jayne L. Smith 2004



Items 59-62 of 64

Items 59-62: Background Information

59. What is your education (Please select all that apply	
Allied Health	
Business	
Computer Science	
Education	
Journalism	
Library Science	
Medicine	
Nursing	
Pharmacy	
Other (please specify)	
60. Are you a licensed pl✓ Yes✓ No	narmacist in the U.S.?
61. How many <u>full-time</u> the development and del	faculty and/or staff are employed by your organization to assist in livery of continuing pharmacy education?
62. How many years hav	



Items 63-64 of 64

	armacy education		eatest impact of commercial supp	
l. Any addit	onal comments	?		
•				



EXIT>>>

Commercial Support of Continuing Pharmacy Education Questionnaire

THANK YOU FOR YOUR PARTICIPATION IN THIS SURVEY.

Please select "Done" at the bottom of the page to submit your survey.

However, if you have changed your mind and no longer wish to part of this research study, please type the words "discard my responses" in the space below:

<< Prev

Done>>

Page 9 of 9



Thank you for your participation in this survey.

If you exited the survey prior to completion, all of your responses have been saved. You can return to the survey from the same computer at a later time to complete.

If you would like a copy of the study summary report or have questions about the online survey, please email the Study Director at jsmith@mail.rx.uga.edu or call (706) 542-5288.

The summary report will be available after data analysis is complete.

APPENDIX B

PLANNING PRACTICES CONSTRUCT INDICATORS

- 1. Presence of company representative at planning meetings
- 2. Pharmaceutical company representative involved in planning discussions
- 3. Program provider has adequate time to review all instructional materials and program content prior to delivery
- Program provider requests to review all instructional materials and program content prior to delivery
- 5. Pharmaceutical company assists in establishment of program objectives
- 6. Pharmaceutical company involved with program evaluation
- A written agreement exists between the educational program provider and supporting company
- 8. Program evaluation requests information from participants regarding commercial bias or equitable distribution
- 9. Selection of Program Speaker(s)
- 10. Recommendation of Program Speaker(s)
- 11. Program Speaker is employed by a pharmaceutical company
- 12. Program Speaker has an existing contractual relationship with pharmaceutical company
- 13. Program Speaker has a prior relationship with pharmaceutical company
- 14. Pharmaceutical company provides a suggested speakers list
- 15. Pharmaceutical company indirectly pays for program speaker fees
- 16. Pharmaceutical company designates funding to pay for program speaker fees
- 17. Use of (or offer to use) a supporting company-sponsored speaker's bureau
- 18. Program speakers fully disclose to audience any consultant or speaker funding arrangements with the supporting company
- 19. Selection of Program Topic(s)
- 20. Recommendation of Program Topic(s)
- 21. Supporting company has a product related to the program topic
- 22. Program topic related to the supporting companies' commercial drug, product and/or service
- 23. Provision of Program Educational Materials (e.g. ppt slides, handouts, etc.)
- 24. Company requests sponsorship of a program they have developed independently
- 25. Company approached PCE office with program proposal
- Pharmaceutical company representative requests that competing products not be mentioned/included in educational program
- 27. Lack of scientific rigor in program developed independently by a pharmaceutical company
- Lack of scientific rigor in program delivered by a speaker with existing relationship with a pharmaceutical company
- 29. Failure to give equitable balance during program to relevant products not sold by the supporting company
- 30. Full disclosure on all educational materials of any relationship between funding organization and program faculty
- 31. Full disclosure during presentation of any relationship between funding organization and program faculty
- 32. Supporting company provides curricular materials
- 33. Program Providers offers educational program produced exclusively by pharmaceutical company
- Offer of gratis use of educational program produced independently by the supporting company
- 35. Pharmaceutical company provides program moderators
- 36. Pharmaceutical company offers to provide a "pre-packaged program"

- Speaker provides "friendly treatment" of the supporting companies products during the presentation
- 38. Pharmaceutical company has influence on educational methods utilized during the program
- 39. Pharmaceutical company develops educational program instructional materials
- 40. Placement of company logo on program-related marketing materials
- 41. Placement of company logo on educational materials (e.g. ppt slides, handouts, etc.)
- 42. Pharmaceutical company banner or logo displayed in the meeting room
- 43. Presence of company representative in meeting room at live programs
- 44. Support of PCE program based on types of pharmacists expected to attend (e.g. clinical pharmacists vs. retail pharmacists)
- 45. Pharmaceutical company has an expressed interest in profile of program participants
- Pharmaceutical company independently advertises or markets the educational program or event
- 47. Full disclosure on all program marketing materials of program provider's relationship with supporting company
- 48. Full disclosure of supporting company funding
- 49. Full disclosure of any significant relationship between the provider, presenter or moderators and the supporting company
- 50. Pharmaceutical company has influence on selection of program venue
- 51. Pharmaceutical company develops educational program promotional materials
- 52. Company promotional materials available during program (e.g. table or display booth setup outside of meeting room)
- 53. Presence of pharmaceutical company representative at meal function
- 54. Presence of pharmaceutical company representative during breaks
- 55. Pharmaceutical company sponsors a meal function
- 56. Pharmaceutical company sponsored a refreshment break
- 57. Pharmaceutical company has promotional materials available outside of the meeting room
- 58. Pharmaceutical company has a table or booth outside of the meeting room
- 59. Pharmaceutical company banner or sign displayed outside of meeting room
- 60. Pharmaceutical company favors (e.g. pens, magnets, etc.) available to participants
- 61. Promotional materials available for the supporting companies' products that are directly related to the educational program topic.
- 62. Pharmaceutical company offers items of minimal value to program participants that could be primarily associated with the professional's practice (e.g. notepads, pens, cooler)
- 63. Pharmaceutical company offers items of minimal value to program participants that are of personal benefit (e.g. golf balls, music CD, gift certificates)
- 64. Pharmaceutical company offers items
- 65. Pharmaceutical company sponsors or provides entertainment in conjunction with educational program
- 66. Pharmaceutical company sponsors or provides recreational activities (i.e. sporting event, concert, show) in conjunction with educational program
- 67. Pharmaceutical company offers to provide a meal function in conjunction with an educational program that is considered of modest value by local standards
- 68. Pharmaceutical company offers to allow program participants to invite a spouse or guest to a meal function that is offered in conjunction with an educational program

APPENDIX C

PLANNING PRACTICES EXPERT PANEL REVIEW DOCUMENTS

Commercial Support of Pharmacy Continuing Education Questionnaire

Instructions: As you complete the survey, please consider the provision of ACPE-accredited pharmacy continuing education when *indirect support* is received from a pharmaceutical company. (*Please do not consider situations where the pharmaceutical company is the continuing education program sponsor or co-sponsor of record.*)

In your opinion, how common are the following practices in the provision of ACPE-accredited pharmacy continuing education when indirect support is received from a pharmaceutical company?

		Nev	ver	\Leftrightarrow	>	Alw	ays
1.	A pharmaceutical company recommends the program speaker(s)	1	2	3	4	5	6
2.	A program speaker has an existing contractual relationship with a pharmaceutical company	1	2	3	4	5	6
3.	A pharmaceutical company recommends the program topic(s)	1	2	3	4	5	6
4.	A supporting pharmaceutical company has a product related to the program topic	1	2	3	4	5	6

APPENDIX D

CATEGORIZED PLANNING PRACTICES INDICATORS

Program Planning:

- 1. Presence of company representative at planning meetings
- 2. Pharmaceutical company representative involved in planning discussions
- Program provider has adequate time to review all instructional materials and program content prior to delivery
- Program provider requests to review all instructional materials and program content prior to delivery
- 5. Pharmaceutical company assists in establishment of program objectives
- 6. Pharmaceutical company involved with program evaluation
- A written agreement exists between the educational program provider and supporting company
- Program evaluation requests information from participants regarding commercial bias or equitable distribution
- 24. Company requests sponsorship of a program they have developed independently
- 25. Company approached PCE office with program proposal

Speaker:

- 9. Selection of Program Speaker(s)
- 10. Recommendation of Program Speaker(s)
- 11. Program Speaker is employed by a pharmaceutical company
- 12. Program Speaker has an existing contractual relationship with pharmaceutical company
- 13. Program Speaker has a prior relationship with pharmaceutical company
- 14. Pharmaceutical company provides a suggested speakers list
- 15. Pharmaceutical company indirectly pays for program speaker fees
- 16. Pharmaceutical company designates funding to pay for program speaker fees
- 17. Use of (or offer to use) a supporting company-sponsored speaker's bureau
- Program speakers fully disclose to audience any consultant or speaker funding arrangements with the supporting company
- Full disclosure on all educational materials of any relationship between funding organization and program faculty
- Full disclosure during presentation of any relationship between funding organization and program faculty

Topic:

- 19. Selection of Program Topic(s)
- 20. Recommendation of Program Topic(s)
- 21. Supporting company has a product related to the program topic
- 22. Program topic related to the supporting companies' commercial drug, product and/or service

Educational Presentation & Materials:

- 23. Provision of Program Educational Materials (e.g. ppt slides, handouts, etc.)
- Pharmaceutical company representative requests that competing products not be mentioned/included in educational program
- 27. Lack of scientific rigor in program developed independently by a pharmaceutical company
- Lack of scientific rigor in program delivered by a speaker with existing relationship with a pharmaceutical company
- Failure to give equitable balance during program to relevant products not sold by the supporting company

- 32. Supporting company provides curricular materials
- 33. Program Providers offers educational program produced exclusively by pharmaceutical company
- Offer of gratis use of educational program produced independently by the supporting company
- 35. Pharmaceutical company provides program moderators
- 36. Pharmaceutical company offers to provide a "pre-packaged program"
- Speaker provides "friendly treatment" of the supporting companies products during the presentation
- 38. Pharmaceutical company has influence on educational methods utilized during the program
- 39. Pharmaceutical company develops educational program instructional materials

Company Logo:

- 40. Placement of company logo on program-related marketing materials
- 41. Placement of company logo on educational materials (e.g. ppt slides, handouts, etc.)
- 42. Pharmaceutical company banner or logo displayed in the meeting room

Other Indicators of Planning Practices:

- 43. Presence of company representative in meeting room at live programs
- Support of PCE program based on types of pharmacists expected to attend (e.g. clinical pharmacists vs. retail pharmacists)
- 45. Pharmaceutical company has an expressed interest in profile of program participants
- Pharmaceutical company independently advertises or markets the educational program or event
- Full disclosure on all program marketing materials of program provider's relationship with supporting company
- 48. Full disclosure of supporting company funding
- Full disclosure of any significant relationship between the provider, presenter or moderators and the supporting company
- 50. Pharmaceutical company has influence on selection of program venue
- 51. Pharmaceutical company develops educational program promotional materials
- Company promotional materials available during program (e.g. table or display booth setup outside of meeting room)
- 53. Presence of pharmaceutical company representative at meal function
- 54. Presence of pharmaceutical company representative during breaks
- 55. Pharmaceutical company sponsors a meal function
- 56. Pharmaceutical company sponsored a refreshment break
- 57. Pharmaceutical company has promotional materials available outside of the meeting room
- 58. Pharmaceutical company has a table or booth outside of the meeting room
- 59. Pharmaceutical company banner or sign displayed outside of meeting room
- 60. Pharmaceutical company favors (e.g. pens, magnets, etc.) available to participants
- 61. Promotional materials available for the supporting companies' products that are directly related to the educational program topic.
- 62. Pharmaceutical company offers items of minimal value to program participants that could be primarily associated with the professional's practice (e.g. notepads, pens, cooler)
- 63. Pharmaceutical company offers items of minimal value to program participants that are of personal benefit (e.g. golf balls, music CD, gift certificates)
- 64. Pharmaceutical company offers items

- 65. Pharmaceutical company sponsors or provides entertainment in conjunction with educational program

 66. Pharmaceutical company sponsors or provides recreational activities (i.e. sporting event,
- concert, show) in conjunction with educational program
- 67. Pharmaceutical company offers to provide a meal function in conjunction with an educational program that is considered of modest value by local standards
 68. Pharmaceutical company offers to allow program participants to invite a spouse or guest to a meal function that is offered in conjunction with an educational program

APPENDIX E

FIRST DRAFT OF PLANNING PRACTICES SURVEY FOR REVIEW BY ADULT EDUCATION GRADUATE STUDENTS AND FACULTY

Pharmacy Continuing Education Questionnaire

Instructions: As you complete the survey, please consider only pharmacy continuing education programs that are accredited by the American Council on Pharmaceutical Education (ACPE).

