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PHARMACISTS' RATING OF RELEVANCE OF AVAILABLE INFORMATION IN
DECIDING THE VALIDITY OF OPIOID MEDICATION PRESCRIPTIONS

A Thesis
presented in partial fulfillment of requirements
for the degree of Master of Science
in the Department of Pharmacy Administration
The University of Mississippi

by

LEONARDO R. TORRES

December 2010

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ABSTRACT

Pharmacists are tasked with making decisions regarding the validity of prescriptions. Some have proposed factors that should be considered when evaluating a prescription's validity. Yet, there is little known about the decision process that pharmacists employ at the time of dispensing and what information pharmacists deem relevant in that decision-making process. Using an online survey instrument, a sample of community pharmacists were divided into three groups and presented with a prescription scenario. They were asked to rate the relevance of information, which is proposed to be appropriate and inappropriate, available at the time of dispensing. They were asked to consider this information in the context of deciding the validity of a prescription. The medications presented in the groups were a schedule-III opioid pain medication, a non-controlled legend antibiotic, or a muscle relaxant with a potential for abuse. A total of 2,328 pharmacists were sent requests to participate. This resulted in 104 usable responses, which represents a response rate of 7.7%. The relevance of the information was shown to differ based on the prescription type. Pharmacists attributed greater relevance to irrelevant factors when deciding the validity of prescription for a controlled substance than they did when evaluating an antibiotic ($p < 0.001$). This also was the case for suspicious factors ($p < 0.001$) and determinative factors ($p < 0.003$). Other factors were explored also. It seems clear that pharmacists are likely to judge different pieces of information about the patient and situation to be relevant depending on the medication being filled. Further research is needed to understand the role that this plays in pharmacists' decisions to fill and willingness to fill different types of prescriptions.

DEDICATION

This thesis is dedicated to my family and friends who helped me along the process. Also, special thanks to my wife, Meigian, and my children Jazmyne, Marco, and Diego, who helped each in their own ways.

In addition I would like to thank my parents, Hilda and Gilbert Torres, for their continued support and belief in my quest for knowledge.

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INTRODUCTION

A prescription is an order for medication for a patient issued by a medical practitioner (Scott, 2005). A patient obtains prescribed medication by getting the prescription filled at a pharmacy. The filling process includes a technician or pharmacist transcribing information into an electronic record of the prescription, printing labels and other information, supplying the medication from stock bottles, measuring or counting the medication, and bottling, labeling and selling the medication to the patient. Thus, a medical practitioner's prescription order has been transformed into medication for the patient at the pharmacy.

There are times when a prescription must be questioned for its validity, as not all prescriptions presented at the pharmacy are valid for processing. The validity of a prescription could be suspect for many different reasons. These reasons can range from relatively simple issues such as illegible handwriting of the prescribing physician or a clerical omission of required information on a prescription, to more difficult problems such as a physician prescribing a medication out of their scope of practice or prescribing a clinically inappropriate dose for a particular medication. Or, the problem can be more disconcerting, such as an attempt of forgery by a patient attempting to illegally obtain a controlled substance. It is the pharmacist that is tasked with recognizing potential problem prescriptions as it relates to the validity of the prescription.

Prescriptions with illegible or missing information are usually easily recognized as needing intervention. Prescriptions that are written outside of the scope of practice for a particular practitioner or clinically inappropriate dosing are also problems that can be recognized without much difficulty. Forged prescriptions, however, are designed to misrepresent the truth and can be understandably more difficult to detect.

A forged prescription is a fake prescription and not valid under any circumstance. A forgery may not be as easy to ascertain because the fake prescription's purpose for existence is to mimic a valid prescription and to scam a pharmacy into dispensing a medication illegally. A good forgery may be difficult to detect but a pharmacist is still tasked with recognizing and making the determination of prescription validity. In the process of determining the validity of a prescription, a pharmacist has a wealth of available information. At the time of filling a pharmacist often has available: patient demographics, patient insurance status, and physician information. The pharmacist also may have, through electronic record, a history of a patient's previous medications; and the pharmacist has the prescription itself. It may have preprinted or computer-generated information about the physician and will also contain written or computer-generated information about the patient, the medication, quantity, directions for use, and sometimes the diagnosis of the condition being treated.

A pharmacist must be aware of the laws and practice standards that regulate prescription validity and his or her corresponding responsibility to dispense medications in accordance with those laws. There are guides and other resources available to pharmacists to help the process of determining the validity of a prescription. Many state boards of pharmacy publish newsletters and the Drug Enforcement Agency publishes a Pharmacist's Manual to help pharmacists evaluate potential forged prescriptions. There are also pharmacy journals, widely available to

pharmacists, in which articles are published to help pharmacists interpret legal issues, including those involving prescription validity.

So, a pharmacist must make the determination of validity by deciding, based on available information, whether or not a prescription is valid for dispensing. A pharmacist has resources of law, practice standards, published guides, and professional experience to aid in determining validity. It is the questioning of a prescription's validity that moves it from the normal course of processing to another course of action.

It is reasonable to imagine the forged prescription might involve a controlled substance pain medication, specifically an opioid. During the normal course of community pharmacy practice, the decision of prescription validity may involve a prescription for an opioid pain medication. Opioids are some of the most widely and commonly prescribed medications in the United States (Rosenblum et al., 2008; Pletcher et al., 2008; Clark, 2002). They are effective medications in pain therapy, but also have possible abuse potential (McCabe et al., 2006; Simoni-Wastila & Tompkins, 2001), and are considered a common choice for forgery attempts (Gilson et al., 2004; Drug Enforcement Agency [DEA], 2004).

Determining the validity of opioid prescriptions may lead to several possible outcomes. One potential outcome could result in a valid prescription going through a decision process, being accepted, and processed for dispensing. As a second outcome, an invalid prescription may raise a "red flag" in the decision process and not get dispensed. These first two outcomes are optimal. Valid prescriptions proceed to dispensing, while forged or clinically suspect prescriptions get a different action.

The third outcome is a false negative. An invalid prescription may go through a decision process and be processed for dispensing. This may result in forged or clinically inappropriate

prescriptions getting dispensed. The consequence of this outcome is less than optimal; dispensing a forged opioid prescription results in a controlled prescription medication being used outside accepted legal parameters. Opioid medications garnered from forged prescriptions may ultimately be used as street drugs (Gilson et al., 2004). In another vein, a clinically inappropriate opioid prescription getting filled may have detrimental health consequences for the patient.

