“See Your Healthcare Provider for a Prescription Today!” The Influence of Direct-to-Consumer Drug Advertising on Nurse Practitioners and Their Patients

Kelly A. Getman-Dissette

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“SEE YOUR HEALTHCARE PROVIDER FOR A PRESCRIPTION TODAY!”
THE INFLUENCE OF DIRECT-TO-CONSUMER DRUG ADVERTISING
ON NURSE PRACTITIONERS AND THEIR PATIENTS

by

Kelly A. Getman-Dissette

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Kelly A. Getman-Dissette
In 1997, the U.S. Food and Drug Administration relaxed the guidelines regarding the advertising of prescription drugs directly to consumers (i.e., direct-to-consumer advertising, DTCA). The purpose of this research was to examine the impact of DTCA on the relationships of healthcare providers with their patients. In order to accomplish this task, in-depth, semistructured interviews were conducted with ten nurse practitioners (NPs). The interviews sought out provider perceptions on four topics as they relate to DTCA: diagnosis and treatment decisions, prescribing practices, additional burden on the provider, and patient trust in the provider. The findings reveal that DTCA has had both positive and negative effects on the relationships between NPs and their patients, but, overall, NPs felt that their relationships with their patients remained strong and undamaged by DTCA.
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CHAPTER I

INTRODUCTION

At the start of the 21st Century, as millions of Americans sit down to watch their favorite television shows or read their favorite magazines, they are deluged with advertisements for prescription medications. The purpose of this study is to examine the impact of this advertising on nurse practitioners (NPs) and their relationships with patients. This work will argue that the advertising of prescription-only drugs directly to consumers (i.e., direct-to-consumer advertising, DTCA) influences patients’ attitudes regarding their healthcare and healthcare providers, therefore affecting the relative power of healthcare professionals and patients in making diagnostic and treatment decisions.

In 1997, the U.S. Food and Drug Administration (FDA) relaxed the guidelines regarding DTCA. The most significant aspect of this change is that it allowed pharmaceutical companies to easily advertise product-specific prescription drugs on television for the first time. Prior to 1997, advertising directly to consumers using product-claims was permitted as long as the advertisements contained a brief summary of the drug’s symptoms, side effects, contraindications, and instructions for use (labeling) (Kessler 1990); a fair balance of benefits and risks; and the submission of advertisements to the FDA for preliminary review (Wilkes, Bell, and Kravitz 2000; Lyles 2002; Pinkus 2002). Because of the summary requirement, it was only possible for drug advertisements to appear in print or on cable television stations in physician-oriented programs, where the summaries were shown later in the program (Kessler 1990; Reeves 1998). In 1997, in response to pressure from consumer advocacy groups and the pharmaceutical industry, the summary requirement was relaxed and a Draft Guidance was
issued to outline how DTCA could ensure "adequate provision" of labeling without the summary (Reeves 1998; Pinkus 2002). This allowed drug companies to advertise their products directly to consumers, as long as the advertisements contained important risk information, as well as a toll free telephone number, an internet address, a current print advertisement where customers could access full labeling information, and a statement indicating that additional information was available through a doctor or healthcare provider (Reeves 1998; Pines 1999; Lyles 2002).

A final Guidance was issued in August of 1999, which was largely the same as the 1997 Draft Guidance, and, since then, DTCA has continued to grow in volume and in expense. A 2000 research brief from the National Institute for Healthcare Management (NIHCM) Foundation states that in 1999, pharmaceutical companies spent $1.8 billion on DTCA, 38.5% more than the $1.3 billion spent in 1998 and 33 times more that the $55 million spent in 1991. Findlay (2001) reports that $1.1 billion of the $1.8 billion spent on advertising in 1999 went toward television commercials. Lyles (2002) reports similar figures for 2000, noting that 64% of advertising expenditures went toward television, 30% toward magazines, and 5% toward newspapers.

Research on the post-1997 DTCA phenomenon has primarily attempted to detail the impact of DTCA on healthcare costs. For example, the NIHCM Foundation (2002) states that retail spending on outpatient drugs has nearly doubled since 1997, and Findlay (2001) reports that the top 24 most heavily advertised drugs accounted for 34% of the $17.7 billion increase in retail spending on prescription drugs from 1998-1999. Sales for these 24 drugs alone increased 41.7% in one year, while sales growth for other drugs only increased 14.4%. In 1999, physicians wrote 34.2% more prescriptions than they did in 1998 for the 25 direct-to-consumer promoted drugs that contributed most to overall drug
spending. In addition, health insurance plans spent 11-14% of their premium incomes on pharmaceutical benefits in 1999, compared to only 7% a few years before (Findlay 2001). According to the NIHCM Foundation (2000, 2002), the average price of a prescription had increased 10% in 1999, and from 2000-2001, it increased another 10%. Finally, in 1999, about 70% of managed care plans provided a three-tiered prescription drug copayment plan, compared to 36% in 1998 (Findlay 2001). These figures clearly demonstrate why prescription drug spending is cited as the fastest growing healthcare expense.

Other research has focused on the attitudes of healthcare providers and consumers/patients toward DTCA. According to Viale (2003), a recent study of 47 nurse practitioners and physician’s assistants (PAs) revealed that some providers felt DTCA was self-serving, while others felt that the advertisements encouraged patients to seek treatment for a valid illness. In contrast, Lipinsky and Taylor (1997) indicated that physicians often have negative opinions of DTCA. In their recent study of 454 U.S. family physicians, they found that 78% of the doctors did not believe DTCA promoted healthy competition between pharmaceutical companies, 75% thought that DTCA increased prices for drugs, and 72% believed that DTCA discouraged use of generic drugs. Similarly, in a 1998 survey of 2,000 physicians (Findlay 2001), 38% of doctors believed that DTCA mostly confused patients, and only 16% believed that the advertisements did more good than harm. Furthermore, most physicians (64%) indicated that they would like to see DTCA decrease or be discontinued.

Just as physicians suspect, there is evidence that consumers often walk away from the advertisements misinformed about many aspects involving the drug. Drug advertising can convince the public that new medications are better than older medications, which is
not always the case (Wilkes et al. 2000). Newer drugs are not necessarily more effective, and their safety profiles are less well understood (Wilkes et al. 2000; Lyles 2002). Also, many people are under the mistaken impression that the advertisements seen on TV have already been approved by the government, but the FDA does not require pre-approval of advertisements before they are aired (Wilkes et al. 2000). Furthermore, in a survey conducted by Wilkes et al. (2000:118), almost half of respondents believed that only “completely safe” drugs could be advertised on TV, and another 22 percent believed that only “extremely effective” drugs could be advertised on TV, neither of which is true. In fact, in a survey of 329 Sacramento County residents, Wilkes et al. (2000) found that respondents who felt most positively about DTCA were those who were also misinformed about the rigor of government regulation. Lyles (2002) adds that almost half of those who view a drug advertisement do not pursue the suggested sources for additional information.

It has also been reported that advertising changes the way the public perceives prescription medications (NIHCM Foundation 2000). Drug advertisements make these medications seem like any other product: first and foremost, the advertisements generate name and brand recognition, boosting sales and profits, and any educational or informational benefit is secondary (NIHCM Foundation 2000). Furthermore, the NIHCM Foundation (2000), in addition to Findlay (2001), expresses concern that mass media promotion of prescription drugs may lead the public to put further faith in pills as the remedy for all their ailments.

The figures above have caused a stir in the medical community and have led several authors to suggest that DTCA also has an impact on the healthcare provider-patient relationship, but there is no consensus as to whether this impact is positive or
negative. Some argue that most of the effects of DTCA on the provider-patient relationship are positive. Those who believe DTCA is good for providers and their patients say that DTCA motivates patients to learn more about medical conditions and treatment options as well as to consult with their doctors about advertisements they have seen (Holmer 1999). In addition, DTCA may lead to more informed patients, and therefore better communication between provider and patient (Lipinsky and Taylor 1997; Morgan, Minks, and Barer 2003). Finally, proponents of DTCA assert that because of the advertisements, patients could be more likely to agree and comply with prescribed treatment regimens (Holmer 1999; Morgan et al. 2003). Others feel very differently, suggesting that DTCA actually damages the provider-patient relationship. DTCA may cause increased patient loads and increased length of visits because providers have to explain to patients why advertised medications may not be the best choice (Rosenthal et al. 2002; Viale 2003). Some authors contend that DTCA affects provider prescribing practices (Hollon 1999; Viale 2003), and may even lead to inappropriate prescribing (Rosenthal et al. 2002). Finally, some allege that the provider-patient relationship is being replaced with the provider-consumer relationship, and the protection that is a result of a provider being required to verify the patient's need for a prescription drug is being eroded (Hollon 1999; Rosenthal et al. 2002). However, to date, there has been no research that can adjudicate between these two positions.

To fill this gap in the literature, this thesis examines the effect of DTCA of prescription drugs on several aspects of the provider-patient relationship: the authority to diagnose illness to make decisions regarding treatment, provider prescribing practices, additional burden felt by providers, and patient trust in the provider. In the traditional, paternalistic models of the provider-patient relationship, the healthcare provider possesses
the authority to make both diagnosis and treatment decisions. According to this model, patients trust their providers to know what is best for them (Szasz and Hollender 1956; Charles, Gafni, and Whelan 1997, 1999). However, several more recent models of the provider-patient relationship discuss differing patient attitudes toward their providers and stress varying degrees of patient participation in decisions (Haug and Lavin 1981; Charles et al. 1997, 1999). In this thesis, I argue that DTCA of prescription drugs influences patients’ attitudes regarding their healthcare and healthcare providers, therefore affecting the relative power of healthcare professionals and patients in making diagnostic and treatment decisions. In turn, this power shift will affect the nature and quality of the social interaction between healthcare professionals and their patients during office visits, with the social interaction being most negative where the relationship models followed by the healthcare professional conflicts with the model desired by the patient.

To examine this research question, I conducted ten in-depth interviews with NPs. These semistructured interviews focused on the subjects’ perceptions of the nature and quality of their interactions with patients before and after the changes in DTCA. NPs were interviewed because of their now prominent role in primary care. The interviews sought out provider perceptions on five topics as they relate to DTCA: diagnosis decisions, treatment decisions, prescribing practices, additional burden on the provider, and patient trust in the provider.

In the next chapter, I discuss the several models of the provider-patient relationship as proposed in the literature. Chapter III gives a brief history of DTCA of prescription-only drugs and an in-depth look at the changes the FDA made in 1997. In Chapter IV, I develop expectations for the effects of DTCA on relative power and social interaction within the provider-patient relationship, and discuss the methods I use to test
these expectations. Chapter V presents the findings of my study, and Chapter VI offers a discussion of the findings, limitations of the study, and directions for future research.
CHAPTER II

THE PROVIDER-PATIENT RELATIONSHIP

In early work on the provider-patient relationship, Szasz and Hollender (1956) developed three models of interaction. The first, and oldest, is the model of *activity-passivity*. This model does not involve reciprocal interaction: the physician, or provider, acts upon the passive patient, who does not “contribute actively or is considered to be inanimate” (Szasz and Hollender 1956:586). This situation is common during emergency situations when the patient is usually seriously ill or injured. Szasz and Hollender (1956) compare this relationship to that of a parent (provider) and an infant (patient). In this model, the provider controls the encounter and makes all medical decisions.

The second, and perhaps most common, model is the model of *guidance-cooperation*. Patients, although ill, are not incapacitated, and are able and expected to seek out and “cooperate” with a provider’s advice. As in the previous model, the provider retains the power in the relationship, but unlike the previous model, both the provider and the patient contribute actively to the relationship. This relationship is compared to that of a parent (provider) and an older, adolescent child (patient). The provider is presumed to know what is best for the patient because he/she possesses knowledge that patients do not, and patients usually accept the provider’s intentions as their own (Szasz and Hollender 1956).

The final model is the model of *mutual participation*. According to the authors, there are three important components to this model: provider and patient have nearly equal power, the parties are “mutually interdependent,” and they participate in ways that are acceptable to each other (Szasz and Hollender 1956:587). This model is commonly
used to manage chronic illnesses. The patient’s life experiences are important for
treatment regimens, and the patient is primarily responsible for carrying out his/her own
treatment program. Szasz and Hollender (1956:587) maintain that this model is “more
appropriate” when the physician and patient are fairly equal in terms of intellect,
education, and general experience.

Szasz and Hollender (1956) point out that in each category, both the provider and
the patient should feel satisfied. However, since the goal of the relationship is to change
the patient in some way, as the therapy and patient progress, new needs emerge, and the
relationship must also change. “Each of the three types of therapeutic relationship is
entirely appropriate under certain circumstances and each is inappropriate under others”
(Szasz and Hollender 1956:591). If a provider is incapable of adjusting to his/her
patient’s new requirements, the patient may cease to improve, or both members will
become dissatisfied in the relationship, and the relationship will end. Patients may seek a
new healthcare practitioner who will meet their needs, and providers will find new
patients who will find success from the “old” methods.

Freidson (1988:318) later added to Szasz and Hollender’s models a fourth “logical
construct,” in which the patient is the active member and the provider is passive. This
type of relationship has not been empirically verified, but Freidson (1988) supposes that it
may occur in a practice that is economically unstable and has clients of high economic,
political, and social status.

As is implicit in Szasz and Hollender’s models, Haug and Lavin (1981) believe
that the provider-patient relationship is rooted in power, specifically in the hands of the
medical professionals. These authors state that the medical
monopoly of knowledge not easily accessible to the public and its claims to a public service outlook...legitimate the profession’s command over the practitioner-client relationship, and institutionalize client obligations to trust professionals and comply with their prescriptions. (Haug and Lavin 1981:212)

However, in the decade preceding the 1981 study, a consumerist approach to the provider-patient relationship had begun to develop (Haug and Lavin 1981; Cockerham 1986; Freidson 1988). This approach has challenged the physician’s authority, encouraged bargaining and negotiation rather than authority acceptance, and focused on purchaser rights and seller obligations. It also implies a narrowed gap in competence between the patient and the provider. Consumers now hold more legitimate power to make their own decisions based on their experience, education, or media claims (Haug and Lavin 1981; Cockerham 1986; Conrad and Leiter 2004).

Similarly, Cassell (1986) concludes that in the fifteen years prior to his work, patients had come to doubt their physicians’ motives. He attributes these changes to: (1) medicine’s embrace of value- and quality-free science; (2) technology, which gives the idea that medicine can be rid of all uncertainty; (3) the change in the character of physicians over time so that the dominant group of physicians is now full-time medical research scientists at academic medical centers, not academically-minded clinicians; and (4) the change in the meaning of “individual” after WWII and the new definition of patienthood (Cassell 1986). Freidson (1988) believes that certain consumer movements have made more information available to consumers, and that many of them are more willing to challenge the authority of physicians. He contends that this consumerism has changed the traditional interaction between a physician and a patient, but not to the point of considering the relationship to be egalitarian.
Haug and Lavin (1981) assert that the consumerist orientation may have changed the provider-patient relationship from a model of dominance to one of bargaining. In a bargaining model, each party “brings different resources to the encounter, and is prepared to negotiate an acceptable set of terms for the relationship, which may include agreements on both diagnosis and treatment” (Haug and Lavin 1981:213). Providers deliver the tradition of authority, knowledge, experience, and the access to other services and medications. Patients have their own knowledge and experience, as well as the right to informed consent and the threat to take business elsewhere (Haug and Lavin 1981). Cassell (1986) argues that the “doctor knows best” era is gone, and patients now see themselves as active partners in the relationship. They want choices and have high expectations, which are “nourished” by the media (Cassell 1986:196).

In order to assess the extent to which patients and physicians embrace a consumerist orientation toward medical care, Haug and Lavin (1981) conducted a survey of primary care physicians and patients in the Midwest. They found that 60% of the public and 81% of physicians self-reported a propensity to consumerism. However, fewer than half of consumers have actually questioned a physician’s authority, and only 8% of physicians would accommodate a challenge from a patient, which Haug and Lavin (1981) interpret to mean that only 8% would be willing to allow patient participation in making decisions. Further analysis revealed that those who were more likely to adopt a consumerist perspective tend to be younger, more knowledgeable, more skeptical of authority and of physicians’ motives, and tended to believe they have a right to make their own healthcare choices. Cockerham (1986) found similar results in a phone survey of 401 adults in Illinois. In fact, Cockerham (1986:11) believes that “the culture of medicine does not promote consumerism among lay persons when direct physician-
patient interaction is required nor provide a context within which such an orientation can
grow within the medical environment.” It has been presumed that doctors should be
authoritative and need leverage over their patients because some procedures may be
painful and patients do not have the expertise to deal with them.