In your opinion, how common are the following practices in the provision of ACPE-accredited pharmacy continuing education programs?

		Nev	Never		\Leftrightarrow		vays
1.	A pharmaceutical company representative is involved in program planning discussions	1	2	3	4	5	6
2.	A pharmaceutical company representative assists in establishment of program objectives	1	2	3	4	5	6
3.	A pharmaceutical company representative assists with program evaluation	1	2	3	4	5	6
4.	A pharmaceutical company representative selects the program speaker(s)	1	2	3	4	5	6
5.	A pharmaceutical company representative recommends the program speaker(s)	1	2	3	4	5	6
6.	A program speaker has an existing contractual relationship with a pharmaceutical company	1	2	3	4	5	6
7.	A program speaker is identified through a pharmaceutical company speaker's bureau	1	2	3	4	5	6
8.	A program speaker has an existing contractual relationship with a pharmaceutical company	1	2	3	4	5	6
9.	A pharmaceutical company designates funding to pay for program speaker fees	1	2	3	4	5	6
10.	A pharmaceutical company representative selects the program topic(s)	1	2	3	4	5	6
11.	A pharmaceutical company representative recommends the program topic(s)	1	2	3	4	5	6
12.	A pharmaceutical company provides educational or curricular materials for a program (e.g. slides, handouts)	1	2	3	4	5	6

In your opinion, how common are the following practices in the provision of ACPE-accredited pharmacy continuing education programs?

		Never		\Leftrightarrow		Always	
13.	A program speaker provides "friendly treatment" of a supporting pharmaceutical company's products	1	2	3	4	5	6
14.	The program sponsor reviews all instructional materials and program content prior to delivery	1	2	3	4	5	6
15.	A pharmaceutical company banner or logo is displayed in the meeting room	1	2	3	4	5	6
16.	A pharmaceutical company representative is present in the meeting room during a live program	1	2	3	4	5	6
17.	A pharmaceutical company offers to support a program based on the participant profile (e.g. practice sites of pharmacists expected to attend)	1	2	3	4	5	6
18.	A pharmaceutical company banner or sign is displayed outside of the meeting room	1	2	3	4	5	6
19.	A pharmaceutical company provides promotional materials for a product that is directly related to the educational program topic	1	2	3	4	5	6
20.	A pharmaceutical company offers items of minimal value to program participants that could be primarily associated with the professional's practice (e.g. notepad, pen, mousepad, calendar)	1	2	3	4	5	6
21.	A pharmaceutical company offers items of minimal value to program participants that are of personal benefit (e.g. coffee mug, golf balls, candy, music CD, gift certificates)	1	2	3	4	5	6
22.	A pharmaceutical company sponsors a refreshment break and/or meal function as part of an educational program	1	2	3	4	5	6
23.	A pharmaceutical company sponsors entertainment and/or recreational activities in conjunction with an educational program	1	2	3	4	5	6

Thank you for your participation in this survey critique!

APPENDIX F $\label{eq:second_practices}$ SECOND DRAFT OF PLANNING PRACTICES SURVEY $\label{eq:second_practic} FOR \ EXPERT \ CRITIQUE$

Pharmacy Continuing Education Questionnaire

Instructions: Circle the *one* number that indicates your opinion of the frequency of the following practices in pharmacy continuing education. Please base your responses on your knowledge of continuing education programs for pharmacists that satisfy state requirements for relicensure.

	How frequently do the following practices occur in the provision of pharmacy continuing education?	Never	Sometimes	Often	Always
1.	A pharmaceutical company representative is involved in program planning discussions	0	1	2	3
2.	A pharmaceutical company representative assists with establishment of program objectives	0	1	2	3
3.	A pharmaceutical company representative assists with program evaluation	0	1	2	3
4.	A pharmaceutical company representative selects the program speaker(s)	0	1	2	3
5.	A pharmaceutical company representative recommends the program speaker(s)	0	1	2	3
6.	A program speaker has a contractual relationship with a pharmaceutical company	0	1	2	3
7.	A pharmaceutical company designates funding to pay for program speaker fees	0	1	2	3
8.	A pharmaceutical company representative selects the program topic(s)	0	1	2	3
9.	A pharmaceutical company representative recommends the program topic(s)	0	1	2	3
10.	A pharmaceutical company offers to support a program based on the participant profile (e.g. practice sites of pharmacists expected to attend)	0	1	2	3
11.	The program sponsor reviews all instructional materials and/or program content prior to delivery	0	1	2	3

	How frequently do the following practices occur in the provision of pharmacy continuing education?	Never	Sometimes	Often	Always
12.	A pharmaceutical company provides instructional materials for an educational program (e.g. slides, handouts)	0	1	2	3
13.	A program speaker provides "friendly treatment" of a supporting pharmaceutical company's product(s)	0	1	2	3
14.	A program speaker omits discussion of a relevant product sold by a competing pharmaceutical company	0	1	2	3
15.	A pharmaceutical company has promotional materials available during an educational program	0	1	2	3
16.	A pharmaceutical company representative is present in the meeting room during an educational program	0	1	2	3
17.	A pharmaceutical company banner or logo is displayed inside the meeting room of an educational program	0	1	2	3
18.	A pharmaceutical company sponsors a refreshment break and/or meal function as part of an educational program	0	1	2	3
19.	A pharmaceutical company sponsors entertainment and/or a recreational activity in conjunction with an educational program	0	1	2	3
20.	A pharmaceutical company has promotional materials available outside of the program's meeting room	0	1	2	3
	A pharmaceutical company banner or sign is displayed outside of the program's meeting room	0	1	2	3
22.	A pharmaceutical company offers items of minimal value to program participants that could be primarily associated with the professional's practice (e.g. notepad, pen, mousepad, calendar)	0	1	2	3
23.	A pharmaceutical company offers items of minimal value to program participants that could be considered of personal benefit (e.g. coffee mug, golf balls, candy, music CD, gift certificates)	0	1	2	3

Thank you for your participation in this survey critique!

APPENDIX G

INTERVIEW QUESTIONS FOR EXPERT CRITIQUE OF SECOND DRAFT OF PLANNING PRACTICES SURVEY

Survey Critique

Name:	Date:
Overall, what did you think about the survey (in	
Would you have completed the survey?	
Instructions?	
Item & Response Format?	
Page 1 – Any trouble with items?	
Page 2: Any trouble with items?	
Were any items missing?	
Do all items belong on survey?	

APPENDIX H CONSEQUENCES CONSTRUCT INDICATORS

- 1. Doctors prescribing habits are influenced
- 2. More willing to prescribe new drugs
- 3. Consultations with advice about new drugs
- 4. More likely to prescribe a drug not clinically indicated
- 5. Information from drug company systematically distorted
- Commercially sponsored educational events could run at a fraction of their cost without unnecessary extras -- expensive lunches & entertainment
- 7. Significant reduction in the amount spent on an educational event would not result in a significant loss in educational opportunity
- 8. Blurred boundaries between education and promotion
- 9. Biased curricula
- Commercial support for education is not actually spent on education -- amenities, visual aids, more promotion, meals, entertainment
- 11. Reduces independence of provider
- 12. Drug companies only present favorable research trial results
- 13. Relationships between faculty and drug companies
- 14. Interactions with drug companies influence behavior
- 15. Sponsored research tends to produce favorable results
- 16. Culture of industry gift giving creates entitlements and obligations that conflict with a pharmacist's primary obligation to patients...breeds a long term sense of entitlement....sense of indebtedness to be repaid by support of the patron's drugs.
- Accepting meals and expenses for travel or accommodation for sponsored educational meetings is associated with an increase in formulary requests for the sponsor's drug.
- 18. Drug company sponsored education has preferentially highlight the sponsor's drug.
- 19. The topics being offered reflect the self-interest of the drug company sponsor.
- 20. Academic institutions are allowing themselves to be the paid agents of the pharmaceutical industry.
- 21. Drug company interests drive PCE topics rather than the needs of professionals
- Drug company funding of PCE contributes to rising drug prices, rising volumes of prescriptions written for the newer, more expensive drugs...decrease in prescribing of older, but effective drugs
- 23. Delivery of PCE is strongly dependent on industry funding
- 24. A large portion of PCE has some form of pharmaceutical company influence
- Elimination of industry funding would result in cost prohibitive education for pharmacists
- 26. Pharmaceutical companies are a valued partner in the provision of PCE
- 27. Important educational activities would not take place without drug company support
- Without industry funding/subsidizing conference fees, pharmacists could not afford the cost of education.
- 29. Without the infusion of industry funding, academic ce departments would not be able to operate financially -- (wording)
- 30. Industry's leading role in PCE serves the overriding mutual interest to ensure that patients receive the most up-to-date and appropriate care..and that pharmacists are thoroughly informed about the latest medical developments..provide the most up-to-date health care..patients are the ultimate beneficiary....provides vital information to health care professionals

- 31. Industry funding is crucial, particularly as funding from other private and government sources becomes increasingly uncertain.
- 32. Many PCE courses would not be offered without industry support
- Industry-supported PCE is a valuable way that information about important scientific developments are conveyed to the pharmacy profession for the benefit of the patients served.
- 34. PCE is a marketing tool used by industry
- 35. Financial support is tied to the promotion of a product..is linked to the marketing objectives of a company
- 36. Industry-supported educational activities are slanted in favor of the financial supporter's products more often than competing drugs ...intended to promote sales
- 37. Companies build their market through professional education..strategic value to enhance corporate image and strengthen brands
- 38. PCE is financially and intellectually tied to the pharmaceutical industry
- 39. Industry involvement lessens the expense of PCE to both providers and participants
- 40. Reduces registration fees, cost to participants
- Industry funded education tend to focuses on drug therapy..instead of a more balanced educational experience (disease mgmt, foundational content, communication, patient care skills, etc.)
- 42. More expensive and/or less effective drugs prescribed/carried in formularies/recommended
- 43. Inappropriate therapy
- 44. Decreased registration fees
- 45. Increased pce funding
- 46. Better programs
- 47. Better learning
- 48. Better patient care
- 49. Drives up the instructional costs/faculty honoraria
- 50. Gives unfair advantage
- 51. Boon for provider
- 52. Improves quality
- 53. Improves currency
- 54. Kickbacks
- 55. Better patient care
- 56. Academic cme cannot operate without the support
- 57. Decreasing institutional support
- 58. increases cost of prescription medications
- 59. Cme has become a very important part of marketing strategies
- 60. Allows educational providers to accomplish their educational mission
- 61. Commercial support for base operations funds
- 62. Limits topics offered
- 63. Themes of draft accme commercial support standards: independence, absence of commercial bias, disclosure of information, mgmt of funds, mgmt of advertising & exhibits
- 64. commercial bias favor one product over another
- 65. Contributed funds could be used for an unintended purpose