False positives, which is the fourth outcome, may also have negative implications for patient care. This occurs when a pharmacist deems a valid prescription to be a forgery when it is not and prevents a patient from receiving a needed medication. If a prescription for a prescribed opioid pain medication is deemed suspect, the patient may be left without pain relief, despite a legitimate prescription.

Given the implications of these latter two negative outcomes, it is worthwhile to further examine the pharmacist's decision process for determining the validity of an opioid pain medication prescription and to explore what information pharmacists use in a prescription decision process. Thus, the purpose of this study is to determine what information pharmacists consider relevant in determining whether a prescription is valid or not and whether the information differs depending on whether the prescription is for a controlled substance or not.

BACKGROUND

LITERATURE REVIEW

The dispensing process starts with a new prescription, then a technician or pharmacist transcribes that information into an electronic record of the prescription, labels and information are printed, stock bottles are used to supply the medication, medication is measured or counted, bottled, labeled for and sold to the patient, the end consumer in the process (Scott, 2005). The prescription is the order for medication for a patient issued by a medical practitioner (Scott, 2005). A prescription may be issued by an individual practitioner who is authorized by governing entities to prescribe medication for patients for a legitimate medical purpose within the prescriber's scope of practice (Fink et al., 2006).

Information available to a pharmacist at the time of filling

Demographics

To fill a prescription, a pharmacist must first gather patient information. The information may be necessary for both legal and business reasons. State and federal laws require certain patients' information be provided prior to or at the time of dispensing of the prescription (Scott, 2005). Also, a third party payer may require specific patient-level information for proper processing and payment. Commonly gathered information includes a patient's name, address, phone number, date of birth, and insurance status.

A prescription for a controlled substance has additional requirements for the patient, prescriber and pharmacist due to federal and state laws and regulations. Controlled substance prescriptions must be dated and signed and in addition to the patient's full name and address it must include the practitioner's full name, address and Drug Enforcement Agency (DEA)

number. The controlled substance prescription must also be “written in ink or indelible pencil or typewritten and must be manually signed by the practitioner” (DEA Pharmacist’s Manual, 2010).

Insurance coverage/ method of payment

Prescription transactions generally involve payment, which offers the pharmacist another opportunity to gather additional patient information. There are two common mechanisms for payment based on whether or not the patient has insurance coverage for prescriptions. Based on this, a patient either pays full price for the prescription at the pharmacy or pays some portion of the amount as determined by the insurance company.

Most prescriptions filled in the United States are covered by prescription drug insurance through a third party payor (Kaiser Family Foundation [KFF], 2005). Patients have a relationship with an insurance company that acts as or hires a pharmacy benefits manager to handle the financial transaction of the medication for the patient. The patient is usually responsible for a cost sharing co-pay and must follow the rules and formularies of the third-party payor. Third-party prescription insurance can be categorized as private, government, or combination of the two.

Private prescription insurance can be obtained by individuals either directly from an insurance company or through an employer who may offer it as a benefit of employment. Private prescription insurance was involved in approximately 46% of national prescription drug expenditures in 2003 (KFF, 2005). Government programs covered another 24% that same 2003 year (KFF, 2005). Many government programs, including Medicaid and SCHIP, are programs designed to help patients in a lower socioeconomic situations. Then in 2006, Medicare, another government insurance program, offered prescription benefits for the nation’s Medicare eligible patients, which is made up of mostly elderly patients. This system enrolled 22.5 million

beneficiaries in 2006 with an increase to 24.2 million beneficiaries in 2007 (KFF, 2007). This government sponsored benefit is managed for patients by private third-party companies. Thus, today the U.S. government pays for over 40% of the dispensed prescriptions.

Prescription history

The patient is the core of any prescription, and it is a patient's legitimate medical need that is the basis for a prescription (Fink et al., 2006). Computerized record keeping enables a pharmacist in a pharmacy that has filled previously filled prescriptions for a patient to have access to those previous prescription records. Such information is in essence additional information available to the pharmacist about the patient in addition to any information provided at the time of the prescription presentation.

Prescription

The pharmacist also has information from the prescription item itself. A written prescription can be delivered in person to a pharmacy by a patient or patient's agent. The prescription can be phoned in from a physician or physician's agent to the pharmacist, faxed, or submitted electronically via secure means (Scott, 2005). A traditional, written prescription generally contains both preprinted and handwritten information. The preprinted information allows the pharmacist immediate access to the prescriber's information, which can include the contact information for the physician including physician's name, the name of the corresponding facility, address, phone number, and fax number. Other possible preprinted details include the type of practice, the practice specialty, other physicians in the practice, and other locations owned by the same clinic.

The handwritten parts of the traditional prescription are usually patient-related and indicate the date the prescription was written, the patient's name and any appropriate demographic information such as birth date, the medication prescribed for the patient, the strength and quantity of the medication, directions for the patient, the number of refills indicated for the medication, and any specific directions for the pharmacist (Scott, 2005). Prescriptions also can have computer-generated information in whole or in part that contains the same information as hand-written prescriptions.

Social Interaction

In addition to demographic information provided by the patient, the pharmacist gathers information from the social interaction. This occurs from traditional initial "first impressions" through to the end of the interaction from observations of patient behavior and conversations. Gender, age, race and ethnicity, and social class are the basic types of categories that are considered universally recognized upon initial human interaction (Fiske & Neuberg, 1990). According to the Fiske and Neuberg (1990) impression formation model, the first step when encountering others, is categorization. Categorization occurs where the perceiver, in this case the pharmacist, places a basic category upon an individual based upon physical features such as age, gender, ethnicity, appearance or dress, verbal or written information providing a category label such as a business card, uniform, or name tag, a configuration of category-consistent cues that linked to past associations such as appearance driving a categorization of social class, or based on other information that arises during the interaction (Fiske & Neuberg, 1990). This categorization is thought to occur "immediately upon encountering information sufficient for cuing a meaningful social category" (Fiske & Neuberg, 1990). In other words, obtaining the information is part of the interaction.

Laws governing the ability to not fill

A pharmacist must abide by the various federal and state regulations that guide prescription dispensing in the United States. Pharmacists stay informed of the laws that govern their profession. Pharmacists have a duty to refuse to fill prescriptions that are not in compliance with state and federal laws and regulations. The Durham-Humphrey Amendment was enacted in 1951 and broadly defines the legal dispensing obligations of a pharmacist. It established that prescription drugs can be dispensed:

"...only (i) upon the written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist (503(b) [21 USC § 353(b)]."

By setting criteria for determining which medications required a prescription not safe to use without medical supervision, this law established the two classes of drugs, over-the-counter and prescription drugs (Fink et al., 2006).