Haug and Lavin (1981) indicate that these results do not, in fact, present a new
model of the provider-patient relationship that cancels out earlier conceptions. Instead,
they support Szasz and Hollender’s (1956) claims that the power in a relationship
between a patient and a healthcare provider is determined by the nature of the illness,
characteristics of the members, and their attitudes toward power and dependence (Haug
may indicate that a consumerist patient who interacts with a traditionally minded
physician, or vice versa, may find conflict. If a consumerist patient finds a consumerist
provider, the relationship is more likely to succeed.

In the present day, research indicates that decision-making authority, to a large
extent, characterizes the provider-patient relationship. And, although decades later,
recent work by Charles and colleagues (1997, 1999) very much reflects the work of Szasz
and Hollender (1956) and Freidson (1988). Like Cassell (1986) and Haug and Lavin
(1981), Charles et al. (1997, 1999) believe that changes have occurred regarding medical
decision-making, which caused a change in the provider-patient relationship.

Charles and her colleagues (1999) cite four assumptions regarding medical
decision-making that were popular prior to the 1980’s: (1) for most illnesses, there is a
single best treatment, and providers are generally well aware of the most current and valid
clinical thinking; (2) healthcare providers know the best treatments available and
consistently apply this information when choosing treatment for their patients; (3)
providers are in the best position to evaluate treatments, and the risks and benefits of each, and to make the treatment decision, due to their expertise and experience; and (4) providers have a legitimate investment in each treatment decision because of their professional concern for the welfare of their patients. During the 1980's these assumptions, which perpetuated a paternalistic model of the provider-patient relationship, were increasingly questioned, and as a reaction to the paternalistic model, new models of decision-making were developed (Charles et al. 1999).

In the paternalistic model, the provider dominates the encounter, diagnoses the problem, and recommends treatment. Here, the provider is an authority figure, acting in what he/she perceives to be the patient's best interest, without consulting the patient regarding his/her preferences. Patient involvement is limited to giving consent to the treatment. Informed consent, considered a patient's right, demands that patients must be at least minimally involved in decisions regarding medical treatment by giving their consent (Charles et al. 1997). However, a newer model, informed decision-making, limits the provider's involvement. The provider provides technical information about treatment options, risks, and benefits, and the decision about which treatment to pursue is made solely by the patient. The provider's preferences are not important. Another model, professional-as-agent, allows the provider to make treatment decisions for the patient (with the patient's consent) because the provider knows or has asked the patient about his/her lifestyle and treatment preferences. The provider's preferences are immaterial: it is only those of the patient that are important, but the provider makes the ultimate decision, on the patient's behalf (Charles et al. 1997).

Charles and her colleagues (1997) note that, although the aforementioned, newer models involve a more active patient, none of them truly involve shared decision-making,
which has come to be viewed as the ideal method. The paternalistic and professional-as-agent models do not involve the patient, although in the latter, the patient provides the provider with more background information and treatment preferences. Alternatively, the informed model does not involve the provider in the treatment decision (Charles et al. 1997).

A fourth model, shared decision-making, has four defining characteristics (Charles et al. 1997). First, shared decisions must involve both the provider and the patient. Other family members or health professionals may be involved, but at the very least the patient and the primary provider must participate for the decision to be shared (Charles et al. 1997). Second, both the provider and the patient must actively participate in the process of making the decision. Patients have to want to share and receive certain information, and they have to share their preferences. Providers must be willing to share information about treatment options, risks, and benefits, willing to question patients about their treatment preferences, and also willing to allow the patient to participate (Charles et al. 1997). Third, an actual exchange of information must occur. Both parties bring resources to the encounter regarding treatment options/preferences, lifestyles, values, habits, etc. They also enter the relationship with a desire to obtain information from the other. If one member does not freely offer the information desired, the other should ask questions in order to obtain it (Charles et al. 1997). Fourth, both parties must agree to the treatment decision. This may involve choosing between two or more different treatments, or choosing to do nothing. The treatment will be accepted by both, even if one party or the other feels that another treatment would have been better (Charles et al. 1997).

In a follow-up article reexamining their 1997 study on shared decision-making, Charles et al. (1999) clarified their earlier models, leaving out the professional-as-agent
model, with respect to decision-making authority in the relationship and the direction of information flow. In the paternalistic model, information is exchanged in one direction: from provider to patient. The patient is the passive recipient of this information. It is assumed that the provider knows best and will select the best treatment option for the patient. The informed model is the opposite of the paternalistic model. Information exchange is again one way, from provider to patient, but in this case, the patient, having received all relevant treatment information, makes the final treatment decision. However, in the shared decision model, information is exchanged two ways: from provider to patient and vice versa. In this case,

all relevant treatment options are on the table, [and] both the provider and patient evaluate these within the context of the patient’s specific situation and needs rather than as a standard menu of options whose impact and outcomes are assumed to be similar for clinically similar patients. (Charles et al. 1999:654)

Stevenson et al. (2000) add that shared decisions must involve participation throughout the provider-patient encounter, and for patient participation to occur, the practitioner is responsible for providing an atmosphere where the patient feels his/her preferences about various treatment options are valued. The provider should help the patient weigh the risks and benefits and ask questions of the patient to avoid any misconceptions, and finally, the provider should discuss the treatment recommendation with the patient, and/or confirm the patient’s preferences (Stevenson et al. 2002).¹

There are no official rules that define a shared decision from one that is not, and although shared decision-making is often considered ideal (Charles et al. 1997; Stevenson et al. 2000), many patients prefer to allow their provider to make the final decision

¹ Of course, characteristics of both the provider and the patient, such as age, race, sex, culture, education, and socioeconomic status influence decision-making. Such factors are recognized as being influential, but are beyond the scope of this work.
regarding their method of treatment, especially when faced with a serious illness (Charles et al. 1997). As with Szasz and Hollender’s (1956) earlier models, the decision-making approach can be different for each provider-patient interaction, meaning it can change from patient to patient, from interaction to interaction, and within one single interaction. Even though a provider may be more comfortable with one interactional style than another, it is important for him/her to respond to the situation and to patient preferences (Charles et al. 1999). The authors stress that there is no one ideal interaction style, and there are approaches that lie between the three models (Charles et al. 1999).

A major drawback to shared decision models is that they are far more time consuming than paternalistic or informed models because of the two way information exchange and negotiation involved in such a decision (Charles et al. 1999). This concern is also highlighted in the DTCA literature; opponents of DTCA argue that DTCA exacerbates this issue. Furthermore, patients and providers may spend large amounts of time negotiating a treatment recommendation if a patient is dissatisfied, taking time away from other needy patients. Then, if a patient continues to be unhappy, he/she can seek out another provider who will honor his/her requests. Also, in spite of the best intentions, treatment decisions may never be completely shared. There is, as Charles et al. (1999:656) put it, “an inherent information and power imbalance in the relationship.” The provider is considered the expert in medical matters and has technical knowledge and clinical experience that patients do not. And when there are other communication barriers—like education, income, culture, or gender differences—the likelihood of a shared decision decreases.
Before the likely of effects of DTCA on models of provider-patient relationships can be explored, it is important to examine the history and current issues regarding DTCA. This task is accomplished in the next chapter.
CHAPTER III

DIRECT-TO-CONSUMER ADVERTISING

Direct-to-consumer drug advertising may seem like a fairly recent phenomenon, but according to Pinkus (2002), medicines have been advertised to the public for more than a century. In the late 19th and early 20th centuries, commercialism was highly praised, the medical profession was highly suspicious, and "natural healers" and quacks, who frequently advertised their services and patented remedies in print, were very popular (Pinkus 2002). For this reason, licensed physicians refused to use patented medications. Furthermore, because it went against "traditional gentlemanly standards of conduct" (Pinkus 2002:146) to engage in profit seeking, genuine medical professionals did not advertise. However, in 1847, the American Medical Association (AMA) was formed and began its efforts to regulate drug advertising, to gain legitimacy, and to change public opinion of the medical profession. With such a small number of members, the organization carried little weight with the public, and their first efforts were not very successful. But by 1900, the AMA was ready to try again. They narrowed their focus in order to force legitimate drugs to fall in line with the "ethics of medicine" (Pinkus 2002:148). Drug makers were now required to release the formulas used to create drugs and refrain from advertising directly to the public. Physicians were asked not to prescribe drugs until the AMA qualifications were met, and journalists began to publish articles citing evidence that many advertised, patented medications were fraudulent. In doing this, the medical profession secured control over pharmaceutical information, and physicians and the AMA gained legitimacy (Pinkus 2002).
Eventually, laws were developed to set standards for the manufacture, evaluation, and distribution of prescriptions, and in 1938 the Federal Food, Drug and Cosmetic Act was passed (Kessler 1990; Wilkes et al. 2000; Pinkus 2002). This act gave power over drug labeling, which includes any written, printed, or graphic materials that are sponsored or supported by the drug's manufacturer, packer, or distributor and which accompany the drug, to the FDA (Kessler 1990). In 1962, jurisdiction over advertising of prescription drugs, once held by the Federal Trade Commission, was shifted over to the FDA, and while physicians retained control over the distribution of prescription drugs, the ban on DTCA was slowly lifted (Kessler 1990; Wilkes et al. 2000; Pinkus 2002). Drug advertisements include anything, other than labeling, which promotes the product and is sponsored by the manufacturer (Kessler 1990).

In 1981, the pharmaceutical industry, touting the educational benefits to the public, requested that it be allowed to advertise prescriptions directly to consumers, and the FDA approved. Rufen®, a branded generic of ibuprofen, was the first product-specific direct-to-consumer advertisement, followed shortly by Pneumovax®, a pneumococcal vaccine, and acyclovir, as well as a host of others (Lyles 2002). However, pharmaceutical companies considered these printed promotions to be "public service campaigns" rather than advertisements (Lyles 2002).

In addition to the product-specific advertisements, two other kinds of advertisements were used: help- or health-seeking advertisements and reminder advertisements (Wilkes et al. 2000; Lyles 2002). Health-seeking advertisements discussed conditions or illnesses, rather than a specific drug, with a plea for consumers to visit their doctors to begin a "treatment program" (Kessler 1990). Reminder advertisements could provide the name of the drug, but make no mention of its clinical
role (Wilkes et al. 2000; Lyles 2002). These types of advertisements were used on television, but were often confusing and of little value to consumers, since one advertisement could not contain both the drug name and the condition it was used to treat (Lyles 2002).

In 1983, a moratorium was placed on the advertising, only to be lifted two years later, with the FDA stating that its current guidelines were adequate to regulate drug advertising (Kessler 1990; Reeves 1998). Companies could advertise directly to consumers using product claims as long as the advertisements followed current regulations, which required a brief summary of drug use instructions, symptoms, side effects, and contraindications (Kessler 1990); a fair balance of benefits and risks; and the submission of advertisements to the FDA for preliminary review (Wilkes et al. 2000; Lyles 2002; Pinkus 2002). Because of this summary requirement, these advertisements could only appear in print or on cable television stations in physician-oriented programs, where the summary could appear later in the program, separate from the advertisement (Kessler 1990; Reeves 1998).

During the 1990’s, the pharmaceutical industry and several consumer advocacy groups petitioned the FDA regarding DTCA. Many groups wanted the restrictions on the advertisements removed, while other consumer groups were completely against DTCA. In 1995, a public hearing was held to discuss the advertising, and in 1996, the FDA considered feedback on the summary and risk information requirements for drug advertisements (Reeves 1998). In 1997, when FDA Commissioner David Kessler, who was opposed to expanding DTCA (Lyles 2002), left the FDA, the summary requirement was relaxed and a Draft Guidance was issued to outline how the advertisements could ensure “adequate provision” of labeling (Reeves 1998; Pinkus 2002). This allowed drug
companies to advertise their products directly to consumers, as long as the advertisements contained important risk information, as well as a toll free telephone number, an internet address, a current print advertisement where customers could access full labeling information, and a statement indicating that additional information was available through a doctor (Reeves 1998; Pines 1999; Lyles 2002). A final Guidance was issued in August of 1999, which, for the most part, was the same as the 1997 Draft Guidance. Since 1997, the volume of DTCA has increased tremendously, and, for better or worse, we are inundated each day and night with television commercials and magazine advertisements proclaiming the benefits of prescription medications.

The preceding history brings us to the current debate over the advertisements. In an age of rapidly rising healthcare costs, especially those of prescription medications and insurance premiums, DTCA has become more important than ever. As previously stated, there is no consensus as to whether DTCA has a positive or negative influence on consumers. Proponents of DTCA include groups such as the pharmaceutical and advertising industries, as well as media in which DTCA appears (Pines 1999). These groups claim that the advertisements educate the public about diseases and available treatments, empower people to seek out necessary treatment, enhance the doctor-patient relationship, improve adherence to prescription drug regimens, and reduce pharmaceutical prices as well as overall healthcare costs for some people who can find relief from drugs instead of surgery (Holmer 1999; Brodie and Levitt 2002; Lyles 2002).

Opponents of DTCA include managed care and the insurance industry (Pines 1999), among others. They argue that the advertisements create demand for prescription drugs, especially newer, more costly drugs; increase use of prescription drugs, which contributes to increased costs; do not adequately convey risk information; encourage
overuse of medications; and damage the provider-patient relationship (Hollon 1999; Brodie and Levitt 2002; Lyles 2002). As briefly discussed above, the increases in sales and spending makes it clear that pharmaceutical companies and advertisers are pleased with the results of their efforts. The advertisements may, in fact, drive a substantial population to visit their healthcare providers and ask about prescription drugs they have seen advertised, but research that explains how this may affect the provider-patient relationship is limited. The remaining section of this chapter discusses literature that hints at the impact of DTCA on providers and their interactions with their patients.

**DTCA and the Provider-Patient Relationship: Recent Research**

As proponents of DTCA would argue, it may be true that, to a certain extent, direct-to-consumer drug advertisements reduce taboos about disease. It may also be true that many people with certain illnesses or disorders, who may not normally do so, visit their providers as a result of viewing a drug advertisement. The NIHCM Foundation (2000) and Findlay (2001) briefly discuss a 1999 *Prevention* magazine and American Pharmaceutical Association survey, to which 1,200 U.S. consumers responded, and an FDA telephone survey of 1,081 respondents. *The Prevention* survey found that 31% of those surveyed said they had spoken with their doctor about a prescription drug they had seen advertised, while the FDA survey found that about 25% of U.S. consumers who had seen an advertisement in the previous three months asked their doctor, for the first time, about an illness or condition. Viale (2003) reports that 81% of FDA respondents believed their doctor welcomed their questions, and 79% discussed an advertised medication with their doctor (Viale 2003).

In fact, the *Prevention* survey reports that of those who saw their doctors after viewing an advertisement, 28% asked their doctor for a prescription, and 23.4% reported
that their doctor complied and wrote them a prescription (NIHCM Foundation 2000; Findlay 2001). *Prevention* used the survey results to project that 54.8 million U.S. consumers had spoken with their doctors about a drug they had seen advertised, 15.3 million requested a prescription for an advertised drug, and 12.9 million received such a prescription (Findlay 2001). However, results from this survey should be received with caution. Respondents to this survey were not a randomly selected sample, but rather *Prevention* readers, a typically health conscious audience that is not necessarily representative of the general U.S. population of consumers. Although, it should be noted that an FDA survey found similar results. Thirteen percent of these respondents asked for a specific prescription drug, about half of those who asked for a drug received it, and 32% received a different drug (NIHCM Foundation 2000; Findlay 2001).

Viale (2003) believes that DTCA could encourage patients to ask for medications that are not appropriate for them, and she worries that advertisements do not offer information on lifestyle changes that could be as important as taking medication. A recent study by Findlay (2001) indicates that physicians worry that the advertisements cause the public to falsely believe that there is a pill to solve every problem, but at the same time, physicians feel pressured to prescribe drugs to patients who request them. Findlay (2001) reported that a study in the early 1980's found that physicians were more influenced by patient requests and drug promotions than scientific sources, and 71% of the respondents to the Lipinsky and Taylor (1997) study believed that DTCA pressured physicians to choose advertised drugs over others. In a cross-sectional survey of 78 primary care doctors and 1431 patients in Vancouver, British Columbia and Sacramento, California, Mintzes et al. (2003) found that, for patients requesting DTCA drugs, the odds of receiving a prescription were 16.9 times those of patients who did not request a
medication. Furthermore, in Sacramento, 80% of patients who requested prescriptions got them, implying that physicians respond to patient pressure.