- 66. Increased dependence on commercial support for pce
- 67. Decreasing financial support from academic institutions
- 68. Increasing honoraria to faculty
- 69. More ce at "pleasure" locations
- 70. Registration fees do not reflect the actual cost of programming
- Academic cme expected to be a profit center for the institution, academic department or program director
- 72. allows pharm co to develop a positive relationship with the pharmacist
- The public perceives that any pharmaceutical company support results in a biased program
- 74. Credibility of academic ce is threatened
- 75. Overt and subtle bias in favor of sponsors and their products
- 76. Drug companies control the agenda for much pce
- 77. Industry funding can urn educational courses into marketing sessions
- 78. Presentation may not give a balanced view of therapeutic options
- 79. Enhance the practice of medicine
- 80. Benefit patients
- 81. Informs healthcare professionals about scientific and educational information
- 82. Informs healthcare professionals about the benefits and risks of products
- 83. Provides scientific and educational information
- 84. Supports medical research and education
- 85. network/communication with healthcare professionals
- 86. ACPE conf: educational materials advance proprietary interests
- 87. Promotional exhibits interfere with educational program
- 88. Honoraria and expenses for faculty are unreasonable
- Relationship creates a sense of duty or loyalty on behalf of ce provider to the commercial interest
- 90. Undue commercial influence on topic selection
- 91. Undue commercial influence on program content
- 92. Undue commercial influence on faculty selection
- 93. PCE program participants more likely to perceive bias or report program is not fair and balanced when commercial support is received for a program.
- 94. CE topics focus on drug therapy topics rather than general pharmacy topics such as skill development, management skills, etc.
- Commercial funding allows greater use of nationally and internationally renowned experts
- 96. Satisfies marketing needs of industry
- 97. Pharmaceutical industry increasingly determines content of pce
- 98. Allows educational conferences to be held in better accommodations
- 99. Encourages brand loyalty
- 100. Help pharmacists keep pace with advances in medical knowledge
- 101. CE programs tilt toward promoting the corporate sponsor's drugs.
- 102. Growing reliance on corporate sponsorship
- 103. Drug companies often determine the overall agenda for ce
- 104. CE topics center around medical conditions that can be treated with expensive brandname drugs and less about subjects from which manufacturers can't profit

- 105. Increased chance that unapproved uses of commercially available drugs are discussed
- 106. Creates culture where pharmacists resist paying even modest amounts for ce
- 107. CE offers pharmaceutical companies a valuable way to communicate with pharmacists
- 108. Contributes to higher drug prices
- 109. Role of pharmacists in exerting an every-increasing influence in the drug-use process cold be compromised through bias introduced into manufacturer-supported programs
- 110. Manufacturers who support pce support only those programs that address areas in which they have products
- 111. Prevents practitioners and their employers from bearing the true cost of their education and training
- Competition with commercial providers results in a reduction of academic and association providers of ce
- 113. Has resulted in easy to attain and potentially lower quality ce
- 114. Ce program may be or may be considered to be promotional in nature
- 115. Program provider does not or not considered to have full control of content.
- 116. Increased chance that alternative treatments are not discussed
- 117. Program reflects sales and marketing goals of the involved pharmaceutical company
- 118. Discussion of unlabeled uses is more prominent
- 119. Increased chance that speakers and/or moderators use a talk scripted by industry or targeted to a specific audience of interest to the supporting company
- 120. Improves relationship between pharmacists and pharmaceutical company
- 121. Pharmacists become more knowledgeable about the industry
- 122. Pharmacists become more familiar with the manufacturing business
- 123. Influences pharmacist on the selection and purchase of drugs
- 124. Increased dependency on the industry for financial support of educational activities
- 125. Academic & industry relationships and roles are heavily intertwined
- 126. Provides pharmacists greater access to disease management information
- 127. Promotes the use of brandname drugs rather than generic drugs
- 128. Influences prescription drug purchases
- 129. Adds to the cost of healthcare
- 130. Makes pharmacists aware of the availability of new drugs
- 131. Penalizes honest companies..if no enforcement, encourages inappropriate acts due to the competition...so everyone on a level playing field.
- 132. Concern about commercial influence on ce has led to increased government regulations and overall attention to the matter.
- 133. Enhanced relations with external bodies (for academy & for industry)
- 134. Future opportunities for research, consulting collaborations for faculty
- 135. Service provided to educational institutions
- 136. Revenue substitution (loss of government funding as private funding increases)
- 137. Departure of faculty to industry

APPENDIX I CONSEQUENCES INDICATORS GROUPING 1

PATIENT CARE: (DRUG THERAPY, RECOMMENDING OR PRESCRIBING A DRUG):

- 1. Doctors prescribing habits are influenced
- 2. More willing to prescribe new drugs
- 3. Consultations with advice about new drugs
- More likely to prescribe a drug not clinically indicated
- 14. Interactions with drug companies influence behavior
- 16. Culture of industry gift giving creates entitlements and obligations that conflict with a pharmacist's primary obligation to patients...breeds a long term sense of entitlement....sense of indebtedness to be repaid by support of the patron's drugs.
- Accepting meals and expenses for travel or accommodation for sponsored educational meetings is associated with an increase in formulary requests for the sponsor's drug.
- 30. Industry's leading role in PCE serves the overriding mutual interest to ensure that patients receive the most up-to-date and appropriate care..and that pharmacists are thoroughly informed about the latest medical developments..provide the most up-to-date health care..patients are the ultimate beneficiary....provides vital information to health care professionals
- Industry-supported PCE is a valuable way that information about important scientific developments are conveyed to the pharmacy profession for the benefit of the patients served.
- 42. More expensive and/or less effective drugs prescribed/carried in formularies/recommended
- 43. Inappropriate therapy
- 48. Better patient care?
- 49. Drives up the instructional costs/faculty honoraria
- 55. Better patient care
- 79. Enhance the practice of medicine
- 80. Benefit patients
- Informs healthcare professionals about scientific and educational information
- 82. Informs healthcare professionals about the benefits and risks of products
- 83. Provides scientific and educational information
- 84. Supports medical research and education
- 100. Help pharmacists keep pace with advances in medical knowledge
- 123. Influences pharmacist on the selection and purchase of drugs
- 126. Provides pharmacists greater access to disease management information
- 127. Promotes the use of brandname drugs rather than generic drugs
- 128. Influences prescription drug purchases
- 130. Makes pharmacists aware of the availability of new drugs

MARKETING:

- 5. Information from drug company systematically distorted
- 12. Drug companies only present favorable research trial results
- 34. PCE is a marketing tool used by industry

- 37. Companies build their market through professional education..strategic value to enhance corporate image and strengthen brands
- 50. Gives unfair advantage
- 51. Boon for provider
- 59. Cme has become a very important part of marketing strategies
- 96. Satisfies marketing needs of industry
- 99. Encourages brand loyalty
- 114. Ce program may be or may be considered to be promotional in nature
- 117. Program reflects sales and marketing goals of the involved pharmaceutical company

FINANCIAL:

- Commercially sponsored educational events could run at a fraction of their cost without unnecessary extras -- expensive lunches & entertainment
- Significant reduction in the amount spent on an educational event would not result in a significant loss in educational opportunity
- Commercial support for education is not actually spent on education -amenities, visual aids, more promotion, meals, entertainment
- Academic institutions are allowing themselves to be the paid agents of the pharmaceutical industry.
- Drug company funding of PCE contributes to rising drug prices, rising volumes of prescriptions written for the newer, more expensive drugs...decrease in prescribing of older, but effective drugs
- 23. Delivery of PCE is strongly dependent on industry funding
- Elimination of industry funding would result in cost prohibitive education for pharmacists
- İmportant educational activities would not take place without drug company support
- Without industry funding/subsidizing conference fees, pharmacists could not afford the cost of education.
- Without the infusion of industry funding, academic ce departments would not be able to operate financially -- (wording)
- 31. Industry funding is crucial, particularly as funding from other private and government sources becomes increasingly uncertain.
- 32. Many PCE courses would not be offered without industry support
- 35. Financial support is tied to the promotion of a product..is linked to the marketing objectives of a company
- 38. PCE is financially and intellectually tied to the pharmaceutical industry
- Industry involvement lessens the expense of PCE to both providers and participants
- 40. Reduces registration fees, cost to participants
- 44. Decreased registration fees
- 45. Increased pce funding
- 53. Improves currency
- 54. Kickbacks

- 56. Academic cme cannot operate without the support
- 57. Decreasing institutional support
- 58. Increases cost of prescription medications
- 61. Commercial support for base operations funds
- 65. Contributed funds could be used for an unintended purpose
- 66. Increased dependence on commercial support for pce
- 67. Decreasing financial support from academic institutions
- 68. Increasing honoraria to faculty
- 69. More ce at "pleasure" locations
- 70. Registration fees do not reflect the actual cost of programming
- Academic cme expected to be a profit center for the institution, academic department or program director
- 77. Industry funding can urn educational courses into marketing sessions
- 88. Honoraria and expenses for faculty are unreasonable
- 102. Growing reliance on corporate sponsorship
- 106. Creates culture where pharmacists resist paying even modest amounts for ce
- 108. Contributes to higher drug prices
- Increased dependency on the industry for financial support of educational activities
- 129. Adds to the cost of healthcare
- Revenue substitution (loss of government funding as private funding increases)

EDUCATION:

- 8. Blurred boundaries between education and promotion
- Biased curricula
- Drug company sponsored education has preferentially highlight the sponsor's drug.
- The topics being offered reflect the self-interest of the drug company sponsor.
- Drug company interests drive PCE topics rather than the needs of professionals
- A large portion of PCE has some form of pharmaceutical company influence
- 26. Pharmaceutical companies are a valued partner in the provision of PCE
- Industry-supported educational activities are slanted in favor of the financial supporter's products more often than competing drugs ...intended to promote sales
- Industry funded education tend to focuses on drug therapy..instead of a more balanced educational experience (disease mgmt, foundational content, communication, patient care skills, etc.)
- 46. Better programs
- 47. Better learning
- 52. Improves quality
- 60. Allows educational providers to accomplish their educational mission

- 62. Limits topics offered
- 64. Commercial bias favor one product over another
- The public perceives that any pharmaceutical company support results in a biased program
- 74. Credibility of academic ce is threatened
- 75. Overt and subtle bias in favor of sponsors and their products
- 76. Drug companies control the agenda for much pce
- 78. Presentation may not give a balanced view of therapeutic options
- 86. Educational materials advance proprietary interests
- 87. Promotional exhibits interfere with educational program
- 90. Undue commercial influence on topic selection
- 91. Undue commercial influence on program content
- 92. Undue commercial influence on faculty selection
- PCE program participants more likely to perceive bias or report program is not fair and balanced when commercial support is received for a program.
- CE topics focus on drug therapy topics rather than general pharmacy topics such as skill development, management skills, etc.
- Commercial funding allows greater use of nationally and internationally renowned experts
- 97. Pharmaceutical industry increasingly determines content of pce
- 98. Allows educational conferences to be held in better accommodations
- 101. CE programs tilt toward promoting the corporate sponsor's drugs.
- 103. Drug companies often determine the overall agenda for ce
- 104. CE topics center around medical conditions that can be treated with expensive brand-name drugs and less about subjects from which manufacturers can't profit
- Increased chance that unapproved uses of commercially available drugs are discussed
- 109. Role of pharmacists in exerting an every-increasing influence in the druguse process cold be compromised through bias introduced into manufacturer-supported programs
- 110. Manufacturers who support pce support only those programs that address areas in which they have products
- 111. Prevents practitioners and their employers from bearing the true cost of their education and training
- 112. Competition with commercial providers results in a reduction of academic and association providers of ce
- 113. Has resulted in easy to attain and potentially lower quality ce
- 115. Program provider does not or not considered to have full control of content.
- 116. Increased chance that alternative treatments are not discussed
- 118. Discussion of unlabeled uses is more prominent
- 119. Increased chance that speakers and/or moderators use a talk scripted by industry or targeted to a specific audience of interest to the supporting company