Included in the prescription class of medications are legend drugs and controlled substance medications such as opiates for pain and amphetamine and amphetamine-like treatments for Attention Deficit and Hyperactivity Disorder. Controlled substances have stricter regulations than other drugs and are classified into schedules: I, II, III, IV, and V. The smaller the number, the greater the DEA considers the medication's abuse potential (DEA, 2010; Longo et al., 2000). Non-schedule prescription medications are called legend drugs.

Appropriate process of determining the validity of a prescription

Validity can be based on either the legality of the prescription at a *prima facie*, judged at first impression, level or on a level of the clinical appropriateness of the therapy. Prescriptions that are suspect as forgeries at a *prima facie* level should be verified with the prescribing physician. The DEA warns: “The forger knows what information is needed on the prescription to make it appear authentic. Pharmacists should be aware of the various kinds of forged prescriptions that may be presented for dispensing” (DEA, 2004).

Clinical appropriateness of therapy has a common sense element to it that is grounded in law. It comes into play when a pharmacist has to decide if a prescription is within appropriate guidelines for a specific medication in treatment of a given condition. The Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, also known as the Controlled Substances Act (CSA), is the main federal law that regulates controlled substances (Abood, 2011). The CSA imposes limits on refills and the expiration date of the prescription and does not interfere with physicians’ medical decisions including choice of drug, duration, or prescription (21U.S.C. §§801-907). But it does limit the scope and legitimacy of the prescription:

“A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription” (Title 21 C.F.R. 1306.04).

The Act positions pharmacists at the center of determining the legitimacy of use based on treatment and scope of the prescriber’s practice. A pharmacist must decide if the prescription is within the course of professional practice of the prescribing physician and that the prescription was written for a legitimate medical purpose (Joransen, 1993). The DEA stresses that in order for a prescription to be valid, a prescription must be issued for a legitimate medical purpose by a

practitioner acting in their normal course of professional practice (DEA, 2010). This determination must be made by pharmacists based on the information available at the time of filling the prescription.

Ethics associated with filling or not filling

Pharmacists can also decide not to fill a prescription for other reasons such as ethical concerns. The pharmacist's right to refuse to dispense a prescription medication based on ethics has been addressed by pharmacy associations. The American Pharmacists Association (APhA) has a pharmacy conscience clause that recognizes individual pharmacist's right of refusal of particular medication based on moral objection and supports the patient's right to access of medication. The clause states:

APhA recognizes the individual pharmacist's right to exercise conscientious refusal and supports the establishment of systems to ensure patient access to legally prescribed therapy without compromising the pharmacist's right of conscientious refusal (AJHP, 1998).

The American Society of Health Systems Pharmacists (ASHP) has a similar clause that balances a pharmacist's moral considerations against a patient's medication access rights:

To recognize the right of pharmacists, as health care providers, and other pharmacy employees to decline to participate in therapies they consider to be morally, religiously, or ethically troubling; further,
To support the proactive establishment of timely and convenient systems by pharmacists and their employers that protect the patient's right to obtain legally prescribed and medically indicated treatments while reasonably accommodating in a nonpunitive manner the right of conscience; further,
To support the principle that a pharmacist exercising the right of conscience must be respectful of, and serve the legitimate health care needs and desires of, the patient, and shall provide a referral without any actions to persuade, coerce, or otherwise impose on the patient the pharmacist's values, beliefs, or objections. (AHSP, 2008).

Instances involving birth control illustrate the conscience clause issues. Plan B (levonorgestrel) is a hormonal birth control medication. It contains a hormonal contraceptive

similar or the same chemical moiety as other hormonal contraceptives (Gee, 2006). Plan B is different and controversial because of timing of the birth control effect. Plan B hormones prevent the implantation of a potentially fertile egg, while other hormonal birth control stop the release of eggs so fertilization cannot occur. Citing conscientious objections over the interference of Plan B with human conception, some pharmacists have refused to fill prescriptions for Plan B based on ethical concerns (Gee, 2006). These refusals have been met with physician activism and legislative action with a concern over patients rights (Gee, 2006). Legislation has been proposed at a national level to require pharmacists to dispense any legal prescription (Guharoy & Noviasky, 2005). The Plan B controversy and the response to it illustrate the unique position pharmacists hold in the access to medication process. In an instance where a pharmacist refuses to fill on ethical beliefs, the proposed law would take precedence over any moral objections (Guharoy & Noviasky, 2005).

Information gathered during the prescription filling process will be processed by pharmacists and used to determine the validity of a prescription and ultimately influence whether a prescription is filled. All of the information gathered and its relevance to the validity of a prescription is considered in the conjunction with the knowledge of the prescription that is being dispensed. Some medications have properties and effects that make them more likely to be illegally sought by some individuals. Given the nature of opioid medications and their addictive attributes, opioids is a class of medications that has legitimate patient uses and has properties that leads some to pursue obtaining the medication illegally.

Opioid Medications

Conditions treated with opioids and the number of people associated with those illnesses

Opioid analgesics are effective for treating pain (Portenoy, 1993; Trescot, et al., 2006) and have become some of the most prescribed medications in the United States (Kuehn, 2007). There were more than 100 million prescriptions in the year 2005 for combination drugs containing the opioid analgesic ingredient of hydrocodone (Kuehn, 2007). Opioid analgesics are used for acute pain, cancer pain, and chronic non-malignant pain.

Acute Pain

Acute pain is classified as pain that is anticipated to be short lived with a recent onset (Zeller et al., 2008). Treatment for acute pain using opioid analgesics is considered to be most common after surgical procedures and can be associated with a variety of diseases and medical conditions including arthritis, gout, sickle cell anemia, inflammatory bowel disease, and hemophilia (Portenoy, 1993). Trauma and other medical events that are treated in an emergency room also warrant use of opioid analgesics (Thomas, 2007). There are many other clinical scenarios where acute pain warrants treatment with opioids (Portenoy, 1993).

Opioid analgesics are considered to be initial therapy for acute pain (Zeller et al., 2008). Acute pain opioid analgesics are ideal if they have a rapid onset of action, short duration of action, minimum risk of respiratory suppression, and few drug interactions (Davis & Srivastava, 2003). Prescriptions for acute pain are usually short term depending on the patient and the condition. Opioid prescriptions for the treatment of pain are considered a good clinical choice: “clinicians accept the use of these drugs for a period that is usually measured in days, during which the process that incited the pain resolves” (Portenoy, 1993).