On the contrary, although the sample was small, Viale’s (2003) recent study of 47 NPs and PAs found that about two-thirds of the providers surveyed said that they would not be more likely to prescribe a prescription drug just because a patient asked for it. Many of these providers felt that it was time consuming to explain drug alternatives to patients, but that providing health information to patients was important.

Lyles (2002) reports that patients want information from their physicians about their medical conditions and treatment options. Furthermore, in the Mintzes et al. (2003) study, the researchers found that 75% of patients in each city believed that patients and physicians should have equal say in treatment decisions. While DTCA may increase the likelihood that patients will discuss advertised products with their doctors, Wilkes et al. (2000) state that physicians do worry that the advertisements are misleading and biased to consumers. In fact, Lyles (2002:84) reports that 24% of respondents to an FDA survey who had seen a drug advertisement said that the advertisements made it “seem like a doctor is not needed to decide whether a drug is right for [them].” Therefore, physicians feel a need to “reeducate” their patients so that they have realistic expectations of prescription drugs and realize that the claims in the advertisements are promotional (Wilkes et al. 2000:121).

Additionally, some research reports that many people who may not, in fact, be afflicted with any adverse condition call their doctors to schedule appointments after viewing the advertisements on TV, which consumes physicians’ already limited time (Findlay 2001; Brodie and Levitt 2002). There is also concern that discussions of drug advertisements will get in the way of more important conversations about the patient’s
illness and possible treatments. When patients ask their doctors to prescribe a drug that they have seen advertised, they may be pressuring their doctors for treatment that is completely inappropriate. Patients may be so overly focused on obtaining certain brand-name drugs that they fail to engage their physician in meaningful discussions concerning their illness (Wilkes et al. 2000).

According to Wilkes and his colleagues (2000), physicians also fear that patients may become angry should the physician suggest a method of treatment other than the drug the patient has requested, especially if this treatment involves no prescription medication. When communication between providers and patients is not effective, patients may not respect or trust their provider’s decisions and they may not adhere to treatment regimens. Viale (2003) states that advertisements may decrease a patient’s faith in his/her healthcare provider and damage the relationship, especially when an advertisement contradicts a provider’s advice. Lyles (2002) reports that, of respondents to a national survey, 25% trust their doctors less now than in previous years, and 18% were not satisfied with the information they received about their conditions and treatment options. Furthermore, Lipinsky and Taylor (1997) report that 89% of physicians surveyed believed that DTCA did not enhance the doctor-patient relationship. Furthermore, in the Wilkes et al. (2000) survey of Sacramento residents, respondents were asked to hypothesize how they would feel if their physician denied their request for an advertised drug. Almost half (46%) indicated that they would be disappointed, 25% said they would try to change their doctor’s mind, 24% thought they would try to get the prescription from a different doctor, and 15% said they might find a new physician. Mintzes et al. (2003) similarly found that 14% of patients said they would find another doctor if their physician refused to prescribe the medication they requested.
While it is important for patients to be informed about their health, drug advertisements certainly do not provide all of the information necessary to make informed decisions about healthcare. Holmer (1999) feels that DTCA is a good way to meet the public’s demand for more health information. He says DTCA empowers consumers by educating them on health conditions and treatments. He also claims that “companies are committed to responsible advertising that enhances the doctor-patient relationship” (Holmer 1999:381). However, Hollon (1999) and Morgan et al. (2003) differ, reminding us that pharmaceutical companies are for-profit entities, and their ultimate goal is to create consumer demand, and therefore profit, not educational benefit to the consumer. Consumers, unlike physicians, do not necessarily have the education and knowledge to assess claims made by the advertisements, nor are they necessarily aware of the range of treatments that could be appropriate for their condition (Hollon 1999).

In order to begin to assess the potential impact of DTCA on different models of provider-patient relationships, I conducted interviews with ten NPs. I discuss the specific content areas that were explored during the interviews, my method of interviewing, and expectations for the research in the next chapter.
CHAPTER IV
THE PRESENT STUDY

The goal of this study is to begin to understand the impact, if any, of DTCA on NPs and the relationships they have with their patients. Of specific interest is how DTCA has affected NP diagnosis and treatment decisions, prescribing practices, burden on the provider, and patient trust in the provider. NPs were chosen as the focus for this project because they frequently provide primary care to patients, including writing prescriptions for drugs. In addition, with the exception of the Viale (2003) study, this group of healthcare providers has not been included in the research concerning DTCA and the provider-patient relationship.

The remainder of this chapter will be divided into three sections. First, I explore expectations for the ways in which DTCA may have impacted the provider-patient relationship, both in general and in terms of the most recent models proposed by Charles et al. (1999). Next, I review NP training and practice and the reasons why NPs should be the subjects of this study. Finally, I discuss the methods used in the present study.

DTCA and the Provider-Patient Relationship: Expectations

As noted by Haug and Lavin in 1981 and by Conrad and Leiter in 2004, a consumerist approach to medicine is becoming more and more common. It is likely that this consumerism has only increased since pharmaceuticals began to be advertised so heavily in popular magazines and on television following the 1997 Draft Guidance. In fact, by representing drugs as though they are just like any other commercial product, and using commands like, “See your doctor about (name of drug)!,” DTCA encourages patients to be consumers. This more active patient, then, is likely to change the provider-
patient relationship by creating additional provider burden and institutionalizing the role of patient as consumer.

More active patient-consumers are likely to seek more authority over their medical care and treatment decisions, to want more options in terms of treatment, and to have increased expectations for both treatment outcomes and provider abilities. Therefore, a consumerist provider-patient relationship will likely involve more negotiation than would a traditional relationship. However, as Haug and Lavin (1981) also stated, it is not expected that a bargaining model will replace the models that are based in authority. During a negotiation, as each member provides his/her side of the argument, there is generally a struggle for power. If the negotiation reveals one clear winner, it is this person who holds the power in the relationship. If both members “struggle” equally and make compromises, the power is more equal. What DTCA, and therefore consumerism, has changed is the assumption that the provider holds the power in the relationship. This may no longer be true.

One danger of this consumer orientation is that patients may be more likely to self-diagnose their problems or conditions, and to decide on the preferred treatment because of information portrayed in advertisements. Advice of the provider may not be as likely to be followed if it conflicts with the patient’s ideas, and patients may “shop around” for a new provider until they find someone who will meet their demands. In addition, providers are likely to feel extra burden because of additional patient loads, reduced time with each patient, and the need to reeducate patients who have been misinformed by drug advertisements.

DTCA may be promoting consumerism in healthcare that is inappropriate, considering that healthcare is not a commodity like dish soap or paper towels.
Advertisements alone do not provide all of the information that is necessary for patients to place all of their healthcare decisions in their own hands, but the advertisements may lead patients to believe this is true. After viewing DTCA, patients may influence their healthcare providers in ways that are detrimental to their relationships. However, it is also possible that providers welcome patient inquiries and increased business. Consumer-minded patients may actually be better informed, and if this is the case, it could mean that office visits, conversations, and treatment regimens are more productive. As was mentioned in the literature regarding the provider-patient relationship, it is expected that patients with a consumer orientation need providers with the same orientation in order to engage in the most beneficial relationship.

A greater shift in patient attitudes regarding their healthcare is also likely to cause a change in models of the provider-patient relationship. More consumer-oriented patients may also cause physicians to change and become more consumer-driven. Therefore, there may be important transformations in the recent relationship models (paternalistic, informed, and shared decision-making) proposed by Charles et al. (1999).

It is expected that the paternalistic model (in which the provider holds all decision-making power), once virtually the only way of practicing medicine, has become even less common than it was even a few years ago. This model may still be desirable for providers because they have spent years becoming trained and educated in medicine. They may feel they deserve to hold authority over their patients, and that patients should respond to provider suggestions. However, as consumerist patients desire more authority in decision-making, the continuation of this type of relationship seems unlikely. Of the three models, this model seems the most likely to be negatively affected, or completely
eliminated, by DTCA, and the model that is most likely to cause conflict between patient and provider.

The next model, the informed model (in which patients have total authority over making decisions), would be the likely result of a complete shift toward consumerism in the mentality of providers and patients. In addition, this model seems most likely, with the influence of DTCA, to truly erode the provider-patient relationship. Since this model involves only the patient in making the final decisions, regardless of the opinion of the provider, it is possible that patients may not receive the best treatment. If this model is taken to extremes, patients may stop seeing their providers altogether, and self-diagnose and seek treatment using the internet. It is expected that this model is becoming more common, but is not yet overly popular. In spite of a more consumer-minded public, it is not likely that patients are making medical decisions completely on their own. For the most part, medical professionals are still needed for patients to access laboratory services and prescription medications.

The final model, shared decision-making, is expected (eventually) to be the most likely, and most positive, result of the effects of DTCA and consumerism. In fact, this model has already been cited by several authors as being the ideal. Indeed, it seems that this model contains the most potential for positive interaction between provider and patient, and to be the most productive relationship, if both members agree to participate. In this model, both patient and provider give and take, and work together to make the decisions that will lead to the best outcome for both parties. Both members are considered equal and important. This model, more than any other, seems to involve consensus and is the most compatible with negotiation techniques that are likely to be employed by both patient and provider. If both provider and patient can agree to this
model, it is likely that patients will be satisfied knowing that their needs are met and considered, and providers will be satisfied knowing that their knowledge is important and that they will not be pressured into an unfavorable choice.

In spite of the potential positives of this shared decision-making model, there may be several reasons that it is not yet the most common. First, it may not yet be the preferred model for healthcare providers, and is therefore met with some resistance. Second, while patients may be more active and desire more authority in making decisions, they may not truly be more knowledgeable. DTCA is not the most reliable source of health information, and poorly informed patients are more likely to be at the "mercy" of their healthcare providers.

One group of healthcare providers that may be suffering the consequences of DTCA is NPs. These providers are playing an increasingly prominent role in healthcare in this country, and are therefore the focus of this study.

**Nurse Practitioner Training and Practice**

The first NP program was started in 1965 at the University of Colorado and focused on pediatric care (Dunn 1997; Wilson 2003). NPs became important in healthcare because they could meet the demands for primary care during a time when there was a shortage in healthcare personnel and healthcare costs were rapidly rising (Dunn 1997; Wilson 2003). Early NP education was conducted by physicians and provided a way for nurses to increase their responsibilities, alter their roles, and increase their professional status (Dunn 1997; Wilson 2003). NP programs were initially very disorganized, in part because many nurse educators were against expanding the roles of nurses, and operated under medical schools or nursing schools (Dunn 1997). Eventually, resistance to the NP decreased, and the educational content of NP programs improved.
Now, most NP programs are master’s level nursing degrees, with various specialization options. Professional responsibilities of the NP depend on whether she/he works independently, is employed by a nursing service, or is employed by a physician, as well as whether the working environment is in community practice or in an acute care/hospital setting (Dunn 1997).

Although some nurse educators still feel that NPs follow a medical model of care, rather than a nursing model (Dunn 1997), an NP is generally considered to be an advanced nurse, usually with graduate level education in theory, clinical practice, and research, and has come to be associated with primary care (Dunn 1997). NPs can choose among several specialties, from pediatrics to gerontology (What is a Nurse Practitioner? N.d.). NPs can perform “technical activities that had previously been the responsibility of the physician (e.g., physical examinations, laboratory tests, diagnosis and treatment of illness, [making referrals], and in certain states, the prescription of medications)” (Dunn 1997:7).

Twenty-six states allow NPs to work without supervision or collaboration with a physician, and 16 states allow NPs to prescribe medications without collaborating with a doctor. NPs cannot prescribe drugs in Illinois, but all other states allow it, with at least some doctor involvement (Cockerham 2004). In Michigan, where this study was conducted, NPs can diagnose and treat various illnesses and health conditions, like high blood pressure, diabetes, sinus infections, injuries, pregnancy, and depression. NPs in Michigan can prescribe drugs, order laboratory tests and therapies, and, if necessary, they can refer patients to specialists. NPs can work under a collaborative agreement with a doctor, or they may practice under their own license, and NPs can accept payment from third party payers (What is a Nurse Practitioner? N.d.).
Methods

To determine whether or not DTCA impacts the NP-patient relationship, as well as the nature of this impact, interviews were conducted with ten NPs. Interviewing is useful for obtaining an in-depth understanding of subjects’ opinions and attitudes, and it provides for flexibility and detail that is not available from a questionnaire (Berg 1995). This flexibility allows the researcher to immediately clarify any misunderstandings or probe for more information on any one topic (Kvale 1996). Interviewing also allows the researcher to obtain non-verbal information such as facial expressions and emotions. The purpose of interviewing is not necessarily to gain quantifiable information, but to better understand the topic of interest from the perspective of the interviewee (Kvale 1996).

Structured, or standardized, interviews follow a strict interview protocol, in which each subject answers the same questions in the same order as the previous participants (Berg 1995). This type of interview is useful for the researcher who wants to compare responses among participants and who knows exactly what he/she wants to learn from the interview. Unstructured, or unstandardized, interviews are the opposite of structured interviews. In this type of interview, the researcher may not know the questions ahead of time, and therefore does not have an interview protocol (Berg 1995). This type of interviewing is more popular in fieldwork when researchers wish to gain more information on their observations.

A third type of interview falls between the two and is referred as the semistructured, or semistandardized, interview (Kvale 1996; Berg 1995). During this type of interview, the researcher asks questions involving predetermined themes in a systematic manner, but also probes beyond these planned questions into topics that arise during the interview (Berg 1995). Researchers using this type of interview understand
that subjects understand the world in different ways, and during the interview, attempt to understand the world from the perspective of the subject (Berg 1995). According to Kvale (1996:5-6), this type of interview seeks to “obtain descriptions of the life world of the interviewee with respect to interpreting the meaning of the described phenomena.”

The interviews in this study were semistructured, and treated as “conversations that have a structure and a purpose” (Kvale 1996:6). All participants were asked the same general questions relating to a set of content areas, in a logical progression. However, interviewees had the opportunity to further discuss the content they felt was most important, within the established topics. The purpose of this project is to understand more deeply the issues that DTCA raises for the provider-patient relationship, and to guide future research. The information obtained from these interviews is not intended for quantification.

One concern with this type of interviewing involves the role of the researcher. The researcher may unknowingly influence subjects’ responses through verbal and bodily responses to subjects’ answers, but also by asking leading questions (Kvale 1996). As long as leading questions are intentional they do not jeopardize results, and in fact, can check the reliability of subject responses (Kvale 1996). Additionally, when interviews are analyzed, there is a possibility of multiple interpretations of the subjects’ responses. Kvale (1996:287) argues that as long as this is due to differing perspectives, and not “biased subjectivity,” alternate interpretations can be a strength rather than a weakness. Finally, the perspectives and expectations of the researcher as well as the interviewee can influence the encounter and the results. Should this bias go unrecognized, Kvale (1996:286) states that interview results will be “invalidated.” However, recognizing this subjectivity can “come to highlight specific aspects of the phenomena investigated, bring
new dimensions forward, [and contribute] to a multiperspectival construction of knowledge" (Kvale 1996:286).

Originally, it was intended that participants for this study would come from the Michigan Council of Nurse Practitioners. One contact person in the Michigan Council distributed an e-mail message (see Appendix B) to other members of the organization. This e-mail message explained the purpose of the study, asked for volunteer participation from those who have been in practice since or before June 1992 (i.e., five years prior to the onset of DTCA television advertising), and listed the researcher’s contact information. NPs who wanted to volunteer to participate could then contact me and set up an appointment for the interview. However, due to a lack of response to the original and follow-up e-mails (of three total responses to the e-mails, two had been in practice long enough to participate), a snowball technique was used to locate additional participants, and the length of time for participants to have been in practice was shortened. Previous participants were asked whether or not they knew of any other NPs who would be willing to participate, and if so, to pass along my contact information. NPs could then contact me, as before, to set up an appointment.

This approach is limited in that the size and nature of the sample make the results less generalizable to the general population. However, this does not trivialize the contribution that these participants’ knowledge could bring to this area of study.

With one exception, interviews for this study took place at the office or home of the NP, at a convenient time for both the NP and the researcher, and lasted approximately one hour. At the start of the interview, I introduced myself and briefly explained the purpose of the project. I then asked the NP for her willingness to participate in the interview, and asked her to sign a consent form (see Appendix C). Each participant was
offered the option of terminating the interview at any time, or not answering any question with which she/he was uncomfortable.