RELATIONSHIPS WITH INDUSTRY:

13. Relationships between faculty and drug companies

- 15. Sponsored research tends to produce favorable results
- 72. Allows pharm co to develop a positive relationship with the pharmacist
- 85. Network/communication with healthcare professionals
- 89. Relationship creates a sense of duty or loyalty on behalf of ce provider to the commercial interest
- 107. CE offers pharmaceutical companies a valuable way to communicate with pharmacists
- 120. Improves relationship between pharmacists and pharmaceutical company
- 121. Pharmacists become more knowledgeable about the industry
- 122. Pharmacists become more familiar with the manufacturing business
- 125. Academic & industry relationships and roles are heavily intertwined
- 133. Enhanced relations with external bodies (for academy & for industry)
- 134. Future opportunities for research, consulting collaborations for faculty
- 137. Departure of faculty to industry

OTHER

- 11. Reduces independence of provider
- 63. Themes of draft accme commercial support standards: independence, absence of commercial bias, disclosure of information, mgmt of funds, mgmt of advertising & exhibits
- 131. Penalizes honest companies..if no enforcement, encourages inappropriate acts due to the competition...so everyone on a level playing field.
- 132. Concern about commercial influence on ce has led to increased government regulations and overall attention to the matter.
- 135. Service provided to educational institutions

APPENDIX J CONSEQUENCES INDICATORS GROUPING 2

SELECTION & PURCHASE OF DRUGS

Selection and Recommendation of Drugs:

- 3. Consultations with advice about new drugs
- 14. Interactions with drug companies influence pharmacist's behavior
- 16b. Culture of industry gift giving breeds a long-term sense of entitlement/indebtedness to be repaid by support of the patron's drugs.
- 22d. Drug company funding of PCE contributes to decrease in recommendation of older, but still effective drugs
- 22e. Drug company funding of PCE contributes to rising volumes of prescriptions recommended for the newer, more expensive drugs
- 42. More expensive and/or less effective drugs are recommended
- 99. Encourages brand loyalty
- 123a. Influences pharmacist on the selection of drugs
- 127. Promotes the use of brandname drugs rather than generic drugs

Drug Purchase:

- Accepting meals and expenses for travel or accommodation for sponsored educational meetings is associated with an increase in formulary requests for the sponsor's drug.
- 42b. More expensive and/or less effective drugs are carried in formularies
- 123b. Influences pharmacist on the purchase of drugs
- 128. Influences prescription drug purchases

PATIENT CARE

- 16a. Culture of industry gift giving creates entitlements and obligations that conflict with a pharmacist's primary obligation to patients
- 30a. Industry's leading role in PCE serves the overriding mutual interest to ensure that patients receive the most appropriate health care.
- 30c. Industry's leading role in PCE serves the overriding mutual interest to ensure that healthcare professionals provide the most up-to-date health care.
- 30d. Industry's leading role in PCE serves the overriding mutual interest to ensure that: patients are the ultimate beneficiary
- Industry-supported PCE is a valuable way that information about important scientific developments are conveyed to the pharmacy profession for the benefit of the patients served.
- 43. Inappropriate therapy
- 55. Better patient care
- 79. Enhance the practice of medicine
- 80. Benefits patients

DRUG INFORMATION

- 30b. Industry's leading role in PCE serves the overriding mutual interest to ensure that pharmacists are thoroughly informed about the latest medical developments
- 30e. Industry's leading role in PCE serves the overriding mutual interest to provide vital information to health care professionals
- 81a. Informs healthcare professionals about scientific information
- 81b. Informs healthcare professionals about educational information
- 82a. Informs healthcare professionals about the benefits of products
- 82b. Informs healthcare professionals about the risks of products

- 100. Help pharmacists keep pace with advances in medical knowledge
- 126. Provides pharmacists greater access to disease management information
- 130. Makes pharmacists aware of the availability of new drugs

PHARMACEUTICAL COMPANY-SPONSORED RESEARCH

- 12. Drug companies only present favorable research trial results
- 15. Sponsored research tends to produce favorable results

MARKETING/PROMOTION

- 34. PCE is a marketing tool used by industry
- 35a. Financial support is tied to the promotion of a product
- 35b. Financial support is linked to the marketing objectives of a company
- 37a. Companies build their market through professional education
- 37b. Of strategic value to enhance corporate image and strengthen brands
- 59. CME has become a very important part of marketing strategies
- 77. Industry funding can turn educational courses into marketing sessions
- 96. Satisfies marketing needs of industry
- 114. CE program may be or may be considered to be promotional in nature
- 117. Program reflects sales and marketing goals of the involved pharmaceutical company

FINANCIAL

General - PCE & Commercial Funding:

- Significant reduction in the amount spent on an educational event would not result in a significant loss in educational opportunity
- 23. Delivery of PCE is strongly dependent on industry funding
- 27. Important educational activities would not take place without drug company support
- 32. Many PCE courses would not be offered without industry support
- 38a. PCE is financially tied to the pharmaceutical industry
- 45. Increased pce funding
- 66. Increased dependence on commercial support for pce
- 102. Growing reliance on corporate sponsorship
- 124. Increased dependency on the industry for financial support of educational activities

Provider Costs/Funding:

- Academic institutions are allowing themselves to be the paid agents of the pharmaceutical industry.
- 29. Without the infusion of industry funding, academic ce departments would not be able to operate financially -- (wording)
- 31. Industry funding is crucial, particularly as funding from other private and government sources becomes increasingly uncertain.
- 39a. Industry involvement lessens the expense of PCE to providers
- 51. Boon for provider
- 53. Improves currency
- 56. Academic cme cannot operate without the support
- 57. Decreasing institutional support
- 61. Commercial support for base operations funds
- 65. Contributed funds could be used for an unintended purpose
- 67. Decreasing financial support from academic institutions

- 71. Academic cme expected to be a profit center for the institution, academic department or program director
- 136. Revenue substitution (loss of government funding as private funding increases)

Cost of Educational Programs:

- 49. Drives up the instructional costs/faculty honoraria
- 68. Increasing honoraria to faculty
- 88. Honoraria and expenses for faculty are unreasonable

Cost of Activities/Amenities outside of Educational Program:

- Commercially sponsored educational events could run at a fraction of their cost without unnecessary extras-expensive lunches & entertainment
- 10. Commercial support for education is not actually spent on education—amenities, visual aids, more promotion, meals, entertainment
- 69. More ce at "pleasure" locations
- 98. Allows educational conferences to be held in better accommodations

Cost to Participants:

- 25. Elimination of industry funding would result in cost prohibitive education for pharmacists
- Without industry funding/subsidizing conference fees, pharmacists could not afford the cost of education.
- 39b. Industry involvement lessens the expense of PCE to participants
- 40. Reduces registration fees, cost to participants
- 44. Decreased registration fees
- 70. Registration fees do not reflect the actual cost of programming
- 106. Creates culture where pharmacists resist paying even modest amounts for ce
- 111. Prevents practitioners and their employers from bearing the true cost of their education and training

Cost of Drugs & Healthcare:

- 22a. Drug company funding of PCE contributes to rising drug prices
- 58. Increases cost of prescription medications
- 108. Contributes to higher drug prices
- 129. Adds to the cost of healthcare

PCE PROGRAMS

Educational Value:

- 46. Better programs
- 47. Better learning
- 52. Improves quality
- 113a. Has resulted in easy to attain ce
- 113b. Has resulted in potentially lower quality ce

Program Topics:

- The topics being offered reflect the self-interest of the drug company sponsor.
 Drug company interests drive PCE topics rather than the needs of professionals

- 62. Limits topics offered
- 64. Commercial bias favor one product over another
- The public perceives that any pharmaceutical company support results in a biased program
- 74. Credibility of academic ce is threatened
- 75. Overt and subtle bias in favor of sponsors and their products
- 76. Drug companies control the agenda for much pce
- 78. Presentation may not give a balanced view of therapeutic options
- 86. Educational materials advance proprietary interests
- 87. Promotional exhibits interfere with educational program
- 90. Undue commercial influence on topic selection
- 91. Undue commercial influence on program content
- 92. Undue commercial influence on faculty selection
- PCE program participants more likely to perceive bias or report program is not fair and balanced when commercial support is received for a program.
- CE topics focus on drug therapy topics rather than general pharmacy topics such as skill development, management skills, etc.
- Commercial funding allows greater use of nationally and internationally renowned experts
- 97. Pharmaceutical industry increasingly determines content of pce
- 98. Allows educational conferences to be held in better accommodations
- 101. CE programs tilt toward promoting the corporate sponsor's drugs.
- 103. Drug companies often determine the overall agenda for ce
- 104. CE topics center around medical conditions that can be treated with expensive brand-name drugs and less about subjects from which manufacturers can't profit
- Increased chance that unapproved uses of commercially available drugs are discussed
- 109. Role of pharmacists in exerting an every-increasing influence in the druguse process cold be compromised through bias introduced into manufacturer-supported programs
- 110. Manufacturers who support pce support only those programs that address areas in which they have products
- 111. Prevents practitioners and their employers from bearing the true cost of their education and training
- 112. Competition with commercial providers results in a reduction of academic and association providers of ce
- 113. Has resulted in easy to attain and potentially lower quality ce
- 115. Program provider does not or not considered to have full control of content.
- 116. Increased chance that alternative treatments are not discussed
- 118. Discussion of unlabeled uses is more prominent
- 119. Increased chance that speakers and/or moderators use a talk scripted by industry or targeted to a specific audience of interest to the supporting company

RELATIONSHIPS WITH INDUSTRY:

13. Relationships between faculty and drug companies

- 134. Future opportunities for research, consulting collaborations for faculty
- 137. Departure of faculty to industry

MISCELLANEOUS

Bias:

- Information from drug company systematically distorted
- 50. Gives unfair advantage
- The public perceives that any pharmaceutical company support results in a biased program
- 75. Overt and subtle bias in favor of sponsors and their products
- 93. PCE program participants more likely to perceive bias or report program is not fair and balanced when commercial support is received for a program.
- 109. Role of pharmacists in exerting an every-increasing influence in the drug-use process could be compromised through bias introduced into manufacturer-supported programs

Providers:

- 11. Reduces independence of provider
- 60. Allows educational providers to accomplish their educational mission
- 74. Credibility of academic ce is threatened
- Competition with commercial providers results in a reduction of academic and association providers of ce
- 135. Service provided to educational institutions

PCE Programs in General:

- 8. Blurred boundaries between education and promotion
- 24. A large portion of PCE has some form of pharmaceutical company influence
- 26. Pharmaceutical companies are a valued partner in the provision of PCE
- 38b. PCE is intellectually tied to the pharmaceutical industry
- 76. Drug companies control the agenda for much pce

Other:

- 131. Penalizes honest companies..if no enforcement, encourages inappropriate acts due to the competition...so everyone on a level playing field.
- 132. Concern about commercial influence on ce has led to increased government regulations and overall attention to the matter.