Cancer Pain

Opioid analgesics are a widely accepted way to manage cancer-related pain. Pain has been reported in upwards of 90% of cancer patients with 67% of the pain in patients with multiple pains related to the disease and 25% contributed to the treatment (Portenoy 1993; Davis & Srivastava, 2003). Cancer-related pain can be acute or chronic. Acute, cancer pain is usually related to procedures or therapies, postoperative pain, or pathology. Chronic, cancer pain can be related to tumor associated pain syndromes or treatment associated pain syndromes (Portenoy & Lesage, 1999).

The mainstay approach to cancer-related pain is opioid, analgesic therapy (Portenoy & Lesage, 1999; Davis & Srivastava, 2003). It is known that different people respond differently to different opioids, the goal is to find one medication or a combination of medications that balances the best analgesia with the fewest side effects for the individual (Portenoy & Lesage, 1999).

It is not uncommon for cancer patients to be on more than one opioid at a time. Combinations of different opioid analgesics are often used to treat pain in cancer patients. Many patients are dosed with a long-acting opioid for continuous use that is supplemented with a prescription for a short-acting opioid dosed on an as needed basis for breakthrough pain (Davis & Srivastava, 2003).

Chronic non-malignant pain

Pain can also be chronic and non-cancer related. Chronic pain is usually defined as pain that has persisted for at least three months following the usual healing time of an acute injury. It is considered pain that occurs in association with a non-healing lesion, or pain that recurs frequently over a period of months (Rosenblum et al., 2008). There have been reports with

estimates that as many as one in three Americans suffers from chronic, nonmalignant pain (Portenoy, 1993). The actual number of patients suffering from chronic pain in the general population is thought to be high and difficult to ascertain (Rosenblum et al., 2008). Newer published reports vary with some estimates at 10% of the population suffering from chronic non-cancer related pain and some double that at 20% (Rosenblum et al., 2008).

This includes patients who suffer from chronic, low-back pain and neck pain, of which 60% still have symptoms 5 years after the first occurrence (Trescot et al., 2006). Non-malignant pain affects the elderly commonly, with some researchers finding 45-80% of nursing home residents experiencing impaired mobility due to the pain (Davis & Srivastava, 2003).

Opioids are a special case in medical therapy

Opioid analgesics are effective for treating pain (Portenoy, 1993; Trescot et al., 2006), and they also have very real negative potential consequences, such as abuse, tolerance and addiction (Longo, et al., 2000). There are questions as to how to keep the balance in favor of optimal pain relief without potentiating the possible negative factors associated with opioid use. Pain treatment goals using opioids should include the alleviation of a patient's pain while keeping the negative consequences in check. Pain relief is the goal that is achieved through optimal use which could be interpreted as an increase in the amount of pain medications used. Increased use, though, also can be a signal that the opioid is being abused (Longo et al., 2000).

Abuse is defined as using a prescribed medication in a fashion other than what the prescriber intended (Longo et al., 2000). This includes taking the drugs for recreational use, taking the drugs in larger amounts than those prescribed, taking the drugs at a greater frequency than prescribed or changing the route prescribed (Longo et al., 2000).

Addiction differs from abuse. The National Institutes of Health (NIH) defines addiction as “a chronic brain disorder characterized by the loss of control of drug-taking behavior, despite adverse health, social, or legal consequences to continued drug use” (NIH, 2000). Longo et al. (2000) adds that addiction is a primary illness that represents itself with “physiologic homeostatic changes leading to tolerance,” with sensitization, withdrawal, and possible cognitive changes (Longo et al., 2000). Greenwald and Narcessian (1999) point out that there is less than 1% risk of iatrogenic addiction for patients who receive opioids for pain (Greenwald & Narcessian, 1999).

Tolerance presents in patients as a need to increase a dose or the dosing frequency to maintain the effectiveness of the medication without a discernible increase in the progression of disease (South & Smith, 2001). Studies in cancer patients have shown opioid increases linked to disease progression rather than the onset of tolerance (South & Smith, 2001). Greenwald and Narcessian (1999) contend that opioid tolerance is commonly misunderstood by healthcare professionals who believe that tolerance limits the long-term use of opioids in pain management (Greenwald & Narcessian, 1999). This incorrect belief that it is common for decreasing analgesic effects requiring higher doses of medication is highlighted by the authors’ assertion that “clinically relevant tolerance to the analgesic effects of opioids seldom develops after the initial days or weeks of therapy” (Greenwald & Narcessian, 1999).

Patients

Patients themselves are aware of the benefits of opioid therapy and are commonly aware of the potential risks of opioid therapy (Paice et al., 1998; Dawson et al., 2005; Palos et al., 2004). Some patients’ concern about the potential negative consequences of opioid use leads to the withholding of indicated proper treatment. Patients’ concerns about tolerance and addiction,

both commonly known negative consequences associated with opioids, were studied as a barrier to cancer pain relief. Paice et al. (1998) found a strong relationship between concern about addiction and concern about tolerance and higher reported pain. Respondents used pain assessment tools to report their pain. This was compared to their score results about their attitude towards opioids. The study reported that fear of tolerance and fear of addiction both had an effect on pain intensity scales showing greater pain scores in those patients with higher fear of tolerance or addiction. Patients in this study were more concerned about increased doses over time: “fear of tolerance showed to have a greater effect on pain intensity scores than did fear of addiction” (Paice et al., 1998).

In addition, Palos et al. (2004) surveyed adults about their pain medication use and found that women were likely to have attitudes deemed “conservative” which decreased the likelihood of taking pain medications when needed. This conservative attitude included concerns about addiction and tolerance to analgesics including opioids (Palos et al., 2004). Dawson et al. (2005) also found concerns about addiction and side effects were inversely related to a patient’s willingness to take opioid medication for pain. The belief held by patients, “people get addicted to pain medications easily,” was a significant predictor of a patient being less willing to take an opioid if prescribed. Interestingly the study also found patient’s beliefs about pain medication were formed in part from the care they received (Dawson et al., 2005).

Physicians

Physicians have a wealth of clinical guidelines from which to choose that highlight opioids’ central role in treatment of pain. But, it is the legal terminology “legitimate medical purpose” that holds the boundary of patients’ needs (Brushwood, 2005). Physicians are aware of the dual nature of these medications and the need to address both the patients’ therapeutic needs

and the law. Physicians have been shown to alter prescribing behavior based on concerns about opiate addiction. A National Center on Addiction and Substance Abuse (CASA) study illustrates that physicians may change their prescribing patterns based on the fear of the risk of addiction of using opioid medication therapeutically (CASA, 2005). Physicians also have concerns about law enforcement agencies misconstruing prescribing large amounts of opioid analgesics as overprescribing (CASA, 2005).