Each NP was then asked a series of questions that related to the impact of DTCA on several areas in her/his professional practice, including prescribing practices, diagnosis and treatment decisions, additional patient burden on the provider, and patient trust in the provider. Based on the research question, an interview protocol was developed. After the introductions were made and the study was described, the interview began by exploring some basic background information, such as how long the NP has been practicing, the setting for her/his practice, her/his specialty, her/his primary client base (i.e., women, children, etc.), and how often she/he prescribes medications to patients. Then, in order to begin to assess the impact of DTCA on the NP-patient relationship, the interview explored the topics of interest: provider prescribing practices, diagnosis and treatment decisions, the amount of burden the provider feels from her/his patients, and patient trust in the provider. The interview protocol can be found in Appendix A.

When the sessions finished, the NPs were given the opportunity to discuss any questions or concerns that arose during the interview, or to revisit any points that needed clarification. The interviews were tape recorded, with the consent of the interviewee, transcribed verbatim, and then examined for evidence of themes within the topics of interest. After transcription and analysis, the tapes were destroyed. Results are discussed for each topic area using direct quotes to support the themes. Interviews also were examined for similarities and differences among respondents, and any themes that arose during the conversations that were not originally part of the interview protocol also are discussed.
There were no foreseeable risks to participants in this study. The nature of the content is not sensitive, and many of the questions covered issues with which NPs must deal in their everyday practice. In fact, this research focuses on a group of healthcare providers that is not typically considered in the body of social research. One intent of this study was to give NPs a chance to formally vocalize and share their opinions on a matter that influences their professional lives. In order to encourage honest conversations, information obtained in the interviews remains confidential. Although interviews were tape recorded, they were transcribed without identifying information. In addition, any part of the interviews used in this thesis, either paraphrased or directly quoted, does not contain identifying information.

This study is considered a pilot study. It is exploratory and seeks to provide the springboard for future research. Possible directions for such research are discussed in Chapter VI. The next chapter reports the results from the ten NP interviews.
CHAPTER V
RESULTS

Characteristics of Sample/Background Information

At the start of each interview, the NPs were asked a series of questions designed to solicit background information, including education, specialty/concentration, length of time the interviewee had practiced as an NP, setting for the practice, primary client base, number of patients seen per day, and the frequency with which medications are prescribed.

Each nurse practitioner (NP) interviewed was female. All were white, and all but one, who was younger, appeared to be between age 40 and 50. With two exceptions, the interviews occurred at the home of the NP, which was usually modest, in a middle-to-upper-middle class neighborhood.

Nurse practitioners in this study have between two and 18 years of experience as NPs, with all but three having practiced as NPs for at least 10 years. Many had practiced for several years as nurses prior to obtaining their advanced practice degrees. Currently, in order to practice as an NP in Michigan, one must hold a current and valid license, a Bachelor of Science (or higher) degree in nursing, have successfully completed a formal advanced program for NPs, and meet the advanced practice certification standards of the American Nurses Credentialing Center (Locke et al. 2000).

In this sample, all but one of the NPs have at least one master’s degree, two have two master’s degrees, and two are currently pursuing (and nearly finished) PhDs. Most of the NPs obtained their master’s degrees from universities in the State of Michigan, including Wayne State, University of Michigan, Grand Valley State University, and
Michigan State University (an extension program offered at Kalamazoo Valley Community College). One NP attended both Columbia and the University of Pennsylvania, and another attended Case Western Reserve University. Of the two NPs who obtained NP certificates before master’s degrees were required, one had attended a program in Milwaukee, and the other (who later earned a master’s degree) attended a program in Minneapolis.

When choosing a master’s degree program, a nurse must select a specialty or concentration. In this sample, three NPs were women’s health specialists, three concentrated in family practice, one specialized in adult health (and now practices in allergy/asthma), one received certifications in women’s health, adult health, and family practice, one NP was certified in both adult health and family practice, and one NP was a women’s health specialist and midwife.

All but one NP indicated that they were employed in private practice or at a clinic, but many have practiced as NPs in more than one capacity. One NP works in a clinic specifically for the uninsured, and three others currently practice in an area where they treat many un- or underinsured patients. In two cases, the NP had previous experience in starting a nurse-based clinic. In one case, the NP is currently employed in an urgent care facility, but she has previous experience in private practice. One NP who works in private practice also works part-time for a county health department. Furthermore, three NPs hold teaching positions at public universities in Michigan in addition to their clinical practice.

In a full day, most of the interviewed NPs treat approximately 15-20 patients. One family practitioner reported treating more patients per day, with a new patient every 15 minutes (because of a very efficiently run office) and one NP, who practices in an
allergy/asthma clinic, treats fewer patients per day. Most NPs reported that the exact number of patients they are able to treat per day depends on the condition or issue(s) for which the patient has made the appointment.

In almost all cases, NPs reported that at least 60% of patients each day leave with a prescription. Two of the NPs (one in allergy/asthma, one in women's health) indicated that typically, each patient leaves with two to three prescriptions. It should be noted that figures, estimates, and percentages are self-reports provided by the NPs.

One final interesting point that arose during several interviews was that many of the providers in this sample do not watch much television (and one does not even read popular magazines), and, therefore, have not seen many of the prescription drug advertisements. This is a potential source of bias in the sample. However, most NPs indicated that they were aware of at least some of the television and magazine advertisements, or had seen the advertising in magazines, and even if they were not familiar with the advertisements, they were well-informed about the products.

Providers' Relationships with Patients

According to the American College of Nurse Practitioners (ACNP), “NPs focus largely on health maintenance, disease prevention, counseling and patient education in a wide variety of settings” (American College of Nurse Practitioners N.d.). “Increasing the health knowledge base of patients and families (consumers) is a vitally important function of nurse practitioner philosophy” (American College of Nurse Practitioners 2001). Therefore it is no surprise that, for the most part, the NPs interviewed for this study practice using a shared decision-making model.
When describing their relationships with their patients, NPs, like the family provider quoted below, frequently described their strong listening skills and their focus on education and disease prevention, which makes them different from doctors.

I personally think I have a pretty good relationship with my patients. I try to be very good about explaining things to ‘em... [A]s a nurse practitioner...I think our role is different. We do a lot more education and patients do appreciate that.

The NPs stressed that they use a nursing model, not a medical model which emphasizes diagnosis and treatment. One women’s health NP described the difference between the two models.

I’m working on a nursing model here. I’m not working on a medical model...[T]he major difference between nurses and medical personnel—whether they’re PAs, or MDs, or DOs—...[is] nurses go into nursing to help people, and they realize that the illness is attached to a human being. Medicine trains you to deal with an illness, or...a specific problem, that just happens to be attached to a human being.

Furthermore, the NPs depicted their relationships with their patients as a “partnership,” where patients are active in their care, and are educated and informed about their options. During appointments, the NPs engage their patients in discussion over health concerns, diagnoses, and treatment, and they believe they excel at explaining the reasoning behind each test that is ordered or decision that is made, as is evidenced by the following from a family practitioner.

Primarily I try to do a lot of teaching, explain to them...why I did the labs I did, what the goals [are]...what the national guidelines are for managing their disease, so that they have a better understanding of...why I wanna make changes in the medications, so they can be a more active participant in their care.

The NPs value discussion with their patients because they feel it is important for patients to “buy into their healthcare” in order to increase compliance with treatment. As a family health NP described:
I always try to bring the patient in because, after all, they’re the person that’s gonna have to abide by the treatment regimen. So I always try and… bring them in, so that they have input into the decision-making process.

Furthermore, these NPs felt that they work for their patients. A women’s health specialist explained:

Really, I’m the person they’re hiring, and I keep them in mind. If it wasn’t for them, I wouldn’t have a job, so I have to do the best I can for them.

Some of the NPs indicated that there were patients who chose not to be active partners in their care. These patients preferred for their providers to make recommendations, and proceed accordingly. Two statements adequately summarize the attitudes of most of the NPs toward this type of patient. The first is from a family provider:

Occasionally you run into people that want you to make the total decision, especially if they don’t know a whole lot about what’s going on, and that’s fine.

The second, an allergy/asthma NP, explained:

There are people that… don’t want to participate as much as others who want to participate fully and be really involved, so you… kind of have to feel the patient out, and again, the role is to meet their needs, so if that’s how they see the interaction…, that’s okay.

The NPs stressed that it was essential for patients to know that they could ask questions or come back if a course of treatment does not work for them, but more importantly, patients should feel comfortable during the appointment and with the end result.

In two cases, providers reported that their interactions with patients depended on the type of problem that an appointment was scheduled to address, and the longevity of the provider-patient relationship. For some issues, like an infection or a sprained ankle, there may be one typical course of action, which usually does not involve much
discussion. However, with a chronic illness or birth control decision, there are more options to consider. A women’s health practitioner simply stated:

It depends on the situation; it depends on the patient. There are some situations that are just not negotiable. For other patients, there are options, and so, then we’ll talk about what the options are... Someone with pelvic inflammatory disease doesn’t have a choice. You get antibiotics and other things done, period... Someone who’s there for birth control or hormone replacement has options. Maybe [these are] limited by their own medical history and experience, but we all start with the same options and narrow them down, and then choose from what’s left.

A family health provider explained that her interaction with patients also depended on how long she has been treating them.

I’ve been at the practice I’m at now for 6 years, and so most of the patients I see, I’ve seen over time, and I’ve developed a relationship, not just with that patient, but with their whole family...I tend to have a lot of extended dialogue, not necessarily about what they’re there for...[S]o they may be following up on...other issues in the home, some recent changes, additions of a new baby, and how that’s affecting the rest of the family members. Families that I haven’t seen before, and come in for a very specific episodic or procedure-type visit, tend to be much more focused visits... Why...are you here today? ...How long have you had the symptoms? Tell me about the symptoms. [H]ave you ever had this before? [T]ell me a little bit of what is your past medical history.

In general, when making treatment decisions, NPs review the patient’s health history and lifestyle, or “the whole patient,” in order to select the best course of action. Most NPs in this sample preferred to offer up to three options, providing the risks and benefits of each, so patients could select the method that would work best for them (usually within the boundaries of their medical insurance).

Overall, discussions with these NPs revealed tendencies toward the shared decision-making model, as proposed by Charles et al. (1997). Both provider and patient were usually actively involved in appointments, in the sharing of information, and in decisions regarding treatment. The NPs enjoyed discussions with their patients, and preferred that their patients were well-informed about medical options. Providers were
eager to answer patients’ questions, and attempted to provide all pertinent information regarding treatment options, risks, and benefits. Providers desired to know patients’ preferences and lifestyles so that chosen treatment methods would suit the patient, and be followed. Furthermore, as will be discussed in greater detail in the section on Diagnosis, Treatment, and Prescribing Decisions, these providers were flexible, and willing to allow patients to choose one course of treatment, even if it was not the provider’s first choice. Most importantly, as evidenced by the providers’ willingness to make decisions for patients who do not wish to participate in shared decisions, these NPs were able to assess and meet their patients’ needs, which is perhaps of greater consequence than fitting into any one patient-provider model.

Diagnosis, Treatment, and Prescribing Decisions

Patient Knowledge and Self-Diagnosis

Of particular interest to this study was whether or not DTCA has affected the manner in which providers make diagnosis, treatment, and prescribing decisions, and the providers’ power to make them. In order to begin to assess whether patients have begun to have more power in the decision-making process than the providers, NPs were asked whether DTCA seemed to increase patient information and knowledge regarding prescription drugs.

The NPs in this study remarked on the success pharmaceutical companies have had in reaching a wide range of audiences. In particular, DTCA has created name recognition for brand name drugs. For example, one allergy/asthma provider related an encounter with a family during which she discussed a treatment for a child’s rash:

NP: ... Well, basically [the] little kid...had eczema, and I said, ‘Oh yeah, I think you have eczema...’ and I was just kind of thinking out loud, and I said, ‘Oh
maybe I’ll give you Elidel.’ [And he said] ‘Elidel, Elidel. Yes, I want Elidel.’

Interviewer: How old?

NP: Little, like four! ...It was because there’s Elidel, and it’s like the Superman type of thing [a character in the advertisement]...[And the mom says, ‘Do you have any samples of that Elidel?’ And I didn’t have any to give her, and...she says, ‘well then I don’t want to take that because it’s $40 copay.’ And the kid says, ‘Oh, I can’t have my Elidel!’...And it’s not like I thought Elidel was the only solution to his problem, so I said, ‘Well, how about some over the counter Cortaid? And I have some samples of that, and then...if it works, you can buy it, and it will be inexpensive.’ ...And that kid’s like, ‘I can’t have Elidel?’ ...and it’s just white cream. How do you know the difference if you put it on...eczema?

Similarly, in the way that Kleenex has become a common name for facial tissues, one brand name drug can become synonymous for the whole class of drugs. The illustration given by a women’s health NP was Lipitor, a cholesterol-lowering medication. The NP reported:

They all ask for Lipitor, and Pfizer made sure with all their slick advertising that that’s...what you ask for, but it’s like Kleenex. It doesn’t mean that you’ll get Lipitor... It’s the class of drugs, [and] Lipitor means a cholesterol-lowering medication now.

Regardless of increased name recognition, none of the providers specifically mentioned any additional patient knowledge concerning prescription drugs due to DTCA. A women’s health NP felt that some patients were more knowledgeable about drugs, but not because of the advertisements. She indicated that the increase was more likely related to

their education levels, their connection, if there is one, to the healthcare industry, their own experiences with medical care.

In fact, a few providers expressed concern that patients, rather than being more knowledgeable, were not informed enough about prescription drugs. To illustrate this point, one women’s health provider discussed an example involving a bladder control drug called Detrol.
Take the... Detrol one. ‘You gotta go, you gotta go right now.’ Well, then people think, ‘Well, I’m leaking, so that Detrol must be good for me because I’m always going.’ No, Detrol doesn’t stop the leak, it just stops the frequency, urgency. So... then you’re trying to explain to them, and they’re saying, ‘but the television says it’s gonna help my problem...’ I think [the advertisements] get a person’s attention, but they don’t necessarily give them all the information they need, and they certainly don’t tell them everything they need to know about that medicine, or that there are other options, or... this isn’t maybe your problem just cause you have one of the symptoms.

Similarly, a family practitioner indicated that some patients may be educated about the drugs, but not be fully aware of the capacity of the medication.

The majority of people that actually bring in an ad are informed, [but] if someone mentions something that they saw on television, they may or may not have the full scope of what the product even is.

Furthermore, the NPs felt that many advertisements did not accurately portray people who suffer from the condition. A women’s health NP felt that DTCA falsely depicted the actors in the advertisements, particularly for ED and sexually transmitted diseases, as happy, youthful, healthy-looking people.

The ads for the erectile dysfunction meds show couples that are very physically affectionate and have a lot of very positive non-verbal behaviors: gazing into each other’s eyes, and stroking each others’ arms. And... from my experience, couples that have sexual dysfunction issues usually are not having those kind of behaviors... And then...the woman who does the ads for... Valtrex, the herpes med, is out dancing and playing around in a thong bathing suit, and I just can’t imagine any of my patients with herpes really feeling comfortable wearing that if they were having an outbreak.

While patients may not actually be more knowledgeable about drugs, several providers indicated that DTCA has been responsible for a small increase in patients who self-diagnose their illnesses. An allergy/asthma provider felt that patients have a tendency to “jump” to conclusions after seeing drug advertisements.

When it’s running all the time on the TV, even if you’re not paying that much attention... it sinks into your brain. Purple pill, da, da, da..., or I have heartburn today, I must have GERD [Gastroesophageal Reflux Disease], instead of maybe I
ate the wrong thing last night… Jump right to the diagnosis…because they have this stuff floating around in their heads from all the ads.

Another family NP expressed similar sentiments:

I think with the ads on TV, they mention symptoms, and…people say, ‘oh yeah, I have this symptom, that symptom, and that symptom, so I must have this diagnosis.’ And so, people are…more attuned to the symptoms that go along with the diagnosis, and they’ll come in and say, ‘well, I think I have reflux disease because I have this, this, and this,’ …and they may very well have it.

In spite of patient’s tendency to self-diagnose, as the quote above shows, patients who do diagnose their own illnesses as a result of drug advertising may not always be incorrect. Two women’s health NPs agreed. One felt that patients were usually correct in diagnosing their symptoms:

Some of them have been really right! …I’d say they’re pretty much in the ball park, for the most part.

The second NP did not feel that her patients were always correct, but she preferred for patients to have spent some time looking into an illness on their own.

Sometimes they’re right. Sometimes they do need this particular medication, or this particular compound of hormones, but sometimes that’s not the best thing. I’d prefer patients that were well educated. Because it’s hard if they have never done any looking into something on their own.

A family provider felt that even if patients were wrong, at least they were aware that their symptoms were problematic, and these symptoms could be checked by a professional.