Deleted Indicators:

- 48. Better patient care (duplicate)54. Kickbacks (not an indicator)
- 63. Themes of draft accme commercial support standards: (not an indicator)
 - a. independence
 - b. absence of commercial bias
 - c. disclosure of information
 - d. mgmt of funds
 - e. mgmt of advertising & exhibits
- 83. Provides scientific and educational information (duplicate)
- 84. Supports medical research and education (duplicate)

- Prescribing (CME/Physicians only):

 1. Doctors prescribing habits are influenced
 2. More willing to prescribe new drugs

 - More likely to prescribe a drug not clinically indicated
 - 22b. Drug company funding of PCE contributes to rising volumes of prescriptions written for the newer, more expensive drugs
 - 22c. Drug company funding of PCE contributes to decrease in prescribing of older, but still effective drugs
 - 42a. More expensive and/or less effective drugs are prescribed

APPENDIX K CONSEQUENCES INDICATORS GROUPING 3

Provider:

- 6 Increased program costs due to unnecessary extras (e.g. expensive meals)
- $_{10}$ $\,\,$ Funding being used for non-essential items (e.g. amenities, visual aids, more promotion, meals, entertainment)
- 11 Reduced independence of providers
- 20 Academic institutions allowing themselves to be paid agents of the pharmaceutical industry
- 23 Strong dependency on industry funding
- 26 Pharmaceutical companies being a valued partner in the provision of PCE
- 29 Allows academic PCE departments to operate financially
- 31 Is crucial, particularly as funding from other private and government sources becomes increasingly uncertain.
- 45 Increased funding for continuing education
- 49 Increased instructional costs/faculty honoraria
- 53 Improved currency for PCE providers
- 56 Allows academic cme to operate financially
- 57 Decreased institutional support
- 60 Educational providers being able to accomplish their educational mission
- 61 A provider's need for this funding for base operational funds
- 65 The contributed funds being used for an unintended purpose
- 66 Increased dependence on commercial support for operation of continuing education
- 67 Decreased financial support from academic institutions
- 68 Increasing honoraria to faculty
- 69 More programs held at "pleasure" locations
- An expectation that academic continuing education units be a profit center for the
- institution, academic department or program director
- 73 Public perception of a biased program
- 74 Decreased credibility of academic ce
- 88 Unreasonable honoraria and expenses for faculty
- A relationship that creates a sense of duty or loyalty on behalf of a continuing education provider toward the commercial interest
- 98 More educational conferences held in better accommodations
- 102 A growing reliance on corporate sponsorship
- A reduction of academic and association providers due to competition with commercial providers (about providers not commercial support??)
- $115 \quad \text{The program provider either not having or not considered to have full control of content} \\$
- 124 Increased dependency on the industry for financial support of educational activities
- 132 Increased government regulation and overall attention to the matter34.
- 135 Is a service provided to educational institutions
- 136 Revenue substitution (i.e. loss of government funding as private funding increases)
- 39a. Lessens the expense for PCE providers
- 93a. An increase in a participant's perception of bias
- 93b. An increase in reports that educational programs are not fair and balanced

Patient:

- A conveyance of information about important scientific developments for the benefit of the
- 33 patients served
- 43 Inappropriate therapy
- 55 Better patient care
- 58 Contributes to increased cost of prescription medications
- 108 Contributes to higher drug prices
- 129 Adds to the cost of healthcare
- 22a. Contributes to rising drug prices
- 30a. An assurance that patients receive the most appropriate health care
- 30c. An assurance that pharmacists provide the most up-to-date health care
- 30d. An assurance that patients are the ultimate beneficiary
- 3a. A pharmacist giving advice to a patient about new drugs featured in a program

Pharmacy Practice:

- 17 An increase in formulary requests for the sponsor's drug.
- 99 Brand loyalty on behalf of a pharmacist
- A compromise to the pharmacist's role in exerting an every-increasing influence in the drug-use process due to bias introduced into manufacturer-supported programs
- Promotion of brandname rather than generic drugs (w/iprogram or by pharmacist?)
- 128 Influence on prescription drug purchases
- 123a. Influence on a pharmacist's selection of drugs (recommendation or purchase?)
- 123b. Influence on the purchase of drugs
- 16b. A culture of industry gift giving that breeds a pharmacist's long-term sense of indebtedness
- to be repaid by support of the patron's drug(s)

 2d. A decrease in recommendation of older, but still effective drugs
- 22e. A rising volume of prescriptions recommended for newer and/or more expensive drugs
- 3b. A pharmacist giving advice to a physician about new drugs featured in a program
- 42a. Recommendation of more expensive drugs
- 42b. Recommendation of less effective drugs
- 42c. More expensive and/or less effective drugs carried in formularies

Learner:

- 9 Biased curricula
- 12 Presentation of only favorable research trial results in the continuing education program
- 18 Education that preferentially highlights the sponsor's drug.
- 19 Topics that reflect the self-interest of the drug company sponsor.
- 21 Drug company interests, rather than the needs of professionals, driving PCE topics
- 25 If reduced or eliminated, would result in cost prohibitive education for pharmacists
- 27 Allows important educational activities to take place
- 28 Affordable educational costs for pharmacists
- 32 Allows the provision of many programs that would not be offered without this support
- 40 Reduced registration fees (i.e. cost to participants)
 - A focus on drug therapy, rather than a more balanced educational experience (e.g. disease
- 41 mgmt, foundational content, communication, patient care skills, etc.)
- 44 Decreased registration fees
- 46 Better educational programs
- 47 Better learning
- 52 Improved educational quality

- Limited topics offered 62
- Commercial bias (i.e. favors one product over another) 64
- 70 Registration fees that do not reflect the actual cost of programming
- 72 A drug company's positive relationship with pharmacists
- 75 Overt and subtle bias in favor of sponsors and their products
- Drug company control of the agenda for much of PCE
- 76 77 Can turn educational courses into marketing sessions
- 78 A presentation that does not give a balanced view of therapeutic options
- 85 A drug company networking/communicating with pharmacists
- Educational materials that advance proprietary interests 86
- 87 Promotional exhibits that interfere with the educational program
- Undue commercial influence on topic selection 90
- 91 Undue commercial influence on program content
- Undue commercial influence on faculty selection 92
 - CE topics focused on drug therapy rather than general pharmacy topics such as skill
- 94 development, management skills, etc.
- 95 Increased use of nationally and internationally renowned experts
- The pharmaceutical industry increasingly determining the content of PCE 97
- Pharmacists keeping pace with advances in medical knowledge 100
- Educational programs that tilt toward promoting the corporate sponsor's drugs 101 CE topics centered around medical conditions that can be treated with expensive brand-
- 104 name drugs and less about subjects from which manufacturers can't profit
- An increased chance that unapproved use of commercially available drugs are discussed 105
- 106 A culture where pharmacists resist paying even modest amounts for continuing education
- Is a valuable way that drug companies can communicate with pharmacists 107 Support of only those programs that address areas in which the manufacturer has
- 110 product(s)
- Practitioners and their employers prevented from bearing the true cost of their education
- and training 111
- 114 An educational program considered to be promotional in nature
- Increased chance that alternative treatments are not discussed 116
- 118 Discussion of a product's unlabeled uses
- An improved relationship between pharmacists and pharmaceutical companies 120
- Pharmacists becoming more knowledgeable about the drug industry 121
- 122 Pharmacists becoming more familiar with the manufacturing business
- 126 Greater access to disease management information
- 130 A pharmacist's awareness of the availability of new drugs
- Easy to attain continuing education 113a.
- 113b. Potentially lower quality continuing education
- Increased chance that speakers and/or moderators use a talk scripted by industry 119a Increased chance that speakers and/or moderators use a talk targeted to a specific
- 119b audience of interest to the supporting company A culture of entitlements and obligations that conflict with a pharmacist's primary
- obligation to patients 16a. An assurance that pharmacists are thoroughly informed about the latest medical
- 30b. developments
- Provision of vital information to pharmacists 30e.
- 36a. Educational activities intended to promote sales
 - Educational activities that are slanted in favor of the financial supporter's products more
- 36a. often than competing drugs
- Has caused PCE to be financially tied to the pharmaceutical industryDeleted Indicators: 38a.
- 38b. Educational programs that are intellectually tied to the pharmaceutical industry
- 39b. Lower expense for participants

- 81a. Information to pharmacists about scientific information
- Information to pharmacists about educational information 81b.
- Information to pharmacists about the benefits of products 82a.
- 82b. Information to pharmacists about the risks of products

Other:

- A relationship between faculty and drug companies 13
- 50 A drug company's unfair advantage
- Is a very important part of the marketing strategies of companies
- 96
- 117
- Satisfies marketing needs of industry
 Reflects sales and marketing goals of the involved pharmaceutical company
 Academic & industry relationships and roles that are heavily intertwined 125 Honest companies are penalized if no enforcement of policies and regulations, penalizes.
- encourages inappropriate acts due to the competition...so everyone on a level playing field.
- Enhanced relations with external bodies for both academy and for industry Future opportunities for research and consulting collaborations for faculty 133
- 134
- 137 A departure of faculty to industry
- 35a. Is tied to the promotion of a product
- 35b. Is linked to the marketing objectives of a company 37a. Is a way for companies to build their market
- 37b. Is of strategic value to companies to enhance their corporate image
- 37c. Is of strategic value to companies to strengthen brands

APPENDIX L EXPERT SURVEY CRITQUE DOCUMENTS

Commercial Support of Continuing Education Questionnaire Survey Critique

Thank you for agreeing to provide an expert critique of this survey instrument, related documents and administration procedures. In addition to the attached documents, I will also be emailing you a link and password for the online questionnaire. Attached is a hard copy of the questionnaire to assist you in noting questions or suggestions as you complete the online version. As you work through the online questionnaire, please choose responses for the items to test the survey administration procedures; however, please know that I am not tracking or analyzing your data and will delete any responses you provide after the critique is complete.

Below are the items I would like to review with you later this week:

Correspondence: Pre-notification email, request for participation email, and implied consent form:

- Would you have completed the survey if you had received the email messages and read the implied consent form?
- Did you have any problems or questions regarding these documents?

Online Questionnaire:

Overall Impressions

- What was your overall reaction to the survey?
- How did you think it looked?
- · Was there anything about the format that made the survey difficult to complete?
- Did you have any problems or questions in a general sense?
- How long did it take you to complete the questionnaire?

Entry Webpage

 Did you have any problems or questions about the instructions or information provided on the initial URL that was provided?

Page-by-Page Review of Items

- For each page of the survey, did you have any questions or concerns about the guiding question, response format and/or individual items?
- Were there any items you didn't want to respond to?
- · Did you have any problems interpreting any of the items?

Thanks again for your assistance. I look forward to speaking with you later this week!

Jayne L. Smith 706-542-5288 jsmith@mail.rx.uga.edu

Email Pre-Notification of Study

Planned distribution date: March 29, 2004

Subject Line: Commercial Support of Continuing Pharmacy Education: Pre-Notification of Study

UNIVERSITY OF GEORGIA

DEPARTMENT OF ADULT EDUCATION

Commercial Support of Continuing Pharmacy Education Survey

We are currently involved in a study of commercial support of continuing education for pharmacists. The past year has been spent researching the many perspectives and dilemmas of commercial support of continuing education programs. We now need your help to successfully complete a study of this issue.

We have created a questionnaire that will help in a better understanding of how commercial support impacts the practice of planning continuing pharmacy education programs and the outcomes for program providers, pharmacists and patients. The questionnaire is designed for planners of continuing pharmacy education programs to report on their knowledge as a continuing pharmacy education program planner, faculty and/or participant.