Efforts to educate physicians and to ease hesitance in prescribing resulted in the Federation of State Medical Boards (FSMB) issuing guidelines for the use of controlled substances for the treatment of pain (Trescot et al., 2006). Also, the DEA clarified their position on using opioids for pain by deferring to and affirming practicing physicians' knowledge about the correct clinical choice for treatment (DEA, 2006; Trescot et al., 2006).

Pharmacists

Pharmacists are the gatekeepers of prescription medication and are responsible for keeping the integrity of the drug system intact (Bessell et al, 2002). The unique position of the pharmacist results in a pharmacist having the role of determining the legitimacy of a prescription at a *prima facie* level, on an interpretive level deciding if the prescription is within the course of a physician's professional practice and deciding if the prescription was written for a legitimate medical purpose (Joransen, 1993). Several studies have illustrated the pharmacist's response in this role to be one of reluctance in both filling and being prepared to fill prescriptions for opioid medications.

Gee and Fins (2003) found in their sample of palliative care experts that nearly three-fourths of the respondents had patients who had encountered barriers to filling a legitimate

opioid prescription. Patients were having trouble getting legitimate prescriptions for opioid analgesics filled at pharmacies. This number (71.1%) was higher in comparison to the rate of patients claiming difficulty (34.2%) for filling legitimate non-controlled non-steroidal anti-inflammatory drugs (NSAID) prescriptions (Gee & Fins, 2003). Barriers that the patients could report included “‘patient inability to afford medications,’ ‘lack of insurance,’ ‘lack of medication benefit,’ ‘pharmacy barriers,’ ‘restrictive hospital or managed care formulary,’ ‘restrictive prescribing laws,’ or absence of economic, regulatory, and organizational barriers.” Of the 71.1% of the palliative care experts expressing patient’s claiming issues in obtaining controlled substances, 52.1% claimed the barriers were pharmacy-specific and included reasons such as pharmacies not stocking the needed medication, pharmacies not open due to restrictive hours, and pharmacists’ objections to filling the medications (Gee & Fins, 2003).

Reluctance to Stock Opioid Medications

A study by Morrison et al. (2000) looked at the pharmacies’ stock of sufficient opioids for dispensing in ethnic minority communities. For the study, opioids were divided into four categories as listed.

- 1) Combination products for the treatment of moderate pain
- 2) Short-acting opioid tablets for the treatment of breakthrough pain
- 3) Short-acting opioids in liquid form for the treatment of severe pain in patients with swallowing difficulties
- 4) Long-acting opioids for the extended treatment of severe pain

The researchers then categorized pharmacy stock as complete, nearly complete, incomplete, or absent. Based on the criteria below (Morrison et al., 2000):

Supplies were considered complete if the pharmacy had in stock an agent in each of the four medication categories nearly complete if the pharmacy had in stock sufficient

medication to treat a patient in moderate or severe pain – that is, a long-acting opioid, a short-acting opioid (tablet or liquid), and an opioid combination product; incomplete if the pharmacy lacked either a long-acting or a short-acting opioid preparation; and absent if the pharmacy did not carry any opioids but did stock other prescription medications.

The results of the study showed that pharmacy respondents did not stock sufficient opioids and thus did not dispense certain opioid prescriptions. The reasons given for not stocking opioids reported by the pharmacists sampled included among other reasons, the fear of fraud for illicit use and fear of robbery (Morrison et al., 2000). This was in step with a 1986 and 2001 survey of pharmacies that did not stock sufficient opioids in minority neighborhoods that included fear of violence, added administrative work, along with a lack of demand as reasons for not carrying opioids for dispensing (Kanner & Portenoy, 1986; Kanner, 2001).

Green et al. (2006) found differences in opioid stock availability comparing across ethnically different pharmacies across Michigan. Ethnic minority areas were less likely to have the necessary stock of opioids compared to pharmacies in predominantly white neighborhoods, regardless of the area's median income and median age. They also found that regardless of racial makeup of an area, lower income area pharmacies had stocking deficiencies for opioids compared to areas of higher income. They also found variations based on the type of pharmacy. Independently-owned pharmacies were more likely to carry opioid medications and corporate or chain pharmacies were less likely to have sufficient stock. Concerns of illicit opioid use along with low demand were cited as reasons for not carrying adequate opioid stock (Green et al., 2006). Greenwald and Narcessian (1999) also looked to quantify the resistance by pharmacists to stocking and dispensing opioids in their pharmacies. They found that the type of drug influenced the likelihood of stocking. The drug methadone was least likely to be stocked (Greenwald & Narcessian, 1999).

Previous relationship affects willingness to fill opioid medications

When examining the willingness of pharmacists to order out of stock medication for patients with opioid prescriptions, Kim et al. (2000) found the overwhelming majority would do so, but only if they had a previous relationship with either the patient or the physician or both. Only a third of the responding pharmacists would place an order for an out-of-stock opioid for an unfamiliar patient and doctor (Kim et al., 2000).

Pharmacists' knowledge and attitudes about opioid medications

Pharmacists' knowledge is lacking

Based on awareness and knowledge, a pharmacist's behavior will differ in regard to treatment of opioid prescriptions. A survey of pharmacists found that pharmacists who went through special training concerning the dispensing of controlled medications, preventing diversion of said products and identifying prescription drug addiction were more likely to check the dose on prescriptions to make sure the prescription doses were within regulations compared to those pharmacists who did not receive the special training (CASA, 2005).

Greenwald and Narcessian (1999) assessed pharmacists' knowledge and attitudes regarding the use of opioids in certain situations. Cancer patients and chronic nonmalignant pain patients were presented in different scenarios to pharmacists to assess their knowledge of the legitimacy based on clinical appropriateness and legality of specific dispensing of opioid prescription scenarios. In interpreting the legality and legitimacy of dispensing opioids in the scenarios, respondents showed they were lacking the knowledge of law and clinical practice to correctly decide based on these factors. The legitimacy and legality of a prescription were misclassified by some pharmacists in all scenarios. The most dramatic case showed only 3% of the respondents believed the legality and clinical appropriateness of a legitimate prescription

written for a patient with chronic nonmalignant pain and a history of opioid abuse (Greenwald & Narcessian, 1999).