I don’t think [DTCA is] getting through to everybody on the symptoms, but at least they’re making people more aware of the fact that the conditions exist…[A] lot of people think that having heartburn every time you eat a piece of pizza is normal. I’ve seen the commercials that actually show you interesting characters…chewing at the esophagus, and showing…that it can cause long-term damage. [It] opens their eyes up that they shouldn’t just be self-treating, that they should come in for treatment if they’re having it frequently.
Patient Requests

While not all of the providers in this study have treated patients who made an appointment just because of DTCA, all of the interviewed NPs have treated patients who requested prescription medications. Oftentimes, these requests were simply for antibiotics for a cold, for a drug the patient already tried and found to be successful, or for a drug a friend or family member recommended. A family NP felt that:

The most common, I would say, is with antibiotics, like Zithromax, which is a very convenient antibiotic. It’s given over three days or five days, it’s given once a day, it’s highly effective. If they’ve had that drug before, or a family member has had that drug, they will ask for it by name.

On the other hand, some drug requests could be directly linked to DTCA. Another family NP acknowledged right away that DTCA has affected her office.

Oh yeah, and it’s impacted our practice. Everybody comes in and wants Nexium because they have heartburn, …and some patients need Nexium. In our population, Nexium is probably one of the most expensive drugs… [A] lot of ‘em will ask about…mostly the stomach stuff, the allergy…Oh, one patient asked about a medication for herpes. But that was pretty much it. …I’d say the two big ones are allergies and the stomach.

Yet another family provider admitted that patients were more likely now than in previous years to ask for medications.

Much more than it used to, yeah…It seems like when there’s a new medication or new drug that comes out, and it’s just being bombarded on television, people come in and say, ‘oh I want, I want this.’ Like the purple pill, ‘I want the purple pill,’ and…there used to be…only one or two medications you would use for heartburn-type symptoms, and now…everybody wants this new one. And then…when…the next new one comes out, then they won’t want the purple pill anymore, they’ll want the new one.

As expected, when recalling patient requests, family practice providers’ patients most often asked for medications for stomach and allergy problems, as well as antibiotics, while women’s health practitioners’ spoke of patients who requested sexual dysfunction
medications, HRT and birth control medications, overactive bladder medications, and antidepressants.

In addition to simply requesting drugs, many providers' patients bring advertisements or flyers, books, magazine articles, and other information about prescription drugs to their appointments. One example came from a women's health provider whose patients brought advertisements to appointments for Ortho Evra. This NP discussed how effective Ortho Evra's marketing has been, and how much more she prescribes that form of birth control compared to other equally effective forms.

I tell you, whoever is their marketing rep for Ortho did a phenomenal job on that when the patch came out. Because people were ripping out and bringing in Good Housekeeping or Ladies Home Journal or Redbook or Cosmopolitan...and, 'I want this patch. I want this.' And then we'll say, 'oh let's talk about it.' But have you ever had anybody bring in something to talk to you about the Nuva Ring? No! Because they didn't have...good enough marketing. ...They should be just as good as the patch, but they're not.

Another women's health NP described requests for Avlimil, a non-prescription supplement, intended to treat sexual dysfunction, whose advertising is similar to that of a prescription medication.

Lately what I can think of is for herbs, Avlimil...And there again, it's herbs! You don't need a prescription for it! That again was slick advertising...and it says...ask your doctor about that, because they did a massive campaign, and they sent us all samples. All it is is...cohosh and some ginko, and...a couple other little fancy herbs, all of which you could have bought at the health food store in the last few years, on your own. But they put it into this little purple pill, and with some slick advertising to make it look like it's a prescription...for a sexual desire.

Two NPs believed that patients brought articles from magazines or the internet to appointments more so than drug advertisements. When specifically asked whether or not patients brought printed advertisements to their visits, a family NP replied:

Oh, not the drug ads as much as stuff as they've pulled off the internet. So, they'll bring stuff in on an obscure disease from the internet that they think they might have, and they'll say, 'you know, I found this, and I'm wondering if this is what I
have,' and I’ll go, ‘Mmm. Well, before I read that, why don’t you tell me what your symptoms are and what you’re feeling, and how long you’ve had them.’

An allergy/asthma provider responded similarly:

I have had people bring in, not necessarily like an ad, but bring articles. Like, sometimes they’ve read a book or have an article, ... or is this antihistamine right for you..., and they’ll say, ‘I read this in here, and I think this one...meets my symptoms,’ or something.

In addition to patients’ general requests for prescription drugs, several NPs raised the issue of patients requesting samples of medications, but most did not attribute any patient expectation of receiving samples to DTCA. Most NPs believed that their patients appreciated samples, especially when starting a new medication, or if they had exceptionally high copays. One provider, who practiced in allergy/asthma, was the exception. She did ascribe her patients’ increased expectation of getting samples to DTCA.

And the other piece is in the sampling because it is advertised...we can give them samples, and then we hook them in, this is a good drug, and then they have to have it..., so then, you’re either writing prescriptions for something that...it may be appropriate..., [but] maybe their insurance doesn’t cover it, and you’re having to do all these prior authorizations to get it approved when you know darn well the other one would probably work fine as well, but they are convinced that [the advertised] one works.

In addition, many providers agreed that the sample medications that were available in their offices were usually the newest drugs available and were often the same drugs that were currently advertised directly to consumers. A family NP explained:

Oh yeah, oh yeah. As soon as they...launch a new drug, you can bet that your drug representative...is gonna be in the office telling you all about this new drug they’ve launched.

Another family provider felt that it was a good thing that the samples in the office matched up with DTCA and direct-to-provider advertising.
That goes hand-in-hand because those are the meds that that particular company is marketing at that time, and yeah, those are the samples that you’re gonna get. Which in some ways is good, in the sense that when a patient comes and asks for that, if you do have a sample you can let them always try it and see if it really is gonna work for them the way they think it is.

Because patients do make so many requests of their providers, NPs were asked about the degree to which patients aggressively demanded that their requests be met. While some providers felt that patients who were pushy were usually those who wanted narcotics, other providers, like the allergy/asthma NP, felt that patients had become more aggressive since the advertising became popular.

Oh yes, and that has definitely changed since the TV ads are on... People come and they say, ‘I think I need this.’ And, you’ll say, ‘Let’s... go through your assessment, and then we’ll discuss... what actually is going on, and then we’ll get to the treatment plan.’ But sometimes they’ll just come in or they’ll say..., ‘I saw this on TV, my neighbor has it, and I want that’...[S]o, again, going back to that whole partnership thing, is I have to meet their needs, but... let’s go through the process, and arrive together at the conclusion, rather than you just coming in and telling me what you think is... appropriate.

A family NP affirmed that she does have some pushy patients, but rather than just denying their requests, she tries to present them with alternatives.

What I always tell people is that the newest thing isn’t always the best thing. The newest thing is usually the most expensive thing, and, especially if cost is an issue, and they have an insurance company that doesn’t wanna pay for the newest then... I’ll tell them, ‘well, if this is something that you really want,’ and if I think that it’s truly indicated, I’ll write the prescription. But I will tell them, too, that ‘if your insurance doesn’t pay for it, then you will have to pay for it,’ and that usually makes them think twice about do they want this newest, best thing.

Another provider, in women’s health, described her patients as “assertive,” rather than pushy. This NP was not particularly bothered by requests for prescriptions, and she asserted that while her patients do not demand drugs, they do not hesitate to ask about them.

Let’s just say my people are quite assertive sometimes. I don’t think they’re pushy because... I don’t think I make them feel like they have to be pushy.
...[I]t’s not like they walk in the room and go, ‘I want you to give me this, and you better give me this.’ It’s more like, ‘Oh, I read about this, and have you heard of this,’ type thing.

In general, the NPs felt that even though patients pressured them for advertised or other drugs, it was not necessarily a problem. Many providers reported that if patients received the drugs they wanted, they were more likely to comply with treatment, and as long as what they wanted to try was not harmful, there was no reason not to prescribe it. The following is an example from a women’s health NP.

I would say unless it’s harmful, I would try to give them what they want... Especially for... things that you know they’re gonna be treated for or something like that, like the Suzanne Somers’ hormones, and I can say to them, ‘your insurance isn’t going to pay a thing for it. I can give you something your insurance will pay for, [but] this is gonna be all out of your pocket.’ I don’t think it’s gonna be harmful for them or anything, and they may still say, ‘I don’t care, I want it, I’ll pay out of my pocket’, so yes, then I would give them what they want because otherwise they’re not gonna take it.

A family NP, when probed about patients who might ask for a drug like Flonase or Nexium (as opposed to narcotics), replied:

...[D]epending on what the situation is, it may be just fine. If they have that condition and they feel that they want to try something, I’m usually pretty open to that...Because you gotta look at the fact that if somebody thinks that something’s gonna work for ‘em, they’re probably gonna have a lot better success, a little bit of that placebo effect.

Alternatively, one family practice NP reported that her patients were less insistent with requests for drugs than when DTCA first started. She stated that in previous years, patients had better insurance coverage and lower copays. Now that copays are so high, patients prefer not to pay for name brand drugs.

They don’t want those drugs when they find out what the copay would be on those. ...They wanted those drugs more when it cost them 10 or 15 dollars a month, but costing them 30 to 50 or more dollars a month, they don’t want those.
Prescribing Decisions

In light of DTCA’s apparent success at heightening name brand recognition and the increase in patient requests for medications, one issue that was of interest for this study was whether or not there would be an impact on prescribing practices regarding generic medications. When asked about the influence of DTCA on patients’ willingness to take generic medications, most providers did not believe that there was any real effect. On the one hand, a family health NP expressed that some patients felt that generic medications were “somehow substandard” just because they were generic. Similarly, a women’s health NP felt that her patients had always resisted generics. She compared the preference for name brand medications to preferences for brand name clothing or shoes.

Patients have always resisted generics. They...always have. And...so, I don’t know that...[DTCA has] made them more or less so. I think that name brand recognition is big in the United States. ...[W]hy do they wear the Nike swoosh instead of Target’s best? It’s...a name brand thing.

Conversely, another family NP felt that her patients trust that she has their best interests in mind when she prescribes generic medications.

Over the last two years, as the copays went higher and higher on brand name medications, the patients that will take a less convenient medication that might have more troublesome side effects but is generic has greatly gone up. ...[A]nd they actually think that you’ve got their best interests at heart now when you prescribe them a generic, versus before if you didn’t give them a brand name medication, they thought you were cheating them.

In fact, most of the providers noted that patients were usually willing to take generics, and a few other NPs reported that patient acceptance of generic medications had increased, mostly due to increased costs of prescription medications. Patients may prefer to take brand name drugs, but neither the patients nor the insurance companies are willing to cover the full cost for brand name medications. As a family provider conveyed:
When you explain…to people that insurance is driven…by drug cost, and that most insurance companies aren’t gonna pay for the newest and best thing if there’s other things out there that will work just as well, and they’re less expensive. And then…if they will end up paying for it if their insurance doesn’t cover it, then they can start to think twice about whether or not they’re willing to fork over the money for this new medication.

Regardless of whether patients favored name brand or generic medications, most providers agreed that patients did not want to adjust their lifestyles in order to treat their health issues; they would rather take pills. Providers did not attribute this solely to DTCA, but advertising seemed to aggravate and encourage the tendency to want an “instant fix.” A family health NP humorously asserted:

I call it the ‘magic wand syndrome.’ …[T]hey come into you and they want a pill to fix everything that ails them. I wouldn’t say it’s everyone. I would say that there is a certain population of patients that want the easy fix…I always make jokes, …like, ‘oh, if my wand was working, I’d look like Tyra Banks,’ so that they get that in life, there’s no easy fixes sometimes…The big one is pain, too. I guess, the 35 and 40 year olds that are starting to have a little bit of knee pain or a little bit of back pain…they…want Celebrex right away, and it’s like, nah. Celebrex is a really good medication, but is probably not the first choice.

Even providers who had not been in practice for very long have noticed an impact from DTCA on patients’ willingness to change their lifestyles. One family provider stated that her patients were “not very” willing to make lifestyle changes, and that DTCA was likely responsible for at least some of this aversion.

[W]hen you have so many commercials saying…this drug can fix this and that drug can fix that…they do kind of get that idea that a pill can fix anything. And they should say eat healthy or exercise, or…stop drinking, but they can just pop a pill to make their stomach stop hurting or their blood pressure or their cholesterol go down, then they don’t have to.

However, the NPs prided themselves on providing education, not just treating disease. A women’s health NP emphasized that it was part of [her] job, as a woman ages, to teach her that lifestyle changes are even more and more important as we age..., or you’re just gonna be lookin’ at heart disease, or whatever, and people don’t want to think about that until we get older.
Only one provider, in women’s health, felt that the advertising might help encourage lifestyle changes, as long as patients were truly bothered by their symptoms. Because some of the advertisements mentioned lifestyle changes, this NP’s patients were more willing to try to make the changes when they also received a prescription for the medication.

[F]or the PMDD’s, I think [DTCA] has helped. For the PMS, PMDD (premenstrual dysphoric disorder) people, when the commercials talk about...this drug will help you with your depression and everything, but you also want to limit your alcohol or you want to increase your exercise... So I think, in that sense, they’re willing. And it really depends, too, on how much they’re bothered by whatever it is... If it is interfering with their activities of daily living, most of them are more willing to change their habits, than if it’s just an occasional driving them nuts type of thing.

In the face of regular requests for prescription medications and resistance to lifestyle change, providers are confronted with both the decision of whether or not they should meet patients’ requests, and with potential consequences should they deny their requests. One possible consequence of denying patient requests is “provider hopping,” or switching from provider to provider until requests are met. Nearly all providers in this sample had experience with patients who provider hopped, but hopping patients, like aggressive ones, were usually those who sought opiate pain medications, or antibiotics for a cold. With one exception, provider hopping was not connected to DTCA. As a family provider explained:

Sometimes it’s things that their other doctor always gave them. I had one patient who insisted that she always got an antibiotic from her other doctor when she had a cold, and she didn’t have asthma, she wasn’t a smoker, there really was no indication for it, and I said, ‘well, I’m really sorry...maybe you could go back and see him if...you think you really need this, but this is self-limiting, 10 days, you’re gonna be better,’ and she did leave. On the other hand, we have drug seekers, who, usually it’s pain meds they’re looking for, and we handle that as it comes up, but, we don’t usually...have somebody who comes in and says..., ‘oh, I wanted Nexium and my doctor wouldn’t give it to me, will you?’
A family health NP explained the importance of not discrediting a colleague in the event that a patient requests a medication that another healthcare professional would not prescribe. She handled these situations by trying to bridge the gap, and still do what we think is right and best for the patient. Yeah, none of us are in the business of just pleasing the patient. Yes, you want your patients to be happy, but you’re not going to do it by compromising what you think is best, and you certainly wouldn’t ever prescribe them something that they wanted only because it was their second time coming in.

In fact, the above statement represents the attitudes of most of the NPs in this sample. If, for whatever reason, providers were uncomfortable prescribing a certain drug, they explained why, in an attempt to “bridge the gap” between what the patient desired and what the provider thought was best.

The allergy/asthma provider who had experienced some DTCA-related provider hopping felt that it was a small percentage of patients, and, depending on the medication, she may or may not choose to prescribe.

I have had some people who do that. ...[T]hat happens more in specialty practice. ‘I went to my primary care provider, they wouldn’t give it to me, so now I’m here to get that.’ And then...it may be appropriate! Sometimes they are correct... ‘I have asthma, I’m coughing, they don’t think it’s really asthma, I heard on an ad, on a commercial that it is asthma, and here I am,’ and...you do the work up.

Although one might anticipate that the NPs would feel some animosity toward patients for increasingly diagnosing their own illnesses and requesting prescription medications, these providers did not feel that way at all. Most NPs indicated that if a request was for a drug that would not harm the patient, they would prescribe the requested medication. One women’s health provider felt strongly that,

if someone is very adamant about what they really will and won’t take, and there’s no reason why they can’t take it, you’re probably better off just to prescribe it and go with it. You’ll have a lot less problems than if you try to give them something that you think is better. Whether either one of you is right or wrong, it doesn’t matter.
Overall, as has been noted elsewhere, providers take patient requests into account when deciding on a course of treatment, but requested medications are not blindly prescribed to pacify a patient. With each patient, the providers go through a process that includes recording or reviewing health history, discussing symptoms and lifestyle issues, uncovering underlying reasons for wanting a particular medication, and determining whether the patient truly has the condition for which the drug is indicated. Then, if the medication is deemed "appropriate" (all other factors aside) most providers would prescribe what their patients wanted, primarily to increase compliance. A women’s health practitioner explained:

I know that compliance has to figure in there. ...[I]f they come in expecting a prescription for the Ortho Evra patch, and I send them out with a sample and a prescription for a birth control pill, that’s not even in the same pharmaceutical company, they may not be very likely to use that.