Within a few days, you will receive an email request to complete the online questionnaire. We would greatly appreciate if you would take 15 minutes of your time to complete and submit the questionnaire.

If there are continuing pharmacy education program planners in your organization who could respond to this survey, please either forward the email request for participation that will be sent to you within a few days, or send their email address(es) to the study director at jsmith@mail.rx.uga.edu. In addition, please send an email to the study director if you would like to be removed from this study group listsery.

Thanks in advance for your help in completing our research study.

Javne L. Smith Ron Cervero

Study Director Professor and Department Head

University of Georgia Adult Education

University of Georgia

Email Request For Participation in Study

Planned distribution date: March 31, 2004

Subject Line: Commercial Support of Continuing Pharmacy Education: Request for Participation

UNIVERSITY OF GEORGIA

DEPARTMENT OF ADULT EDUCATION

Commercial Support of Continuing Pharmacy Education Survey

Dear Fellow Pharmacy Continuing Educator:

Over the years, commercial support has played a central and growing role in the provision of continuing pharmacy education. Much attention has been cast on this issue recently in journal articles, at professional conferences, and through emerging policies and regulations. We now need your help to successfully complete a study on commercial support of continuing pharmacy education.

As a full-time pharmacy continuing educator, as well as a doctoral candidate under the direction of Dr. Ron Cervero, I am currently involved in a research study to explore how commercial support impacts the practice of planning continuing pharmacy education programs and the consequences for the provider organization, pharmacists, and patients. We hope this information will be useful to all administrators and planners of continuing pharmacy education.

We hope you will agree to be part of this study. The online questionnaire will require no more than 15 minutes to complete. Your expertise and participation are very important to the success of this study.

Of course, your participation is voluntary. All data that you provide will be confidential and only summary data will be reported at the conclusion of the study. An implied consent form is available at the below website for review prior to entry to the online survey. The results of the survey will be made available to you after the study is complete by sending an email request to jsmith@mail.rx.uga.edu.

You can access the online survey via the URL and password below:

URL: to be added Password: to be added

Feel free to forward this request for participation to other continuing pharmacy education program planners in your organization who you feel could contribute to this research study. In addition, please send an email to the study director at jsmith@mail.rx.uga.edu if you would like your email address removed from this study group listsery.

We are available to answer any questions you might have by sending an email to <u>jsmith@mail.rx.uga.edu</u> or calling (706) 542-5288.

Thank you in advance for your assistance.

Sincerely,

Javne L. Smith Ron Cervero

Study Director Professor and Department Head

University of Georgia Adult Education
University of Georgia



Thank you in advance for taking the time to complete this survey!

Commercial support plays a central role in the provision of continuing pharmacy education and your expertise as a program planner will help us in a better understanding of the many dimensions of this important issue.

- Your participation is voluntary and the results will be kept confidential. For more information about your rights in agreeing to participate in this study, click here to review the *Implied Consent* Form.
- There are a total of 59 items on the questionnaire and it should take no more than 15 minutes to complete.
- Maximize your browser window for easiest viewing of the online questionnaire.
- The password is available in the request for participation that was emailed to you.
- Please base all of your responses on your knowledge as a planner of continuing pharmacy education programs approved by the Accreditation Council for Pharmacy Education (ACPE). If applicable, please also base your responses on your knowledge of ACPEapproved continuing pharmacy education programs as a program faculty and/or program participant.
- If you prefer to print and submit your questionnaire via mail or fax, you can open a pdf version by clicking here [URL to be added] and submit via fax or U.S. mail.
- If you have any questions or problems, please contact the Survey Director, Jayne L. Smith, at jsmith@mail.rx.uga.edu or call (706) 542-5288.

If you are a planner of ACPE-approved continuing pharmacy education programs:

Click Here to Begin the Survey

http://www.rx.uga.edu/main/home/ce_dept/survey/index.htm

2/1/2004



Implied Consent Form

This is notification of implied consent for the research study titled *Provision of Commercial Support for Continuing Pharmacy Education: Practices and Consequences*. The purpose of this research is to understand the impact of commercial support on the provision and outcomes of continuing pharmacy education. Please know that this research activity is being conducted by the below individuals and may be published.

Jayne L. Smith
Study Director
University of Georgia
(706) 542-5288
jsmith@mail.rx.uga.edu
Add Complete address & phone numbers

Ron Cervero Professor and Department Head Adult Education University of Georgia

Your participation is voluntary. You may withdraw at any time without penalty, or skip any questions that you feel uncomfortable answering. It should take approximately 15 minutes to complete the online questionnaire.

All of your responses will be confidential and will not be associated with your name or email address; however, a unique number will be assigned to each respondent through use of a "cookie" that has no meaning outside of the survey website. If necessary, this will allow each respondent to return to an incomplete survey and be taken directly to the point of exit.

Please note the following:

Internet communications are insecure and there is a limit to the confidentiality that can be guaranteed due to the technology itself. However, once the completed survey is received by the researchers, standard confidentiality procedures will be followed. In addition, only summary data will be reported.

In addition, given that communication via the Internet is more risky in regards to privacy, if you prefer, you can open a pdf version of the survey instrument located at *URL* to be added, complete by hand, and then submit via fax or US mail to:

Jayne L. Smith Study Director Mailing address (give adult ed or cop??) Fax number

If you have any questions, do not hesitate to ask now or at a later date. You may contact Jayne L. Smith, Study Director at (706)542-5288 or issmith@mail.rx.uga.edu.

Additional questions or problems regarding your rights as a research participant should be addressed to Chris A. Joseph, Ph.D., Human Subjects Office, University of Georgia, 612 Boyd Graduate Studies Research Center, Athens, Georgia 30602-7411; Telephone (706) 542-3199; E-Mail Address IRB@uga.edu

>>RETURN TO SURVEY<<



Commercial Support of Continuing Pharmacy Education Questionnaire

Items 1-8 of 59

Think about all of the continuing pharmacy education programs approved by ACPE over the last few years that you know received commercial support. FOR WHAT PERCENTAGE OF THOSE PROGRAMS do you think the following practices occurred?

	0%	1- 25%	26- 50%	51- 75%	76- 99%	100%
1. A pharmaceutical company representative assisted with establishment of program objectives))))))
2. A pharmaceutical company representative <i>recommended</i> the program topic(s)						
3. A pharmaceutical company representative <i>selected</i> the program topic(s))	J)	J))
4. A program speaker had an existing relationship with a pharmaceutical company						
5. A pharmaceutical company designated funding to pay for program speaker fees))	J)	J)
6. A pharmaceutical company representative <i>recommended</i> the program speaker						
7. A pharmaceutical company representative <i>selected</i> the program speaker(s)	J	J	J)	J	J
8. A pharmaceutical company offered to support a program based on the participant profile (e.g. practice sites of pharmacists expected to attend)						



Commercial Support of Continuing Pharmacy Education Questionnaire

Items 9-16 of 59

Think about all of the continuing pharmacy education programs approved by ACPE over the last few years that you know received commercial support. FOR WHAT PERCENTAGE OF THOSE PROGRAMS do you think the following practices occurred?

	0%	1-25%	26-50%	51-75%	76-99%	100%
A pharmaceutical company representative assisted with program evaluation)))	J))
10. A presentation was scripted by a pharmaceutical company	0					
11. A presentation was targeted to a specific audience of interest to the supporting company	J))	J	J	J
12. The program provider reviewed all instructional materials and program content prior to delivery						
13. A pharmaceutical company provided instructional materials to a program speaker (e.g. slides, handouts))	J)))	J
14. A program speaker provided preferential treatment of the supporting pharmaceutical company's product(s)						U
15. A program speaker omitted discussion of a relevant product sold by a competing pharmaceutical company)	J)	J)	J
16. A pharmaceutical company had promotional literature (e.g. brochures, pamphlets) available in the classroom during a program	U					



Commercial Support of Continuing Pharmacy Education Questionnaire

Items 17-24 of 59

Think about all of the continuing pharmacy education programs approved by ACPE over the last few years that you know received commercial support. FOR WHAT PERCENTAGE OF THOSE PROGRAMS do you think the following practices occurred?

	0%	1-25%	26-50%	51-75%	76-99%	100%
17. A pharmaceutical company representative was present in the classroom during a program))))))
18. A pharmaceutical company banner or logo was displayed in the classroom					0	
19. A pharmaceutical company sponsored a refreshment break and/or meal function as part of a program)))))	J
20. A pharmaceutical company sponsored entertainment and/or a recreational activity in conjunction with a program						
21. A pharmaceutical company had promotional literature (e.g. brochures, pamphlets) available outside of the classroom	J))))	J
22. A pharmaceutical company banner or sign was displayed outside of the classroom				0		0
23. A pharmaceutical company offered items of minimal value to participants that could be primarily associated with practice (e.g. notepad, pen, mousepad, calendar))	J))	J	J
24. A pharmaceutical company offered items of minimal value to participants that could be considered of personal benefit (e.g. coffee mug, golf balls, candy)			U			



Commercial Support of Continuing Pharmacy Education Questionnaire

Items 25-38 of 59

In your opinion, what is the effect of commercial support of continuing pharmacy education on the following outcomes?

	Decrease due to commercial support	Not Affected by commercial support	Increase due to commercial support
25. Overall revenue of continuing pharmacy education providers)))
26. Institutional funding for pharmacy continuing education providers	0		0
27. A continuing pharmacy education provider's financial dependency on industry)))
28. A continuing pharmacy education provider's allegiance to a supporting pharmaceutical company	0		9
29. Overall cost of continuing pharmacy education programs due to non-educational expenses (e.g. breaks, meals, and/or facilities)	J))
30. Faculty honoraria and fees		0	
31. Use of nationally and internationally renowned experts as program faculty)	J)
32. Program registration fees for participants	0	0	
33. Willingness of pharmacists to incur the full cost of a continuing pharmacy education program)))
34. Pharmaceutical company influence on program content			
35. A continuing pharmacy education provider's control of program quality	J))
36. Overall variety of program topics offered		0	
37. Program topics that reflect the self-interest of a pharmaceutical company)))
38. Perception of bias on the part of program participants			



Commercial Support of Continuing Pharmacy Education Questionnaire

Items 39-53 of 59

In your opinion, what is the effect of commercial support of continuing pharmacy education on the following outcomes?