Joranson and Gilson (2001) also found pharmacists' knowledge to be lacking in certain situations regarding opioid pain medications. They found this despite finding a majority of the responding pharmacists (87%) were confident in their ability to recognize a diversion attempt where a person was attempting to obtain controlled substances from a pharmacy for other than legitimate medical purposes. They found varying percentages of responding pharmacists to be unaware of the legal and legitimate dispensing of opioid medications depending on the scenario presented. A legal and legitimate scenario involving a cancer patient with chronic pain, who also had a history of opioid abuse revealed that only 64% of the pharmacists respondents expressed confidence in the validity of a prescription for this patient. This is in contrast to the overwhelming 93% of respondents who were confident in the legality and medical legitimacy of dispensing opioids for more than several months for pain patients with a malignancy and history of opioid abuse (Joranson & Gilson, 2001).

For the nonmalignant pain scenarios, 57% of respondents expressed confidence in dispensing opioids for an extended period as legal and accepted practice. But only 8% of the pharmacists viewed the prescribing and dispensing of opioids for more than several months to a patient with chronic nonmalignant pain and a history of opioid abuse as legal and acceptable medical practice (Joranson & Gilson, 2001).

The legal and legitimate scenarios in the Joranson and Gilson (2001) study were similar to the Greenwald and Narcessian (1999) study that had patients with previous substance abuse issues included in some of the scenarios compared against scenarios with patients with no substance abuse. All the scenarios presented in both studies were considered to be both legal and

legitimate as presented by the researchers and should have arguably had 100% confidence rate as valid by responding pharmacists (Joranson & Gilson 2001).

Doucette et al. looked at pharmacists' knowledge and practices in regard to cancer pain management and found pharmacists to have a knowledge deficit in some areas. Less than 50% had correct answers when responding to the statements that involved tolerance risk, risk of addiction, respiratory depression, and the inevitability of cancer pain (Doucette et al., 1997). The results of these studies leave the impression that information other than legal and clinical factors were being used to make the decisions about dispensing opioid prescriptions.

Strategies available for pharmacists to use when filling

There are published strategies to help pharmacists make better decisions about legitimate prescriptions when filling prescriptions. The DEA publishes a handbook for pharmacists with specific recommendations for handling potentially illegitimate prescriptions. Included in those recommendations are descriptions of characteristics of forged prescriptions:

“Prescription looks ‘too good’; the prescriber’s handwriting is too legible; quantities, directions or dosages differ from usual medical usage; prescription does not comply with the acceptable standard abbreviations or appear to be textbook presentations; prescription appears to be photocopied; directions written in full with no abbreviations; prescription written in different-color inks or written in different handwriting; or the prescription has apparent erasure marks.” (DEA, 2004)

Also, criteria that may indicate that a prescription may not have been issued for a legitimate medical purpose:

- “The prescriber writes significantly more prescriptions (or in larger quantities) compared to other practitioners in your area.
- The patient appears to be returning too frequently.
- Prescription, which should last for a month in legitimate use, is being refilled on a biweekly, weekly or even a daily basis.
- The prescriber writes prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time. Drug abusers often request prescriptions for ‘uppers and downers’ at the same time.
- Patient appears presenting prescriptions written in the names of other people.

- A number of people appear simultaneously, or within a short time, all bearing similar prescriptions from the same physician.
- Numerous ‘strangers,’ people who are not regular patrons or residents of your community, suddenly show up with prescriptions from the same physician” (DEA, 2004).

Brushwood and Carlson took the pharmacist’s role as healthcare professional that includes the function of verifying facially suspect prescriptions and summarized a framework recommended by the DEA to address “dubious” prescriptions (1991). The framework uses a decision tree that starts at the encounter of a “dubious” prescription and offers strategies for correctly addressing the issue. The step-by-step instructions include the facial examination of a prescription, correspondence with the prescribing physician, and interviewing the patient for further information (Brushwood and Carlson 1991). The steps are intended to enable the correct handling of a prescription where the validity is doubted on a *prima facie* basis, in other words, this system provides a step-by-step basis to ensure that a valid prescription gets filled and that an invalid one does not.

The question remains as to what information is being considered that would initiate the pharmacist questioning the legitimacy of a prescription. There are resources available to pharmacists that offer suggestions to aid in determining the validity of a prescription. Brushwood (2001) offers a stepwise approach pharmacists could use when determining the legitimacy of a prescription (Brushwood, 2001). This systematic approach includes several steps with each subsequent step increasing the likelihood that further investigation of the validity of a prescription will be necessary.

Brushwood outlined the first step as “irrelevant factors.” They include off-label uses, aggressive demands, dose and frequency increases (2001). These factors include patient behaviors such as aggressive demands and frequency increases. They also include prescription

factors such as dose increases and off-label uses. The factors alone, as Brushwood notes, do not indicate by themselves an illicit prescription (Brushwood 2001).

“Suspicion factors” were outlined as the next step in the process and were a key to start suspecting the validity of the prescription. These included patient behaviors of distracting behavior, frequent loss of medication by the patient and a patient requesting opioids only on a multi-medication prescription (Brushwood, 2001). Other prescription factors in this step included seeing the same drug from many prescribers (Brushwood, 2001).

Following the “suspicion factors,” “confirmation factors” were described as a definite sign that a prescription was more than likely illegal. In this step, a patient refuses prescriber inquiry, refuses partial supply, or refuses the pharmacy a copy of their identification (Brushwood, 2001). These patient behaviors according to Brushwood (2001) are telltale signs of an illicit prescription and the pharmacist should take appropriate action.

The final steps in Brushwood’s system are the “determinative factors.” These include a known past forgery from a patient or the knowledge of street drug use by the patient (Brushwood, 2001). A pharmacist is encouraged to be dubious of prescriptions associated with these factors. Brushwood concludes that the suggested process is by no means conclusive and adds: “This step-wise approach is offered only as a suggestion for a process that might be effective in helping pharmacists do their jobs well” (Brushwood, 2001, p. 115). Brushwood’s conclusion highlights the pharmacist’s reliance on available and imperfect information in deciding the legitimacy of a prescription (Brushwood, 2001). The decision process for determining legitimate prescriptions is made by pharmacists. The information that is available to pharmacists in guiding them on the legitimacy of prescriptions still must be used by the pharmacist in making a decision.

Summary

Patients experience barriers to getting opioids filled in pharmacies. Studies show sometimes the medications are not available in certain areas and that this availability deficiency is more likely to occur in low income neighborhoods. Studies show legitimate prescriptions are sometimes deemed invalid by pharmacists and also pharmacists have a reluctance to fill valid prescriptions in certain situations, as defined by prior history and patient presentation. These barriers and the reluctance to fill prescriptions for opioids and stock opioids, and an inability to completely determine the legitimacy of controlled substance prescriptions suggests that pharmacists may not always be using situationally defined, objective criteria to make these decisions. It raises the question as to how pharmacists are using the information available to them when making decisions to fill opioid medications.