**Direct Impact of DTCA on Prescribing**

In general, the NPs had varying opinions on whether or not DTCA directly impacted their prescribing choices. Two family practice and one women’s health providers felt positively that DTCA had not affected their prescribing decisions. The first provider, a family NP whose practice has a policy to prescribe generics whenever possible, plainly stated:

I have no interest in medications that we can’t prescribe anyway because they’re not on formulary, and without contact with the drug reps myself, I don’t hear about the new things coming out, and so I’m only likely to hear from them from

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2 During many interviews, NPs discussed direct-to-provider advertising, in addition to DTCA, as a potential influence on prescribing patterns. For example, a family provider noted:

It’s always interesting to me, too, from the viewpoint of being detailed by the pharmaceutical reps, and being deluged with ads for meds when they’re new...If a new medication comes out that treats cholesterol, the gold standard cholesterol treatment drug really bumps up their ads because they wanna stay on too. And...I just find it very comical that...the drug reps come in and if they have access to our drug room, they kind of rearrange the shelves so that their product is prominent. You open the door, and there it is!

However, further analysis of direct-to-provider drug advertising is beyond the scope of this work.
studies that I read, and those are more likely to be done on drugs that have been out for awhile.

The remaining two providers who did not feel affected by DTCA indicated that they based their choices on other factors, and did not prescribe drugs just because they were new. The family health NP explained:

> [W]hen I was doing my nurse practitioner role, one of the physicians that I worked with...said, ‘you know there’s so many drugs out there, and there’s constantly new drugs coming out...Pick a few drugs out of each class that you feel comfortable with, and really learn those...[b]ecause...then you can feel very comfortable prescribing those.’ And I think he was absolutely right. ...[S]ometimes...our choices are influenced by...what the patient already came to you on from another healthcare provider, and they’re doing just fine on that, or the insurance company helps to sway your view, but...I’m not really too crazy about jumping on the bandwagon with the newest drug out there because it’s happened over and over again historically that, yes, those drugs have gone through all the FDA stuff that they’re supposed to,... [b]ut there’s been a number of ‘em that have been pulled off the market after...actually being out in the general public for like a year because they caused problems.

Three providers, two in family health and one in women’s health, were more vague about whether or not they felt an impact from DTCA. In response to being asked how drug advertising affected her choices, a women’s health provider answered:

> Well, I think we’re pretty open in that practice to just about anything, so it isn’t a big issue for me if a patient comes in and says, ‘I want this drug.’ If there’s no reason you can’t have it, fine. And I think in other practices, especially where providers are very hooked on only using certain drugs because they know how to prescribe them, they know the side effect profile, they like to keep it just nice and tight...[m]aybe for them it’s a problem.

A family health NP noted the following:

> [A]s a provider, I’ve just been real skeptical of a lot of the things I see on TV, so I try to take it all with a grain of salt. And again, if something new comes out, it makes me wanna pick up a journal or look at some research and say, ‘Okay, all right. What’s...really the low-down on this medication? Is this something I can feel comfortable about prescribing for somebody?’

The remaining four providers, two in women’s health, one in family practice, and one in allergy/asthma, felt that DTCA had definitely impacted their prescribing choices in
at least a small way. The women's health providers were influenced specifically by advertisements for Ortho Evra, a form of birth control popularly known as "the patch."

One such provider related the following:

Oh, I would say yes for the Ortho Evra. Because even though...I know there's 70 some varieties of the birth control pill out there, and there's the ring and the patch..., when the patch first came out..., I know for a fact when somebody said I need a...method of birth control, I'd say, 'well would you like birth control pills, would you like da, da,' and I know I never automatically said the patch... It's something you have to get used to trying to offer. So, I think probably that did direct how I prescribe.

Finally, the allergy/asthma provider felt that most providers were likely to be affected by DTCA.

I can go in the cupboard so,... I give [samples] to the people who can use it for free, and then...I tend to write it more, because...there it is, in my cupboard, it's on TV when I go home, and...[s]o, I think the direct-to-consumer advertising probably has impact on the providers as well. Because that's what patients come and ask for, and we're inundated wherever we go.

**Effects of Insurance**

One factor that arose, which seemed to affect everyone's prescribing decisions more than DTCA, was health insurance. Many providers agreed that while they may prefer certain drugs over others, in the end, the insurance companies dictated what drugs patients received. In fact, two family health providers reported that they consult a program on their palm pilots for the patient's formulary before prescribing anything. One of these providers explained:

[E]verybody has a different formulary. I have a hand-held computer that I have a lot of that information and so, when I'm prescribing, I can look at what kind of prescription coverage they have, and if I'm lucky, their formulary's in there, and I can look at...right there what the alternatives are.

In other cases, providers jumped through bureaucratic hoops in order to find medications that an insurance company would cover. A family provider described experiences trying
to prove failure with preferred drugs in order to prescribe a treatment that would prove to be successful for her patients.

Generally, I’ll talk to them about what I think would be our best options. Oftentimes, unfortunately, we are regulated in our treatments so by insurance companies because even though I may say that drug A would be the best drug of choice for this particular condition for this particular patient, their insurance company may not feel that way. Whether it be HMO, whether it be Medicaid, ...they have a formulary of what they will pay for...[F]or example, if you have a patient with high blood pressure...there’s many different classes of blood pressure medication, and they will pay for certain ones out of each of those classes. Well, if you’ve tried other medications, and then maybe wanna come back to the one that you originally thought, they may, if you’ve had failures on the others, then accept to pay for that...Unless you can [prove it] up front...but again, that’s extra work for you to have to go and get a prior authorization...through in order for it to be paid for. So, it’s very time consuming sometimes because of those constraints.

In general, there are many factors that NPs must consider when choosing which medications to prescribe to their patients. The NPs in this study always try to consider their patients’ best interests and involve their patients in prescribing decisions. NPs may have their own treatment preferences, and though they are often constrained by the limits of prescription formularies or preferred drug lists, they make every effort to meet their patients’ requests and needs.

**Provider Burden**

Overall, providers did not express any overt burden as a result of DTCA. However, there seemed to be some slight differences in opinion between providers who began practicing after 1997, and those who started practicing before 1997. For this reason, these results will be discussed in two sections, entitled *Pre 1997 Practitioners* and *Recent NP Graduates*. NPs who fall into the category of *Recent NP Graduates* were not asked questions designed to obtain a “before and after” perspective on DTCA.
**Pre 1997 Practitioners**

Providers who have been in practice for at least 10 years felt that patients may be more knowledgeable or informed regarding healthcare in general (as opposed to knowledge of prescription drugs), but, as demonstrated by the following women’s health NP, they did not attribute this additional patient knowledge solely to the advertising.

In this day and age, most everybody has read on the subject, had a friend with an opinion on the subject, or gone on the internet long before they come in to see you...My patients are very well read. For the most part, they’re very knowledgeable...and they like to be part of their healthcare.

Most of the NPs in this sample concurred that healthcare information was more widely available than in years past, in self-help books and on the internet, but that this information was not always reliable. For example, the women’s health specialists referred to patients who brought in a book, recently authored by actress Suzanne Somers, about hormone replacement therapy (HRT) to their appointments. Patients asked if they could be treated with the HRT that Ms. Somers used and discussed in the book, but the providers were reluctant to prescribe this particular combination of hormones. One such NP, when asked whether or not patients now were better educated about their health than when she first started practicing felt:

Well, yes and no. I think yes in the viewpoint that there’s...much more access to medical information through the internet, and through the ads that are seen in the magazines and that sort of thing. But no in that...sometimes it’s dangerous to have just a small amount of information, and they hear something, and because it’s in print think that it must be true. ...[A]n example of that is Suzanne Somers (Chrissie from Three’s Company) just wrote a book about hormone replacement. Now here’s an actress, no medical training, who herself has a history of breast cancer [known to be a risk associated with HRT], and has written a book recommending hormone replacement. I haven’t read it, but I must have at least one patient a day who comes in saying that they read Suzanne Somers’ book and they want what she had. It may not be the best option for them!
Other providers felt that additional patient knowledge varied from patient to patient. A family practitioner reported:

You have your group of patients who always want to know everything anyway, and now they have more access to the information, and...the information they have tends to be more accurate and a little bit more up to date, where before, same group of patients, the information they accessed tended to be not as accurate and more out of date. And so you had to do a lot more reeducating. And now I'd say we do a lot more filling in the blanks with that group of patients. But you still have vast numbers of patients who are clueless, who just don’t have the time or the energy or the resources to access the information, don’t know how to access it.

Another family practitioner expressed that patient knowledge depended on the type of patient, but when specifically asked whether patients’ knowledge had been influenced by advertising, she agreed that it had.

I think so, yeah, because, prior to when they could advertise in magazines and on TV, you didn’t often have people come in and ask you for specific medications, but once they started advertising...then people would come in and say, ‘I saw this on TV, and I think this is what I need for what I have.’

As previously discussed, providers generally want their patients to be well informed, but better informed patients often ask more questions. For many providers, this translates into spending additional time educating patients about the treatment, explaining benefits, risks, and appropriate use of medications, as well as addressing any additional patient concerns. In response to being asked whether DTCA caused her to spend more time with her patients, a women’s health NP responded:

I think sometimes, yeah. If...they’re asking for something that you don’t think they really need, or they really don’t need, or whatever, I’d say yeah, it takes a lot longer. But otherwise, it’s like, ‘Oh that’s good! We can try that for you. That’s not a problem,’ type of thing. But then...we have to delve into why do you want to try it, so, we would have maybe delved in it already, and maybe we wouldn’t have.

A family provider commented:

And so they’ll be looking for information about a specific drug that they really don’t know if they need or not, and they don’t know what it’s for, but they saw an
ad for it. And so, I’m finding I’m using more patient time explaining what medications are used for and why [patients] may or may not need that medication.

Another family NP, who believed her interactions with patients contained “teachable moments,” explained that with everything that needs to happen during a fifteen minute appointment (review the patient history, perform the exam, document the chart, outline a treatment plan) these moments are very small. Unfortunately, not much time is left to converse with patients about why they are, or are not, a candidate for a particular medication.

In addition to spending extra time educating patients about various treatment options, some providers have spent time clearing up misconceptions that have resulted form drug advertisements. A family health NP said:

I think what happens is...they’ll hear something in an ad, or they’ll read something in an ad, and it...[doesn’t] have an opportunity to go in depth, and...[patients] only hear kind of what they wanna hear, too, so they’ll come in with maybe a preconceived idea, but then when you tell them, ‘well yes, that’s true, but also it goes along with that, and that goes along with that.’ ‘Oohhh, I didn’t think of that,’ or ‘Oh, I didn’t realize that could happen.’

Furthermore, since DTCA began, providers found that they spend additional time addressing concerns over side effects. Because the FDA requires DTCA to provide important risk information, television and magazine drug advertisements list potential side effects. Providers expressed some frustration with this issue, because patients may have heard or read about a side effect of a particular medication, but do not have all the information they need to know how the potential side effect applies to them, or whether they need to worry about it at all. A family NP reported:

Actually the most troublesome area is when [the patients] find out...oh, this drug could have all these side effects, but they don’t understand the chances for those side effects are very, very low, and that they really, really need the medication.
The provider quoted above also specified:

That’s the only area where I would say that you can really tell that [patients are] getting information that you might not have given them. Because I might tell them one set of...possible side effects, then say, ‘These might be transient, kind of persevere, and they’ll go away...’ But I don’t always say, ‘You might get headaches, you might get nausea, maybe your stomach will be upset,’ because...if you tell them that fifty different things are gonna happen, they will all happen at some point, and then they’ll quit the medication, and you have to try to find another medication, and they all have the same side effects.

An allergy/asthma provider expressed related sentiments using the example of sexual side effects resulting from anti-depressant or anti-anxiety medications.

[W]ell sometimes if you’re less depressed, the sexual side effects of the drug are not gonna be a problem because you’re happier. Right now you’re having a sexual problem because you’re depressed! ...You have to work through the whole process with the patients, and the drug and its side effects are up and front and center, instead of being...part of the things you would want to discuss about the medication once you’ve reached a decision what to prescribe. You start off there, instead of concluding there, so it can just change the whole dynamic of the relationship sometimes, or the conversation.

This NP also explained that some drugs used to treat depression can aggravate anxiety and are not appropriate for some patients. However, when patients hear advertisements for depression medications that mention potential sexual side effects, they do not want these drugs, even though they may be more appropriate for the patient’s symptoms.

Again, side effects are placed “front and center,” as providers must attempt to convince the patient to agree to a treatment other than the one he or she requested.

While many NPs attributed additional concern over side effects to DTCA, other providers felt that patients know more about side effects because they read the information in other sources and desire to be more in control of their healthcare. A family healthcare provider explained the following:

I’ve been practicing, fifteen years as a nurse practitioner...and in that time, I think that they may have become more educated about asking about what the side effects are. I have more and more patients who actually read the little pamphlet
they get from the pharmacist...that talks about side effects. I've had patients who haven't taken their medication because they read the side effects...Well, like, this patient read some side effects, and...she's worried that it was going to upset her stomach, and it was like Naprosyn or something, and I said, 'well do you take Ibuprofen?' 'Well, yeah.' 'Well, it's...in that same class. If that doesn't bother your stomach, this probably won't.' Take a few doses and see.' So, in that way, I think patients are paying more attention, and sometimes for the good, sometimes...to their detriment. As a provider, it makes it more difficult...[b]ecause it's more time consuming, but I think it's good in the end, that people are more aware of what they're taking and what the side effects are.

However the issue of the amount of time spent with patients does not involve only the NPs and the patients. Managed care companies frequently dictate the amount of time providers can spend with their patients, and these companies continually push for shorter visits and increased volume of patients treated. A women's health NP explained:

Managed care feels that we can see a person in five to seven minutes. I agree...It takes me five to seven minutes to do an exam..., but you have to put duct tape over their mouth, and you have to put duct tape over my mouth. Because I will do their exam in five to seven minutes...but don't ask me to...talk to them or do anything else... So, with all the new information..., they're gonna come in and have more questions..., and managed care is saying you've gotta see patients faster. Well, then don't give them all this information because how are we going to do that? ...[P]atient education is a wonderful thing, but it does cause us to spend more time, and that's not bad, but managed care doesn't understand that.

Another women's health NP expounded on this issue in terms of Medicaid reimbursement.

[W]e're finding out in medicine that's not very productive as far as reimbursement and that kind of thing. ...[I]f I see a Medicaid woman for a problem..., the office gets sixteen dollars. Out of that sixteen dollars, there's overhead..., so are you saying my time is worth $1.30 an hour? ...I may be exaggerating, but really, if overhead runs seventy percent, just to provide a service, and then somewhere in there you're gonna pay me out of that, it's just not cost effective.

Patients who have additional healthcare knowledge may ask more questions and require more of their providers' time, but this increase does not translate into an increase in patient volume. A few NPs who have been in practice at least ten years reported that
they treat more patients now than in previous years, but most of them did not feel that this was a direct result of DTCA. When asked if she was seeing more patients every day as a result of DTCA, a family practice NP responded:

No. No. I think [DTCA is] just another thing that comes up when you’re seeing patients. Very few patients, I think, are making appointments to come in because of direct-to-consumer advertising than would have come in before. ...[M]aybe a couple a month at the most.

Two practitioners attributed an increase in patient volume in their practice to a change in venue: both left family practices, one transferred to urgent care and the other to asthma/allergy. Another NP attributed the increase in patient load to her increased knowledge and abilities, but also to unemployment in the city where her clinic for the uninsured is located.

[Part of it is my knowledge and my ability to see more patients because I’m better at what I do. The number of patients I see a day lately has increased. For our practice, the reason is that unemployment is up in the city..., and for young men, black men, it’s about 50%. So, that age group, a lot of them have no health insurance...[I]t’s very difficult to provide healthcare for uninsured because there’s so many more steps to get any kind of care for them.

One final increase that providers have noticed that relates to DTCA is an increased expectation of the benefits of prescription drugs. In general, the providers’ opinions are expressed well by the following from a women’s health NP:

Our society has gotten to the point where we think many medications will solve things rather than personal responsibility or lifestyle change...We’ve gotten to be a society that doesn’t want to experience pain or discomfort or any irritation in our plans.