	Decrease due to commercial support	Not Affected by commercial support	Increase due to commercial support
39. Overall <i>number</i> of continuing pharmacy education programs offered)))
40. A pharmacist's recommendation to <i>physicians</i> about drugs featured in a continuing pharmacy education program			
41. Brand loyalty on behalf of the pharmacist)		
42. A pharmacist's awareness of the availability of new drugs			
43. A pharmacist's access to disease management information)))
44. Cost of prescription drugs		0	
45. Cost of OTC drugs			
46. A pharmacist's knowledge of advances in pharmacy care			
47. A pharmacist's recommendation to <i>patients</i> about drugs featured in a continuing pharmacy education program)	J)
48. Quality of pharmacy care		0	
49. Formulary requests for the supporting company's drug(s))	J)
50. Use of more expensive drugs	0	0	0
51. Use of newer drugs	J		
52. Use of older, but still effective drugs			
53. Use of brand name rather than generic drugs))	



Commercial Support of Continuing Pharmacy Education Questionnaire

Items 54-56 of 59

54. What is your role in ACPE-approved continuing pharmacy education? (Please select all that apply)
Program Planner
Program Faculty
Program Participant
55. What is your educational background? (Please select all that apply)
Allied Health
Business
Computer Science
Education
Journalism
Medicine
Nursing
Pharmacy
Other (please specify)
56. Are you a licensed pharmacist in the U.S.?
→ Yes
→ No

<< Prev

Next >>



Commercial Support of Continuing Pharmacy Education Questionnaire

Items 57-59 of 59

57. Which best describes your organization?
Educational Company
Government Agency
Hospital or Health System
Pharmaceutical Manufacturing or Research-Based Company
Professional Association
→ Publisher
School or College of Medicine
School or College of Pharmacy
Other (please specify)
58. How many full-time faculty and/or staff are employed by your organization to assist in the development and delivery of continuing pharmacy education?
59. How long have you worked in the development and delivery of continuing pharmacy education?
J 1-5 years 1-5 years 1-6 years 1-7 years 1-7 years 1-8 years 1-9 years 1-9 years 1-1 years 1-1 years 1-1 years 1-1 years 1-1 years 1-2 years 1-3 years 1-4 years 1-5 years 1-7
● More than 5 years

APPENDIX M STUDY PRE-NOTIFICATION EMAIL NOTICE

Distribution Date: March 29, 2004

PRE-NOTIFICATION OF RESEARCH STUDY Commercial Support of Continuing Pharmacy Education Jayne L. Smith* & Ronald M. Cervero University of Georgia Department of Adult Education

Dear Continuing Pharmacy Education Provider:

We are currently involved in a study of commercial support of continuing education for pharmacists. The past year has been spent investigating the many perspectives and dilemmas of commercial support of continuing education programs. Based on our research, we have created a questionnaire that will help in a better understanding of how commercial support impacts the planning of continuing pharmacy education programs and the outcomes for program providers, pharmacists and patients.

We now need your help to successfully complete an IRB-approved study of this important issue. You will receive an email request on Wednesday to complete the online questionnaire. The questionnaire will ask you to report on your knowledge of commercial support as an ACPE-accredited provider of continuing pharmacy education. We would greatly appreciate if you would take 15-20 minutes of your time to complete and submit the questionnaire.

If there is someone in your organization responsible for continuing pharmacy education who you feel could better respond to this survey, please either forward the email request for participation that will be sent to you within a few days, or send their email address to the study director at jsmith@mail.rx.uga.edu. There will only be three additional contacts via this study group email list. Please send an email to the study director if you would like to be removed from this study group email list at this time.

Thanks in advance for your help in completing our research study.

Jayne L. Smith*, M.Ed. Study Director & Doctoral Candidate Adult Education, University of Georgia

Ronald M. Cervero, Ph.D.
Professor and Department Head
Adult Education, University of Georgia

*Jayne L. Smith is also on the public service faculty at the UGA College of Pharmacy where she currently serves as Assistant Director of Distance Learning for the Office of Postgraduate Continuing Education and Outreach. All work on this research study is in her capacity as doctoral candidate in the UGA Department of Adult Education, independent of her faculty appointment at the UGA College of Pharmacy.

APPENDIX N STUDY REQUEST FOR PARTICIPATION EMAIL

Distribution Date: March 31, 2004

REQUEST FOR PARTICIPATION

Commercial Support of Continuing Pharmacy Education Survey Jayne L. Smith* & Ronald M. Cervero University of Georgia Department of Adult Education

Dear Fellow Continuing Pharmacy Education Provider:

Over the years, commercial support has played a central and growing role in the provision of continuing pharmacy education. Much attention and debate has been cast on this issue recently in journal articles, at professional conferences, and through emerging policies and regulations. We now need your help to better understand the important issue of commercial support of continuing pharmacy education.

As a full-time pharmacy continuing educator at the UGA College of Pharmacy*, as well as a doctoral candidate under the direction of Dr. Ronald M. Cervero, I am currently involved in a research study to explore how commercial support impacts the planning of continuing pharmacy education programs, and the consequences for the provider organization, pharmacists, and patients. We anticipate this information will be useful to all administrators and planners of continuing pharmacy education.

We hope you will agree to be part of this IRB-approved research study. The online questionnaire should take 15-20 minutes to complete. Your expertise and participation are very important to the success of this study.

Of course, your participation is voluntary. All data you provide will be confidential and only summary data will be reported at the conclusion of the study. A summary of survey results will be made available to you after the study is complete by sending an email request to jsmith@mail.rx.uga.edu.

You can access the implied consent form, online questionnaire and other information about this study via the URL and password below.

http://www.rx.uga.edu/main/home/ce_dept/ce_provider/survey.htm Survey Password = provider

If you feel there is someone in your organization responsible for continuing pharmacy education who could better contribute to this research, please forward this request for participation or send their email address to the study director at jsmith@mail.rx.uga.edu. There will only be two additional contacts via this study group email list. Please send an email to the study director if you would like to be removed from this study group email list at this time.

We are available to answer any questions you might have by sending an email to ismith@mail.rx.uga.edu or calling (706) 542-5288.

Thank you in advance for your assistance.

Sincerely,

Jayne L. Smith*, M.Ed. Study Director & Doctoral Candidate Adult Education University of Georgia

Ronald M. Cervero, Ph.D. Professor and Department Head Adult Education University of Georgia

*Jayne L. Smith is also on the public service faculty at the UGA College of Pharmacy where she currently serves as Assistant Director of Distance Learning for the Office of Postgraduate Continuing Education and Outreach. However, all work on this research study is in her capacity as doctoral candidate in the UGA Department of Adult Education, independent of her faculty appointment at the UGA College of Pharmacy

Additional questions or problems regarding your rights as a research participant should be addressed to Chris A. Joseph, Ph.D., Human Subjects Office, University of Georgia, 612 Boyd Graduate Studies Research Center, Athens, Georgia 30602-7411; Telephone (706) 542-3199; E-Mail Address IRB@uga.edu

APPENDIX O STUDY FOLLOW-UP EMAIL

Distribution Date: April 12, 2004

FOLLOW-UP REQUEST FOR PARTICIPATION
Commercial Support of Continuing Pharmacy Education Survey
Jayne L. Smith* & Ronald M. Cervero
University of Georgia Department of Adult Education

Dear Fellow Continuing Pharmacy Educator:

On March 31 we sent an email request seeking your help in better understanding the role and outcomes of commercial support in the provision of continuing pharmacy education. If you have already completed and submitted the questionnaire, please accept our sincere thanks.

If you have not completed the questionnaire, we still need your expertise to successfully complete this IRB-approved research study. Your input is important to understanding the many dimensions of commercial support of continuing pharmacy education.

Your participation is strictly voluntary and you may be assured of confidentiality. Access to the online questionnaire will close soon, so we would greatly appreciate if you would complete and submit your responses today.

You can access the implied consent form, questionnaire and other information via the URL and password below:

http://www.rx.uga.edu/main/home/ce_dept/ce_provider/survey.htm Survey Password = provider

If you feel there is someone in your organization responsible for continuing pharmacy education who could better contribute to this research study, please forward this request for participation or send their email address to the study director at jsmith@mail.rx.uga.edu. Also, please send a request to the study director if you would like your email address removed from this study group list. (Note: There will be only one additional follow-up request sent to this email list.)

Jayne L. Smith*, M.Ed. Study Director & Doctoral Candidate Adult Education University of Georgia

Ronald M. Cervero, Ph.D. Professor and Department Head Adult Education University of Georgia *Jayne L. Smith is also on the public service faculty at the UGA College of Pharmacy where she currently serves as Assistant Director of Distance Learning for the Office of Postgraduate Continuing Education and Outreach. However, all work on this research study is in her capacity as doctoral candidate in the UGA Department of Adult Education, independent of her faculty appointment at the UGA College of Pharmacy

Additional questions or problems regarding your rights as a research participant should be addressed to Chris A. Joseph, Ph.D., Human Subjects Office, University of Georgia, 612 Boyd Graduate Studies Research Center, Athens, Georgia 30602-7411; Telephone (706) 542-3199; E-Mail Address IRB@uga.edu

APPENDIX Q

STUDY FINAL REQUEST FOR PARTICIPATION EMAIL

Distribution Date: April 26, 2004

FINAL REQUEST FOR PARTICIPATION

Jayne L. Smith* & Ronald M. Cervero University of Georgia Department of Adult Education Commercial Support of Continuing Pharmacy Education

Dear Fellow Continuing Pharmacy Educator:

This is a final request for your participation in an important study on the provision of commercial support for continuing pharmacy education. If you have not had a chance to complete the survey, we are still hoping you will find time in your busy schedule to help us out. If you have already completed the survey or have forwarded the request for participation to another continuing pharmacy educator in your organization, we truly appreciate your assistance.

The purpose of the questionnaire is to seek your expertise in a better understanding of the practices and consequences of commercial support for continuing pharmacy education. We are writing one final time to make sure all providers of continuing pharmacy education programs have an opportunity to offer their input to help us gain a better understanding of the many dimensions of commercial support for continuing pharmacy education. The questionnaire will only take 15-20 minutes of your time to complete and will only be available for a few more days.

Please note that the survey will close on Monday, May 1, 2004. You can access the implied consent form, online survey and other information about this study via the URL and password below.

http://www.rx.uga.edu/main/home/ce_dept/ce_provider/survey.htm
Survey Password = provider

Please be assured that you will receive no further correspondence requesting your participation in this study; however, if you feel there is someone in your organization who could better contribute to this research, please feel free to forward this request for participation.

Thanks again for your assistance.

Sincerely,

Jayne L. Smith*, M.Ed. Study Director & Doctoral Candidate Adult Education University of Georgia Ronald M. Cervero, Ph.D. Professor and Department Head Adult Education University of Georgia

*Jayne L. Smith is also on the public service faculty at the UGA College of Pharmacy where she currently serves as Assistant Director of Distance Learning for the Office of Postgraduate Continuing Education and Outreach. However, all work on this research study is in her capacity as doctoral candidate in the UGA Department of Adult Education, independent of her faculty appointment at the UGA College of Pharmacy

Additional questions or problems regarding your rights as a research participant should be addressed to Chris A. Joseph, Ph.D., Human Subjects Office, University of Georgia, 612 Boyd Graduate Studies Research Center, Athens, Georgia 30602-7411; Telephone (706) 542-3199; E-Mail Address IRB@uga.edu

APPENDIX Q

RANK-ORDER LISTING OF PLANNING PRACTICES ITEMS BY MEAN PERCENTAGE OF PROGRAMS

		Maan 0/	Frequencies							
Rank	Item	Mean % (SD)	0%	1- 25%	26- 50%	51- 75%	76- 99%	100 %		
1	13. The program provider reviewed all instructional materials and program content prior to delivery	60.6 (45.0)	34	11	4	6	12	59		
2	4. A program speaker had an existing relationship with a pharmaceutical company	36.1 (32.6)	21	44	21	20	15	7		
3	5: A pharmaceutical company designated funding in their grant to pay for program speaker fees	35.1 (38.4)	48	23	17	10	16	16		
4	18. A pharmaceutical company representative was present in the classroom during a program	32.4 (30.8)	26	42	22	19	14	3		
5	20. A pharmaceutical company sponsored a refreshment break and/or meal function as part of a program	31.5 (34.23)	39	37	15	16	14	8		
6	8. A pharmaceutical company offered to support a program based on the participant profile	25.6 (32.9)	55	29	16	13	7	9		
7	6. A pharmaceutical company representative recommended the program speaker	25.2 (30.4)	41	45	21	7	10	6		
8	2. A pharmaceutical company representative recommended the program topic(s)	21.3 (26.3)	47	40	26	7	6	3		
9	22. A pharmaceutical company had promotional literature available outside of the classroom	20.0 (26.8)	52	40	19	7	8	2		