Research Question: What information do pharmacists find relevant when deciding the validity of an opioid prescription?

Of all the available information available to a pharmacist, what information does a pharmacist rely on when the decision is made to either fill a prescription or take another route of action? In making decisions about the validity of a prescription, pharmacists are likely to use the information available at the time of filling the prescription. As discussed, there are recommendations as to what information should be used and how that information can help to determine the veracity of a prescription. What is not known is what information pharmacists consider relevant in determining whether a prescription is valid or not.

Study Objectives

Objective 1: To determine the level of relevance pharmacists attribute to specific information available during the prescription filling process when determining the validity of a prescription.

Objective 2: To determine if pharmacists attribute different levels of relevance to specific information available during the prescription filling process when determining the validity of a prescription of a controlled versus non-controlled prescription.

Hypotheses

H1: Pharmacists attribute greater relevance to **irrelevant factors** when deciding the validity of a prescription for a prescription for CIII medications than to non-scheduled prescriptions.

H2: Pharmacists attribute greater relevance to **suspicious factors** when deciding the validity of a prescription for a prescription for CIII medications than to non-scheduled prescriptions.

H3: Pharmacists attribute greater relevance to **confirmatory factors** when deciding the validity of a prescription for a prescription for CIII medications than to non-scheduled prescriptions.

H4: Pharmacists attribute greater relevance to **determinative factors** when deciding the validity of a prescription for a prescription for CIII medications than to non-scheduled prescriptions.

H5: Pharmacists attribute greater relevance to **DEA factors** when deciding the validity of a prescription for a prescription for CIII medications than to non-scheduled prescriptions.

METHODOLOGY

Design

A cross-sectional, three-group, between groups design was employed.

Sample

Licensed practicing pharmacists are experts in the information sought when filling prescriptions and determining their validity. It can be argued that any licensed practicing pharmacist has the ability to assess the validity of a prescription offered by a patient for filling and dispensing. It is reasonable to ask a licensed practicing pharmacist to rate the relevance of a particular piece of information associated with a prescription scenario as it relates to prescription validity.

A national list of licensed community pharmacists was purchased from a healthcare database service for use in this study. Then a non-probability, random sample of pharmacists from the list was selected to participate in the study.

Sample size

Based on a medium effect size and using G-Power software, an effect size of 0.25 was estimated, as recommended by Cohen (1992), with an alpha 0.05, at a power of 0.95. The suggested sample size is 194, or 97 per group (Faul & Erdfelder, 1992). Based on this, a sample size of 105 per group would be sufficient and accommodate possible liberal effect-size estimation. To ensure that 105 pharmacists per group completed the study, it was estimated that surveys would need to be sent to 2100 pharmacists (i.e., 1050 per group). This would be a response rate of 15%. Previous response rates of community pharmacists were sought to predict

the response rates for this study. The response rates for participants in a web-based survey to assess the attitudes toward and factors affecting implementation of medication therapy management services by community pharmacists in Texas garnered an 11.8% response rate (MacIntosh et al., 2009). Another web-based survey of community pharmacists assessed the knowledge of and attitudes toward oral chemotherapy and was able to capture a 22.5% response rate (O'Bryant & Crandell, 2008). Based on these, a conservative 15% response rate seemed reasonable.

Survey Instrument Design

The objectives of this study were met by creating a measure to assess the relevance that pharmacists assign to various pieces of information used to assess the validity of a prescription in a given scenario. Each pharmacist was asked to read a prescription scenario and then answer questions about the validity of the prescription. The scenarios and survey questions are shown in Appendix A.

Pharmacist participants were asked to rate the relevance of each specific piece of information as it relates to prescription validity in the scenario using a 7 point Likert-type scale. Relevance is defined as the information being assessed having a sensible or logical connection to the matter at hand (Merriam-Webster, 2009). In this study the connection would be with the validity of the prescription.

The information presented for relevance was gathered from information available to a pharmacist at the time of filling as presented in the previous chapter. Also, the DEA publishes a handbook for pharmacists "Pharmacist's Manual: An Information Outline of the Controlled Substances Act of 1970" (2004).

The DEA has guidelines for pharmacists to use in determining the validity of prescriptions (DEA, 2004). Specifically, the DEA in its publication “Pharmacists Manual,” offers several characteristics of a fraudulent prescription that a pharmacist should look for in assessing validity.

Additionally, the DEA stresses that in order for a prescription to be valid, a prescription must be issued for a legitimate medical purpose by a practitioner acting in their normal course of professional practice. They offer these criteria in guidance of recognizing prescriptions that may have not been written for a legitimate medical purposes:

- The physician writes significantly more prescriptions larger quantities compared to other practitioners in the area.
- The patient appears to be returning too frequently and requesting early refills.
- The prescriber writes prescriptions for antagonistic drugs, such as depressants and stimulants, to be taken at the same time.
- Patient appears presenting prescriptions written in the names of other people.
- A number of people appear simultaneously, or within a short time, all bearing similar prescriptions from the same physician.
- Numerous "strangers," people, who are not regular patrons or residents of your community, suddenly show up with prescriptions from the same prescriber. (DEA, 2004)

Also, there is guidance available to pharmacists through journals and State Board of Pharmacy newsletters, including publications authored by Brushwood (2002) that offer a stepwise approach to determining fraudulent prescriptions. Brushwood (2002) classified information available to a pharmacist in a proposed, stepwise manner and labeled the information as irrelevant factors, suspicious factors, determinative factors, and confirmatory factors:

Step 1: Irrelevant Factors

- Off-label use.
- Aggressive demand.
- Dose/frequency increases.

Step 2: Suspicion Factors

- Distracting behaviors.

- Frequent loss.
- Only opioids.
- Same drug, many prescribers
- Always cash and always brand.

Step 3: Confirmation Factors

- Refuses prescriber inquiry.
- Refuses partial supply.
- Refuses to permit photocopying of identification.

Step 4: Determinative Factors

- Past forgery.
- Knowledge of street drug use. (Brushwood, 2002)

Available information at the time of filling, including those criteria outlined by the DEA (2004) and by Brushwood (2002), was presented to pharmacists as possible information pieces to consider. In addition, information of past known opioid addiction (Joranson & Gilson, 2001; Greenwald & Narcessian, 1999) was presented as a factor to consider. Additionally, information that might be available but not captured in the mentioned categories was presented for consideration. The pharmacists were asked to determine the relevance of each specific piece of information when considering the validity of a prescription. Participants were divided alphabetically by last name and asked to consider only one type of medication and one piece of information at a time.