Providers felt that DTCA gives patients the idea that prescription medications will work quickly and solve their problems, but that patients fail to see “the whole picture.” An allergy/asthma provider explained:

I do think people are on more medications than ever before..., so that there’s some reason that people come to...offices looking for medications to treat
problems, and that, in general, people look for medical solutions rather than lifestyle things that might be causing their symptoms. So yeah, I guess I would say that the advertisements give the idea that there’s a solution to all your healthcare problems.

Instances of patients seeking medical solutions provided by the NPs included patients who believed that diet changes were no longer necessary if there were pills to lower cholesterol; patients who wanted prescriptions for stomach acid, but not additional tests to ensure that there was no ulcer or stomach cancer; and a patient who did not believe her anti-inflammatory medicine was working properly because it did not immediately relieve all her pain. These examples demonstrate that patients not only expect to receive prescription drugs from their providers, but also that patients truly believe that prescription drugs will heal their ailments with the least possible effort.

Only one provider indicated her that patients’ additional reliance on prescription drugs had nothing to do with DTCA. In particular, the women’s health NP mentioned that women often seek prescription medications for sexual dysfunction and depression, when what they really need is sleep and counseling.

I think they...think of pills as being a magic cure. So many people are so stressed nowadays, whereas, if you think fifteen, twenty, thirty years ago..., most of the women I saw twenty years ago came in, got their birth control, or their hormone replacement therapy, and they went home. Nowadays, they’re torn in so many different directions, and they’re just burnt out. We’re doing so much more with antidepressants and anti-anxiety drugs, and I really think it’s just a lifestyle issue...I don’t think the advertising has anything to do with it.

However, as the NPs stated throughout the interviews, education is an important part of their practices, and it is something of which they are very proud. Despite increases in length of appointments, concern over side effects, time spent clearing misconceptions, and expectations for medications, these practitioners did not believe that
discussion of drugs and medications detracted from other health issues. A family health
provider adequately summarized the general consensus:

I think one of the strengths of nurse practitioners is that they are in that education
mode...so medication, I’m always telling them, ‘Here’s the benefits, here’s the
side effects,’ and if, when they pay for it, here’d be the cost, so that they can make
an educated decision. I think the difference is people used to listen to me before,
but it was sort of like half listening..., and now...they’ll ask me more questions.

Given the significance of education to the NP profession, it is not surprising that
only one provider, in allergy/asthma, felt that patients made unnecessary appointments as
a result of DTCA. She estimated that this percentage of patients, about 10%, was usually
people who wanted prescriptions for conditions like GERD, which may be better treated
by lifestyle changes.

Yeah, I think they do...A small percentage, about ten percent of people...I can sit
here and think about people with GERD, who made appointments unnecessarily,
who..., when you take history, and they’re drinking fourteen cups of coffee and
they’re smokers, and...they certainly could make some lifestyle changes first, but
you have to jump to purple pill.

Most other NPs agreed with the following family provider that if the visit addressed a
patient’s need, then it was not unnecessary:

I think...if that’s an opportunity for you to educate people, that this is a teachable
moment, then I don’t consider that an unnecessary appointment... If that’s why
they came in to see us, because they wanted this medication or they wanted to talk
about this, then...you’re actually addressing that.

**Recent NP Graduates**

Because three of the providers who were interviewed for this study began their
practice in or after 1997, their experience as NPs has always been influenced by DTCA.
Therefore, they are not as likely as their counterparts who have practiced longer to notice
additional burden from DTCA. For this reason, these providers were not asked questions
that were designed to assess this “before and after” perspective, specifically with regard to additional patient knowledge, patient volume, or time spent during appointments.

For the most part, none of these NPs believed that they spent unnecessary time discussing drugs, reeducating patients, or clearing up misunderstandings about drugs or conditions as a result of drug advertising. These providers explained that discussing drugs and side effects was an important part of their jobs. A family NP noted:

I think that...the education component of that... – what the medication is, and the side effects, and that kind of thing – we spend time with, but I don’t think that’s... the biggest focus of the visit.

Another family provider had a similar opinion:

[T]he biggest percentage of the time you’re going over what their symptoms are, asking them questions about their health and...the course of their current illness. Then, it depends on the patient. If it’s something that is something simple... here’s an antibiotic, take it everyday for the next week...pretty much it’s done, versus...somebody that is asking for something that I don’t think they should have, and we have to spend time going over...why my thought is better than what they want.

A women’s health provider, who began her practice in 1997, observed that one area where she might spend more time discussing drugs could be HRT, but she did not give much explanation about why.

In terms of additional patient concern over side effects, this group of providers did not notice anything of consequence, but like the providers who had practiced longer, these NPs said that most patients had high expectations for how well they would feel as a result of taking prescription drugs. Patients frequently do not understand that medications take time to start working, or that there may be no short-term fix for certain problems.

One family provider explained:

[Peop]eople always have an expectation of instant gratification. I’m gonna take this pill and my pain, my symptoms, my fever, whatever, will be gone five minutes later. ...[I]n reality, it takes thirty minutes for the pill to be absorbed, and many
drugs take days worth of treatment before the symptoms are gonna go away…I don’t think [the advertisements are] getting that message that it takes a few days for the treatment to work.

**Provider Perception of Patient Trust**

In general, providers did not report any significant change in their patients’ attitudes or expectations regarding their providers, or any negative results from DTCA. Several providers noted that because of their willingness to admit when they were unsure about a medication and to engage in discussion, patients were able to relate to them, “connect…on a personal level,” and perhaps even trust the providers more. Patients seemed to appreciate conversing about the pros and cons of new medications and treatment options with their providers, which helped them understand that their provider “has a bit of an investment” in their healthcare. A family provider felt that:

I think if anything maybe people will trust me more, because if I’m able to converse about the new medications and show them the pros and cons [trailed off]…I’m thinking that that will help build the trust.

A women’s health NP explained that when she did not have an immediate answer to a patient’s question about a medication, she used her “nurse practitioner prescribing book” with her patients to find the information. She felt that her patients truly trusted her.

They’re very comfortable. I…think they truly trust me, cause I’ll tell ‘em, ‘I’m really sorry, I don’t know anything about that,’ or I’ll say, ‘Boy, you know, you were right, I was wrong…’ I think that’s why so many patients connect with me on a personal level.

In particular, at least two providers mentioned that relationships with patients were built over time. Once a level of trust has been established, patients can feel comfortable asking questions and trust the provider’s judgment. As a family practitioner stated:

I’ve had the same…. for the most part, many of my patients, over six years, and so I’ve really built that relationship. …[T]hey might feel more comfortable asking a
question about a drug they’ve seen on an ad, but...I doubt that it’s in any way been negative on our relationship...If you’ve proven that your judgment is sound, and that you care about what’s best for them, I think that you’re pretty... safe from direct-to-consumer ads.

The one change that four providers mentioned that was specifically a result of DTCA was their patients’ expectation that the provider would know what is currently advertised on television and the content of the commercial. As previously mentioned, several providers in this sample did not watch much television, and, therefore, were not necessarily familiar with which drugs are currently advertised directly to the public. A women’s health practitioner indicated that her patients are real surprised when I tell them, ‘I don’t know what you’re talking about,’ and they’ll look at me, and go, ‘What do you mean? You haven’t seen that commercial?!’ I don’t watch television.

Another provider in family health said:

I mean, I think they expect you to be informed. It’s hard sometimes for us cause I don’t watch a lot of TV all the time, so...somebody will say, ‘Oh, did you see the ad?’ Like, ‘No, what ad?’

However, the providers usually know the properties and uses of the drugs, and this expectation was not a problem for their practice.

Only one provider in this sample reported that she had experienced an increased expectation from patients that she would prescribe a medication, particularly for erectile dysfunction. This provider, an allergy/asthma NP who formerly worked in family practice, indicated that patients believed that they could make an appointment and receive a prescription, like “a drive through,” without a complete examination or workup.

However, this expectation did not apply as much to other diseases or conditions.

Well sometimes now...they expect you to prescribe...what they want. My thing for that would be like the erectile dysfunction drugs. They come in, they want this because the ad says ask your doctor today [if] a free sample is right for you, so...what - if you’re male? ... So, people, men come in and they think if they say
they want this that you’re supposed to give it to them, that it’s a drive through type of an idea versus maybe there’s a work up that needs to be done to determine the origin of the problem...[T]he, the other ones, no, not as much, but they’re... obviously for a medical problem, where [ED is] more like everybody has this and we should all take care of it!

The following chapter, Chapter VI, provides a summary of key findings. In addition, the final chapter discusses implications of the findings of this study on the healthcare cost crisis and provides direction for future research.
CHAPTER VI
DISCUSSION

Summary of Key Findings

Results from this study demonstrate that, in fact, the paternalistic model of the provider-patient relationship, in which the provider is an authority figure acting in his/her perceived best interest of the patient, who has limited involvement except to give consent to treatment (Charles et al. 1999), is not (currently or formerly) the preferred method used by NPs. Providers in this study were most likely to use a shared model, in which they included their patients as active participants in their healthcare. Rather than simply prescribing one method of treatment, NPs usually outlined several options, weighing risks and benefits, from which patients could choose the option that best fit their lifestyles. Furthermore, these providers were accepting of a patient’s choice, even if the NP felt that another option would have been better. Most providers stressed that their relationships with patients were partnerships, and providers wanted their patients to be satisfied with the results of their office visits.

Charles et al.’s (1999) informed model, while becoming a more realistic possibility due to increasing patient requests for specific treatments, is not widely used or accepted by NPs. Providers admitted that patients were more knowledgeable about healthcare than in years past, and that there have been increases in self-diagnoses, but they felt that the information that patients received was not always correct. While providers welcomed knowledgeable patients and sought patient input, no provider was willing to prescribe treatment without first discussing why a patient felt he/she needed a
certain medication and analyzing whether or not the patient was a good candidate for that choice.

Most importantly, from a patient-care standpoint, NPs in this sample indicate that they were able to accommodate patients’ needs, whether this included an active patient who asked many questions and made requests, or a more passive patient, who still preferred to allow the provider to make treatment decisions. Providers recognized that different patients and different conditions may require differing levels of provider involvement, and these NPs were willing to listen and respond to their patients’ needs.

The fact that so many patients bring to their providers medication requests or copies of drug advertisements indicates that, as Haug and Lavin (1981), Cockerham (1986), Freidson (1988), and Conrad and Leiter (2004) suggested, consumerism in medicine is continuing to grow. In fact, the name “direct-to-consumer advertising” itself supports this trend. The pharmaceutical industry chose to label its targeted audience “consumers” rather than “patients,” presumably in an effort to encourage the public to be active consumers of prescription drugs, who perceive their medications in the same way that they do any other retail product, and who potentially demand to receive certain products from their healthcare providers, thus potentially driving up pharmaceutical sales and profits.

As for providers’ opinions on DTCA itself, NPs in this study supported both positive and negative claims made by previous authors. NPs felt that drug advertisements were “slick,” and that they increased brand name recognition. Increasingly, patients present requests for specific medications, like Nexium or Flonase, rather than asking for something to treat their stomach pain or runny nose. Providers in this sample, in support of Hollon (1999), Wilkes et al. (2000), Brodie and Levitt (2002), and Lyles (2002), felt
that DTCA was misleading and unrealistic, overplaying drug benefits while understating drug risks and side effects. Some providers also felt that drug advertising caused patients to worry excessively about side effects (which are often similar from drug to drug), and even to stop taking their medications. In addition, consistent with findings by Findlay (2001) and Viale (2003), these NPs believed that DTCA did not provide information about lifestyle changes, and that it gives the illusion that pills are a quick fix for health problems, that everyone is taking drugs, and that an advertised drug is the only option for the condition it is designed to treat.

However, NPs did not believe that DTCA was entirely negative. As proposed by Holmer (1999), NPs in this study felt that DTCA did provide some education to patients. According to providers, DTCA offers basic information about the advertised drug and the condition for which the drug is intended to treat, and it offers a place to begin an appointment. In addition, DTCA seems to help some patients to talk about issues that they might not otherwise discuss, and it helps to raise awareness of certain illnesses and treatment options.

For the NPs in this study, educated patients were preferred, but DTCA does not seem to provide the amount of educational benefit that its proponents would like to believe. Providers have not seen any real increase in drug knowledge since DTCA began, and for the most part, providers worry that patients do not have enough information about prescription medications. Yet, as previously mentioned, in spite of not having additional drug information, patients increasingly self-diagnose their medical conditions. Providers estimated that patients recognize symptoms listed in the drug advertisements and draw conclusions about their own health. This trend toward self-diagnosis was not particularly
problematic for these NPs because they tend to use shared decision-making and welcome patient input, even if patients are incorrect.

In addition to self-diagnosis, providers regularly treated patients who requested specific medications. Many of these requests are neither new nor unexpected, and include antibiotics for a cold and narcotic pain relievers. However, other requests specifically relate to DTCA, such as those for Nexium, Flonase, or Ortho Evra, especially when products are first advertised. Some patients even bring written materials, like magazine advertisements, about the drugs to their appointments. Following the recommendations of the advertisements, patients not only request (and sometimes expect) a prescription, but they also ask for samples of the medications.

Not surprisingly, providers have noticed extra pressure for medications from their patients since DTCA began. While these providers were not especially bothered by patient requests, and they did not feel that most patients were overly aggressive when it came to DTCA-related drug requests, as Findlay (2001) and Conrad and Leiter (2004) suggested, providers do seem to feel some obligation to give patients what they want. While DTCA-related provider hopping was generally not an issue faced by these NPs, patient reluctance to engage in lifestyle changes as a part of a treatment plan was a problem. As the literature suggests, these providers believe that DTCA impacts patients’ expectations of prescription drug benefits, specifically in that it reinforces the image that a pill will solve problems and that other efforts are not important. Increasingly, patients expect medical solutions to their illnesses, and DTCA perpetuates the belief that a pill will relieve symptoms quickly and completely. Following a nursing model of education, these providers do not blindly prescribe requested treatments, but they do recognize that patients are more likely to comply with treatment when they receive what they feel is
best. Most providers reported that, if possible and appropriate for the condition being treated, they would meet patients’ requests.

When specifically asked whether or not DTCA directly impacted their prescribing practices, responses were mixed. Three providers felt that DTCA had no impact on their choices. One provider worked in a practice that, as a policy, prescribed generics, and two others preferred to prescribe medications with which they were familiar and knew to be effective. Three providers were vague, or uncertain, about the impact of DTCA on their prescribing decisions. They preferred to keep an open mind, considering requests and analyzing the profiles of new and requested medications. Four remaining providers felt that DTCA had definitely influenced their prescribing. With the prevalence of the advertisements, along with active patients who request advertised medications, they felt it was unlikely that healthcare providers with prescribing authority would not be affected by DTCA. Providers’ desires to meet patients’ requests seems to support this view that DTCA does impact prescribing, even if only indirectly through its impact on consumers. If consumers see drug commercials, desire those medications, ask their providers for those drugs, and receive prescriptions for them, then DTCA has influenced the providers’ decisions.

However strong the effects of DTCA and patient requests may be on provider prescribing choices, in the end, it is perhaps more frequently a patient’s insurance company that dictates what drug he/she will or will not take. With prescription drug formularies, preferred drug lists, and tiered prescription plans that prefer generics to name brands, providers estimated that patients were most likely to take the medication that costs them the least, as determined by their insurance company, even though they would rather take a name brand drug.
In terms of overt burden on providers as a result of DTCA, NPs in this sample did not report anything of consequence. Additional patient knowledge regarding healthcare in general was not attributed to DTCA, and often varied from patient to patient. However, increased length of patient visits often was attributed to DTCA. Frequently, patients had questions about medications or the advertisements they had seen, and providers spent time clearing up misconceptions about prescription drugs or addressing additional concern over side effects as a result of DTCA, which is a change for those who practiced prior to DTCA. This research, then, supports concerns expressed by Hollon (1999) and Morgan et al. (2003) that pharmaceutical companies do not overly concern themselves with educational benefits of the drug advertisements, and, as evidenced by additional concern over side effects and misconceptions resulting from the advertising, patients do not have the knowledge and education needed to assess the claims made by the advertisements.

In spite of the seeming inconvenience, additional length of office visits was not a troubling concern for providers. Contrary to statements proposed by Wilkes et al. (2000), these NPs did not feel that discussion of drugs detracted from other important issues, or that patients made unnecessary appointments as a result of DTCA. However, lengthier appointments are a problematic issue for managed care. At the same time that a wealth of healthcare information is available to patients via the internet, self-help books, DTCA, etc., which inevitably leads to increased desire for discussion with one’s provider, managed care pushes for decreased appointment lengths and increased patient loads.