		Mean % Frequencie				encies			
Rank	Item	(SD)	0%	1- 25%	26- 50%	51- 75%	76- 99%	100 %	
11	24. A pharmaceutical company offered items of minimal value to participants that could primarily be associated with practice	19.6 (27.8)	49	48	11	7	7	4	
12	23. A pharmaceutical company banner or sign was displayed outside of the classroom	15.3 (26.6)	71	32	10	4	7	3	
13	14. A pharmaceutical company provided instructional materials to a program speaker	13.3 (22.5)	63	45	10	3	3	3	
14	1. A pharmaceutical company representative assisted with establishment of program objectives	9.9 (20.8)	84	29	10	1	2	3	
15	25. A pharmaceutical company offered items of minimal value to participants that could be considered of personal benefit	9.4 (20.2)	86	27	8	3	2	2	
16	3. A pharmaceutical company representative selected the program topic(s)	8.9 (20.9)	91	24	5	3	3	2	
17	10. A pharmaceutical company representative reviewed content for medical accuracy	8.4 (22.3)	96	21	4	0	3	4	
18	7. A pharmaceutical company representative selected and/or invited the program speaker(s)	8.3 (20.1)	93	24	6	0	5	1	

		Moon 0/	Frequencies					
Rank	Item	Mean % (SD)	0%	1- 25%	26- 50%	51- 75%	76- 99%	100 %
19	11. A presentation was scripted by a pharmaceutical company	5.8 (19.6)	106	14	2	0	1	4
20	15. A program speaker provided preferential treatment of the supporting pharmaceutical company's product(s)	5.4 (11.4)	86	38	3	0	0	1
21	21. A pharmaceutical company sponsored entertainment and/or a recreational activity in conjunction with a program	4.8 (16.9)	108	16	0	1	3	1
22	16. A program speaker omitted discussion of a relevant product sold by a competing pharmaceutical company	3.5 (9.5)	100	26	1	0	1	0
23	17. A pharmaceutical company had promotional literature available in the classroom during a program	2.7 (10.5)	113	13	1	1	1	0
24	9. A pharmaceutical company representative assisted with program evaluation	2.6 (10.8)	115	10	3	0	0	1
25	19. A pharmaceutical company banner or logo was displayed in the classroom	1.9 (8.5)	115	13	0	0	1	0

APPENDIX R

RANK-ORDER LISTING OF CONSEQUENCES ITEMS BY MEAN VALUE

			Frequencies					
Rank	Consequences of Commercial Support	Mean (SD)	Decreases due to commercial support (-1)	Not Affected by commercial support (0)	Increases due to commercial support (1)			
1	18. A pharmacist's awareness of the availability of new drugs	.82 (.38)	0	23	106			
2	15. Overall number of CPE programs offered	.81 (.47)	4	17	109			
3	7. Use of nationally and internationally renowned experts as program faculty	.78 (.47)	3	23	104			
4	19. A pharmacist's access to disease management information	.72 (.47)	1	33	93			
5.5	27. Use of newer drugs	.70 (.46)	0	38	89			
(tie)	1. Overall revenue of CPE provider organizations	.70 (.56)	7	25	99			
7	22. A pharmacist's knowledge of advances in pharmacy care	.68 (.53)	4	33	90			
8	3. A CPE provider's financial dependency on industry	.66 (.51)	2	39	84			
9	6. Faculty honoraria and fees	.62 (.59)	7	36	87			
10	23. A pharmacist's recommendation to patients about drugs featured in a CPE program	.53 (.52)	1	57	68			
11	13. Program topics that reflect the self-interest of a pharm co	0.52 (.59)	6	49	73			
12	14. Perception of bias on the part of program participants	0.49 (.57)	5	56	69			
13	5. Non-educational expenses for a CPE program	0.48 (.70)	15	37	78			
14	24. Quality of pharmacy care	0.45 (.57)	5	60	62			

			Frequencies					
Rank	Consequences of Commercial Support	Mean (SD)	Decreases due to commercial support (-1)	Not Affected by commercial support (0)	Increases due to commercial support (1)			
15	20. Cost of prescription drugs	0.44 (.51)	1	69	56			
16	25. Formulary Requests for the supporting co's drug(s)	0.41 (.49)	0	74	52			
17	26. Use of more expensive drugs	0.38 (.49)	0	77	48			
18	16. A pharmacist's recommendation to physicians about drugs featured in a CPE program	0.34 (.54)	4	76	47			
19	21. Cost of OTC drugs	0.33 (.49)	1	82	42			
20	4. A CPE provider's allegiance to a supporting pharm co	0.32 (.51)	3	83	44			
21	29. Use of brand name rather than generic drugs	0.26 (.52)	5	84	38			
22	10. Overall quality of a CPE program	0.19 (.62)	15	75	39			
23	17. Brand loyalty on behalf of the pharmacist	0.18 (.42)	2	101	25			
24	2. Institutional funding for CPE providers	0.14 (.75)	28	53	46			
25	12. Overall variety of program topics offered	-0.01 (.74)	36	59	35			
26	11. A CPE provider's control of program quality	-0.13 (.38)	19	108	2			
27	28. Use of older but still effective drugs	-0.19 (.62)	38	74	14			
28	9. Willingness of pharmacists to incur the full cost of a CPE program	54 (.57)	75	50	5			
29	8. Program registration fees for participants	62 (.67)	94	23	13			

APPENDIX S EIGENVALUE FOR FACTOR SOLUTIONS

Total Variance Explained

	Initial Eigenvalues			Rotatio	n Sums of Squared Loadings		
Component	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %	
1	4.846	16.711	16.711	3.673	12.666	12.666	
2	3.668	12.647	29.358	3.423	11.802	24.468	
3	2.363	8.147	37.505	3.136	10.813	35.281	
4	1.799	6.204	43.709	2.050	7.070	42.351	
5	1.619	5.582	49.290	1.731	5.970	48.322	
6	1.295	4.467	53.757	1.576	5.436	53.757	
7	1.209	4.169	57.926				
8	1.168	4.026	61.952				
9	1.033	3.563	65.515				
10	.973	3.354	68.870				
11	.926	3.193	72.063				
12	.850	2.930	74.993				
13	.763	2.632	77.624				
14	.702	2.420	80.044				
15	.668	2.305	82.349				
16	.611	2.108	84.458				
17	.594	2.050	86.507				
18	.536	1.849	88.356				
19	.481	1.658	90.015				
20	.452	1.557	91.572				
21	.417	1.439	93.011				
22	.384	1.324	94.334				
23	.322	1.110	95.444				
24	.302	1.043	96.487				
25	.275	.950	97.437				
26	.239	.826	98.263				
27	.187	.645	98.908				
28	.179	.616	99.524				
29	.138	.476	100.000				

Extraction Method: Principal Component Analysis.

APPENDIX T

RANK-ORDER LISTING AND ILLUSTRATIVE EXAMPLES OF OVERALL IMPACT OF COMMERCIAL SUPPORT RESPONSES

Rank	Item and Examples of Responses	n
1	Increased quantity of CPE programs"Commercial support has been very important in increasing the amount of programs available.""The ability for continuing education providers to present more educational	22
2	programs with more pharmacists participating." Increased quality of CPE programs "The ability of providers to offer high-quality continuing education." "Commercial support plays a key role in making quality educational programs available to many pharmacists." "Since the changes occurred to the PHRMA code and the involvement of OID, I have seen an increase in the quality of the programs because of the hands-off approach the big pharmaceutical companies are taking. Smaller pharmaceuticals must not have gotten the memo!"	18
3	Decreased CPE program registration costs for pharmacists "Commercial support has kept the cost of CE down for pharmacists." "Lowering the costs of CE programs for pharmacists."	16
4	Increased use of expert faculty for CPE programs "Increase in national thought leaders as faculty." "If done appropriately, the commercial support of CE is able to provide quality faculty."	12

Rank	Item and Examples of Responses	n
	A. Culture of expectation for free or reduced cost of CPE for pharmacists resulting in less value on CPE	11
	"The abundance of commercial support in some venues appears to have had the overall effect of detracting from the educational goals of pharmacy education as a whole. It seems that most pharmacists base their CE choices on which programs are offered free of charge or at the nicest restaurants rather than on the topic and educational goals of the program being offered."	
	"Pharmacists in general are now unwilling to pay for their own CE. They think all CE should be free and have no idea how much money comes in from Pharma to support their CE. It is a gift from Pharma but they don't acknowledge it."	
	"I think pharmacists do NOT want to pay a dime for CE because they are able to get so many commercials for free."	
5.5 (tie)	"Pharmacists place less value on the CE and see it all too often as a method for the drug companies to sell product rather than teach CE. The availability of free CE with a meal has diminished the response to quality CE that is paid for by the pharmacist."	
	B. A CPE provider's financial dependency on industry	
	"It has encouraged the dependency of the pharmacy profession on financial support from pharmaceutical manufacturer's thereby diminishing the profession's control over its own future.	
	"This limits CE providers to reliance on drug companies for financial support."	
	"We'd be out of business if it wasn't for commercial support. My primary role is to manage the conflicts that commercial support raises.	
	"Allows the institution to withdraw its support of a CE unit forcing it to be totally self-supporting."	

Rank	Item and Examples of Responses	n
7	Increased access to new information (e.g. drugs, disease management)	
	"Provides pharmacists with updates on management of specific diseases and drug classes."	
	"More available information on new drugs, clinical trials, future disease treatments."	
	"Greater awareness of new drugs resulting in better patient care."	
8	CPE used as a marketing strategy by pharmaceutical companies resulting in biased programming	
	"The greatest impact of commercial support has been pharmaceutical marketing in the guise of CE."	
	"Commercial support of programs is not totally altruistic: having a large number of pharmacists, nurses or others in one place at one time makes their communication/marketing efforts more efficient."	9
	" for the overall provider industry I think the impact has been on the topics and content presented. Companies providing support expect to get their message out there about their products."	
	A. Increased variety of CPE program topics	
9.5 (tie)	"Without commercial support it is difficult to offer a broad range of topics with excellent speakers due to costs."	
	"More funding and resources are made available to provide a broad range of new topics."	
	B. Decreased variety of CPE program topics	8
	"With the PhRMA changes, we are finding it more difficult to provide a variety of program topics and speakers.	
	"It has hampered some of our responsiveness to the needs of pharmacists. For instance, there are fewer programs on skill development than on drugs. We tend to see the same topics done over and over again."	

Rank	Item and Examples of Responses	n
11	A non-commercial CPE provider's increased competition with commercial CPE providers "The biggest threat are the marketing firms that are becoming ACPE providers. Their survival depends on funding from industry. When they were intermediaries between providers and industry they could be controlled. Our recent experience with them indicates that they are influenced by their need to turn a profit." "drug companies now support commercial organizations which promote free CE which cuts into our own CE & may put us out of business if it	5
12.5 (tie)	continues." Improved access to CPE programs (e.g. alternative delivery methods) "Encouraging and supporting different types of programming and alternative methods of program delivery especially the increase use of online or web-based programming." Decreased quality of CPE programs	
	"Quality has suffered due to commercial pressures." "Less credibility of the information (real or imagined)."	4
14	Policies and regulations regarding the provision of CPE programs "More hoops to jump through, more excuses to say no to support." "The Office of Inspector General and Pharma guidelines."	3
15	Increased cost of CPE faculty honoraria and fees "As a by-product of commercial support, the cost of securing quality faculty has risen."	2
16.3 (tie)	A. CPE program participants more willing to report biasB. Increase in non-educational expensesC. Decreased quantity of CPE programs	1