Regardless of the negative effects that providers have noticed from DTCA, for the most part, they did not feel that DTCA has had any negative effect on their relationships with patients. Contrary to concerns proposed by Viale (2003), according to the NPs,
DTCA has not seemed to decrease patient trust or faith in their providers. NPs attributed this continued sense of trust to their willingness to admit uncertainty, to discuss treatment options (along with the risks and benefits of each), to answer questions, and to address any other concerns with their patients. The only change in expectations of them that providers noted was that patients expect providers to be familiar with televised DTCA. For several of these providers, this expectation goes unmet, as they watch minimal or no television. While providers noted that patients were generally surprised when the providers were not aware of a particular advertisement, no one found this to be a problem for the practice.

In the end, discussions with providers revealed that most patients do want more authority in treatment decisions. Many patients are influenced by DTCA and seek out medications or more information about what they see in the advertisements. However, patients continue to obtain the advice of their healthcare providers, and do not immediately seek alternate care upon initial dissatisfaction with a provider’s suggestion. It would seem that providers, like the NPs in this study, who have a positive attitude toward discussion with their patients will not be negatively affected by DTCA and consumer-minded patients.

**Implications of Findings on Healthcare Cost Crisis**

The costs associated with DTCA are a particularly perturbing and contentious issue in healthcare. On the one hand, it is possible that with increases in the rate at which patients recognize their symptoms and/or self-diagnose as a result of the advertisements, patients who might not have otherwise been treated make appointments with their healthcare providers. It is also possible that because of this symptom recognition or self-diagnosis, patients are treated sooner than they might otherwise have been, and therefore
prevent more drastic and more costly future treatment measures. In addition, as providers readily admit, research and development for prescription medications is costly, and DTCA may help to fund some of these projects. However, when sales from the most heavily advertised drugs far outweigh sales for other drugs, and average prescription prices are increasing in double digit percentages from year to year, it is difficult to argue that DTCA is not contributing to increasing healthcare costs.

Because DTCA increases name brand recognition, patients/consumers request name brand medications from their providers, which is likely to further amplify resistance to cheaper generic medications. Moreover, as patients increasingly self-diagnose, and as expectations of the benefits of prescription medications escalate, so too does the publics’ reliance on medical solutions for health-related conditions. This leads to more demand for costly medications, and greater numbers of people who are taking them. Therefore, people, and insurance companies, are spending more money on prescription drugs, even if they are generic. And, as lifestyle habits continue to fall by the wayside because of growing reliance on medicine, health problems continue to increase, causing the need for more prescription drugs, and even higher costs to the consumer.

Drug costs are an especially crucial issue when we face a faltering economy and tumbling insurance coverage. As costs of prescription drugs soar, the amount of insurance coverage that employers are willing to supply continues to plummet. More and more, employers must alter the coverage that they offer employees, frequently by increasing copays and by moving to tiered prescription plans, in which generics are the cheapest option, followed by preferred brands, and then all others (Trude et al. 2002).

Furthermore, in spite of the fact that NPs do not find it problematic, increased patient questions and discussion and longer appointments do create additional burdens on
the healthcare system. If DTCA encourages patients to ask more questions of their providers, discussion time and overall lengths of appointments will increase, thereby potentially leading to fewer patients treated per day, or at the very least, less attention paid to those who have fewer questions.

**Directions for Future Research**

As previously stated, this research was designed to be a pilot study, and was intended to inform future research. The sample was small, nonrepresentative, and limited to NPs. Participants were selected using a snowball technique, and while unintended, there was little variation in NPs’ specialty or type of practice. Future work should increase the sample to include other types of healthcare providers, especially physicians. NPs’ focus on education and prevention may influence their opinions causing them to feel less threatened, or at the very least to feel differently about DTCA than would physicians, who operate under a medical model. Evidence from this study shows that patients appreciate a provider who is willing to spend time discussing questions and concerns, and physicians who are unable to meet patients’ needs for a greater role in their own care would likely have somewhat more negative opinions about DTCA, and perhaps even experience more provider hopping. Further interviews and a survey would be useful to obtain more information and validate or refute the results of this work.

In addition, in order to begin to obtain quantitative data on the extent to which DTCA influences provider prescribing, it would be useful to obtain percentages of providers who, as a general policy, meet patients’ requests for advertised medications. Because it is probable that DTCA impacts provider prescribing, at least as far as it impacts consumers, it would be valuable for future research to survey consumers about
their attitudes concerning DTCA, and the degree to which they are persuaded by the advertisements.

Finally, it is essential for future research to focus on DTCA’s effects on healthcare costs. Such a study could attempt to obtain data from drug companies and pharmacies to compare the quantities and costs (both retail and production) of advertised, other name brand, and generic medications that were dispensed, both before and after the start of DTCA. It would then be useful to examine treatment plans (both before and after the start of DTCA) for patients with conditions for which advertised medications are available (such as acid reflux, attention deficit, or allergies) to compare the average costs of treatments that include DTCA drugs to costs of treatments without DTCA drugs.

A study of the impact of DTCA on healthcare costs could also examine employer-provided healthcare plans, specifically prescription drug benefits, before and after DTCA started. Of particular interest would be changes in the cost of the plan to the employer and to the employee, as well as in the type of plan that was offered. It might be fruitful to follow the changes in drug formularies for several healthcare insurance companies over the course of a year or more to determine whether alterations coincided with current advertisements. Without additional efforts to study the impacts of DTCA on our healthcare system, we concede to the commodification and potential erosion of our healthcare by pharmaceutical companies.

At a time when potent prescription medications are promoted to the public, filling magazine pages between articles on new appliances and organizing a closet or locking in a 30 second commercial spot between an insurance carrier and a national pizza chain, healthcare providers are more important than ever. These are the professionals who are charged with helping the public to sort through the jumbled pieces of health information
it receives through the Internet, self-help books, and advertisements. However, one must question the extent to which a provider can remain immune to the persuasions of pharmaceutical companies. To say nothing of the efforts to target providers directly, it is likely to be increasingly more difficult for providers to use sound, medical judgment when patients frequently arrive at appointments with preconceived notions of what they think need. In addition, one must also question the extent to which a consumer-minded public is willing to heed the advice of its healthcare practitioners. For the NPs in this study, lack of patient trust was not a concern, but for others, the issue may be more pronounced.

Of course, it is not the argument of this author that it is wrong for a person to exert control over her/his own body or to play an active role in making the decisions that affect it. However, DTCA, above all else, is advertising. It is ill advised for anyone to believe she/he is afflicted with a given condition or needs a certain medication based solely on an advertisement. Symptom recognition and earlier treatment are certainly positive results of DTCA that extend beyond profit margins. But perhaps the risks associated with DTCA, such as inappropriate drug use, inappropriate prescribing, increased reliance on medications, unwillingness to commit to lifestyle change, increased drug costs, and increased burden on providers, are of far greater consequence. Does not the possibility of the negative impact of DTCA on our healthcare system warrant further consideration of, at the very least, the rules and regulations that govern the advertising?

As one of the NPs remarked:

Once you realize it's marketing, then the point is to put it in the right places. We control cigarette advertising, we control alcohol advertising, and I think drug advertising needs to be controlled that way as well.
Medications are not a retail product like any other. The practice of medicine need not be veiled behind a dark cloak of secrecy, but neither should it be treated like the laundering of clothing. When advertising persuades us to purchase one detergent over another, the risk is minimal. When advertising persuades the layman to convince a professional healthcare provider to prescribe one medication over another, the risk is far greater, if not only to the patient’s health, but also to her/his pocket book.
REFERENCES


APPENDIX A

Interview Protocol
Areas to be explored:

I. Background Information

Questions asked would be similar to the following:
- Where did you complete your education?
- What is your specialty/who are your primary clients (e.g., women, men, children)?
- How long have you been practicing as a NP?
- What is the setting for your practice (i.e., hospital, private practice)?
- Could you approximate the frequency with which you prescribe medications?

II. General Information

Questions asked would be similar to the following:
- Could you describe your view of the provider-patient relationship/how do you perceive your relationship with your patients?
- Could you describe a typical interaction with a patient?
- Could you describe your general opinions on DTCA?

III. Diagnosis/Treatment Decisions

Questions asked would be similar to the following:
- Could you discuss some reasons for patient appointments, if related to DTCA?
- How knowledgeable do patients seem to be about prescription drugs?
- Is it common for patients to pressure you for certain prescriptions or diagnoses?
- Do you believe that DTCA has had any effect on your medical decisions?

IV. Prescribing Practices

Questions asked would be similar to the following:
- How do you decide which drugs to prescribe?
- Do you believe DTCA has impacted these decisions?
- What is your policy on fulfilling patient requests for specific prescription drugs?
- How do patients typically react when you refuse a request for a specific drug?
- How do patients typically react to suggestions for alternative treatments or lifestyle changes, especially since DTCA became so popular?

V. Provider Burden

Questions asked would be similar to the following:
- Can you estimate the number of patients you see now compared to before DTCA became popular?
- How knowledgeable do you think patients are with regard to health and disease?
- Has this changed since DTCA became popular?
- Do patients seem to be misinformed about conditions/diseases after viewing drug advertisements?
- What do you perceive to be patients’ expectations for prescription drugs, and have they changed at all because of DTCA?
• Could you estimate the amount of time you spend discussing prescription drugs/treatments with patients, both now and before DTCA popularity?

VI. Provider’s Perception of Patient Trust
Questions asked would be similar to the following:
• Have there been any changes in the way you interact with your patients since DTCA became popular?
• Do you believe there have been changes in patient expectations of you and trust in you, now and before DTCA popularity?

VII. Closing Questions
Questions asked could include:
• Would you be willing to share your opinions on the continuation of DTCA?
• Are there any additional thoughts that you wish to share regarding DTCA or the provider-patient relationship?
APPENDIX B

Subject Selection E-Mail Text
Message from Ms. Ford to Michigan Council of Nurse Practitioners:
Dear Colleagues:

I have recently been contacted by a graduate student at WMU who is working to complete her Master of Arts degree in Sociology. In order to complete her master’s thesis, she is interested in conducting interviews with several nurse practitioners to discuss direct-to-consumer drug advertising and its impact on the nurse practitioner-patient relationship (see the message below for more details). I would encourage you to consider participating in this project, which will offer nurse practitioners, a group that is not ordinarily considered in social research, an opportunity to formally vocalize their opinions regarding this matter. If you are interested in volunteering for an interview, please contact Kelly Getman via e-mail at [e-mail address] or at the phone numbers listed at the bottom of this message.

Sincerely,
Laura Ford

Original Message to Ms. Ford:
Ms. Ford,
Good evening. My name is Kelly Getman, and you may recall that Dr. Victoria Ross e-mailed you regarding my master’s thesis a couple of months ago. She recently remembered to pass your name along to me, so I am contacting you now to find out if you would still be interested in participating in my study.

To complete my thesis, I would like to interview 10 nurse practitioners about their opinions on direct-to-consumer drug advertising and the impact it has had on their relationships with patients. In addition, Dr. Ross mentioned to me that you were a member of the Michigan Council of Nurse Practitioners, and that you might be able to connect me with a few other nurse practitioners who might be interested in being interviewed for my study. I would ask for one face-to-face, hour-long session, and the main criterion for participation is that the nurse practitioner has been practicing since June 1992 (five years prior to the change in the regulation of the advertising).

In order to satisfy the requirements of the Western Michigan University Human Subjects Institutional Review Board, it is important that participants volunteer and do not feel pressured to participate. Would it be possible for you to send an e-mail message to the members of the Michigan Council asking them to volunteer to be interviewed for my study?

I look forward to hearing from you soon. If you prefer to speak in person, feel free to call me in the evening at home [phone number] or between 10 am and 3:30 pm at WMU [phone number].

Thank you in advance,
Kelly Getman
APPENDIX C

Informed Consent Document
The Influence of Direct-to-Consumer Drug Advertising on Nurse Practitioners and Their Relationships with Patients

Western Michigan University
Department of Sociology
Principal Investigator: Dr. Susan M. Carlson
Student Investigator: Kelly Getman

You have been invited to participate in a research project entitled “The Influence of Direct-to-Consumer Drug Advertising on Nurse Practitioners and Their Relationships with Patients.” This study is intended to understand the impact of direct-to-consumer prescription drug advertising (DTCA) on the nurse practitioner-patient relationship. The purpose of this project is to fulfill the thesis requirement for the Master of Arts degree in Sociology.

You will be asked to participate in one 45-60 minute interview session with Ms. Getman, to be held in a mutually agreeable location. The session will involve a discussion of your opinions on DTCA and its impact on your relationships with your patients. You will also be asked to provide general information about yourself as a healthcare provider, such as the length of time you have practiced, the type of setting in which you practice, and your nursing specialty. At the end of the interview, there will be a period during which you will have the opportunity to clarify any questions or misunderstandings that may have occurred during the interview.

As in all research, there may be unforeseen risks to the participant. One potential risk is that you may feel that this interview is an inconvenience in your schedule. You may reschedule or terminate the session at any time if you feel significantly bothered.

One way in which you may benefit from this activity is by formally vocalizing and sharing your opinions on a matter that influences your professional life. This research focuses on a group of healthcare providers that is not typically considered in the medical sociology literature.

All of the information obtained during this interview is confidential. This interview will be tape recorded and transcribed, but your name will not appear on any of the tapes or written documents in this research project. Once the interview has been transcribed and analyzed, the tape will be destroyed. Parts of this interview may be used for reporting purposes, but no names or other identifying information will be attached to any written documents that result from this session. Any forms associated with this research will be retained for at least three years in a locked file in the Kercher Center for Social Research.

You may refuse to participate or quit at any time during the study. If you have any questions or concerns about this study, you may contact either Kelly Getman at [phone number] or Dr. Susan M. Carlson at 269-387-6173. You may also contact the chair of the Western Michigan University Human Subjects Institutional Review Board at
269-387-8293 or the WMU vice president for research at 269-387-8298 with any concerns that you have.

This consent document has been approved for use for one year by the Western Michigan University Human Subjects Institutional Review Board as indicated by the stamped date and signature of the board chair in the upper right corner. Do not participate in this study if the stamped date is more than one year old.

Your signature below indicates that you have read and/or had explained to you the purpose and requirements of the study and that you agree to participate.

_______________________________  _______________________
Signature                        Date

Consent obtained by: ____________________________  _______________________  
initials of researcher             Date
Note that signed copies, with signatures obscured in order to protect the identities of the subjects, of the consent document are on file with the Graduate College.
APPENDIX D

HSIRB Protocol Clearance
Date: May 20, 2004

To: Susan Carlson, Principal Investigator
   Kelly Getman, Student Investigator for thesis

From: Macy Lagecwey, Ph.D., Chair

Re: HSIRB Project Number: 04-04-30

This letter will serve as confirmation that your research project entitled “See Your Healthcare Provider for a Prescription Today! The Influence of Direct-to-Consumer Drug Advertising on Nurse Practitioners and Their Relationships with Patients” has been approved under the expedited category of review by the Human Subjects Institutional Review Board. The conditions and duration of this approval are specified in the Policies of Western Michigan University. You may now begin to implement the research as described in the application.

Please note that you may only conduct this research exactly in the form it was approved. You must seek specific board approval for any changes in this project. You must also seek reapproval if the project extends beyond the termination date noted below. In addition if there are any unanticipated adverse reactions or unanticipated events associated with the conduct of this research, you should immediately suspend the project and contact the Chair of the HSIRB for consultation.

The Board wishes you success in the pursuit of your research goals.

Approval Termination: May 20, 2005
Date: July 29, 2004

To: Susan Carlson, Principal Investigator
   Kelly Getman, Student Investigator for thesis

From: Amy Naugle, Interim Chair

Re: HSIRB Project Number: 04-04-30

This letter will serve as confirmation that the change to your research project "See Your Healthcare Provider for a Prescription Today! The Influence of Direct-to-Consumer Drug Advertising on Nurse Practitioners and Their Relationships with Patients" requested in your memo dated 7/22/04 and clarified in your memo dated 7/29/04 (new recruitment method) has been approved by the Human Subjects Institutional Review Board.

The conditions and the duration of this approval are specified in the Policies of Western Michigan University.

Please note that you may only conduct this research exactly in the form it was approved. You must seek specific board approval for any changes in this project. You must also seek reapproval if the project extends beyond the termination date noted below. In addition if there are any unanticipated adverse reactions or unanticipated events associated with the conduct of this research, you should immediately suspend the project and contact the Chair of the HSIRB for consultation.

The Board wishes you success in the pursuit of your research goals.

Approval Termination: May 20, 2005