Participants were asked to consider either a legend drug (amoxicillin) or a schedule III controlled substance opioid pain medication (hydrocodone/acetaminophen combo) in a prescription scenario. The drug Soma[®] (carisoprodol) was also included for consideration for a third group of participants. At the time of the proposal of the study, carisoprodol was a legend drug in all but two states. It was suggested that carisoprodol be added as a third group because of its mainly non-controlled status and its abuse potential.

Individual participants were asked to consider different pieces of information for relevance for the legend drug, the scheduled drug, or the carisoprodol. For example, a participant was asked to consider the relevance of an irrelevant factor for an amoxicillin prescription, then the relevance of a determinant factor for an amoxicillin prescription, then the relevance of a DEA factor for an amoxicillin prescription, and so on, for different pieces of information.

The demographics of responding pharmacists was collected for analysis including gender, age, practice zip code, years in practice, degree type (PharmD., B.S.), and the years since last practice degree was obtained. Main practice type (independent retail, chain retail, hospital, institutional, other) and affirmation of community pharmacy practice was collected to ensure the participants practice community pharmacy as pharmacists.

To determine face validity of the survey instrument, three pharmacists who practice in community pharmacy were asked to review the survey instrument. It is important to assess face validity to ensure the measures adequately represent all facets of the concepts being measured. The survey instrument was modified based on their comments for spelling and grammar modifications.

Additionally, the survey instrument was pre-tested by administering it in its electronic version to five pharmacists. The pre-test was important in determining the length of time required to complete the survey and to assess the clarity of instructions and items. Based on the feedback from the pre-test, the survey instrument was revised for grammar in the instructions for completion.

Data Collection

The prescription medications in the scenarios were presented as a prescription for a non-scheduled legend drug (amoxicillin), a schedule III medication (hydrocodone/acetaminophen combo), and Soma[®] (carisoprodol). A three-group design was needed to test study hypotheses. The survey instrument with scenarios was reviewed by the IRB of The University of Mississippi before commencing the data collection. Participant incentives were not used.

An invitation to participate in an Internet survey was distributed to the sample pharmacists using a third-party vendor who distributed requests by email. The Internet survey was hosted online by SurveyMonkey[™]. By email, the sampled pharmacists received an invitation to participate along with a link to the survey. Respondents were assigned to one of the three groups by asking them to click on one of three links based on the starting letter of their last name. The survey was fielded for one week, after one week a reminder email including the survey link was sent out to the sampled pharmacists thanking them for their participation or encouraging them to participate if they have not done so. Data collection was closed at four weeks after the initial email.

Analysis

Data was analyzed using the Statistical Package for Social Sciences (SPSS) software (Chicago, IL). Response rates were calculated. A sample description using frequencies and percentages or means as appropriate was determined. Descriptive statistics, including mean and standard deviations were calculated for all measures. Reliability of measures was assessed by calculating Cronbach's alpha. Hypotheses were tested using MANOVA with appropriate post-hoc tests.

RESULTS

Sample Description and Descriptive Statistics

A total of 2,328 pharmacists were sent email requests to participate in the survey. Of those, 126 of the email messages were returned as undeliverable. The undeliverable emails included both hard bounces (an attempt at an email address where nothing was delivered due to a bad email, domain, and connection or configuration problem) and soft bounces (sent to a valid address but were filtered or rejected by the intended address).

Of the 2328 pharmacists emailed there were 157 responses (6.77% response rate), considering undeliverable emails, the usable response rate 7.7% (157/2202).

Of the 157 respondents that accessed the survey, 104 of the surveys were retained for analysis. Twenty-three of the 157 that accessed the survey were excluded because they were not pharmacists. Thirty surveys were opened and started but there were no responses making them ineligible for analysis.

Table 1: Description of Work Setting for Survey Respondents

	Other	Grocery Store Pharmacy	Institutional Inpatient	Institutional Outpatient	Mass Merchand. (Big Box) Pharmacy	Multiple Store Indep.	Single Store Indep.	Traditional Chain	Total
Amoxicillin group	4	0	2	5	0	6	26	1	44
Carisoprodol group	4	4	0	2	1	5	15	0	31
Hydrocodone /Apap group	1	0	0	4	0	12	12	0	29
Total	9	4	2	11	1	23	53	1	104

Indep. = Independent Apap = Acetaminophen

Table 1 provides a description of the sample across each of the three groups (amoxicillin, carisoprodol, hydrocodone/apap) and as a whole. More than half of the pharmacist respondents identified themselves as practicing in single store independent pharmacies. The second largest group identified themselves as multiple store independent pharmacists. There were also institutional outpatient pharmacists, institutional inpatient pharmacists, grocery store pharmacy pharmacists, mass-merchandiser chain pharmacists, and traditional chain pharmacists. There were significant differences in practice type distribution across the groups with a Pearson Chi-Square of 26.17 ($p = .025$). Additionally there were nine respondents that identified their main practice setting as “other.” These included various specialty pharmacies (Table 2). There were no significant differences in other practice type distribution across the groups with a Pearson Chi-Square of 23.96 ($p = .464$).

When asked about the number of years (rounded to the nearest whole number) they have been in pharmacy practice, the respondents answered with mean of 23.2 years in practice (Table 3). There were 44 female respondents and 59 male, one respondent did not respond to the gender demographic question. There were no significant differences in gender distribution across the groups with a Pearson chi square of 2.69 (p value= .669) (Table 4). In the sample, there were a total of twenty-six pharmacists who reported having PharmD practice degrees. There were no significant differences in PharmD distribution across the groups with a Pearson Chi-Square of 2.492 (p = .288) (Table 5). Eighty respondents reported having Bachelor-level practice degrees reported, and there were no significant differences in Bachelor Degrees distribution across the groups with a Pearson chi square of 2.43 (p = .296) (Table 5).

Table 2: Other Practice Type

	None Indicated	Mail Order (pain mgmt)	Pain Speciality	Pharmacy in Med. Clin.	Also in Retail	Clinic	Closed Door Respiratory Pharmacy also	Closed Door Long Term Care Community Pharmacy	Compounding Pharmacy	Home Infusion	Retail 304b Pharmacy within a Medical Clinic	Long Term Care Closed Door Independent Pharmacy	Hospital but Per Diem retail	Total
Amoxicillin	39	0	1	0	1	0	0	0	1	1	1	0	0	44
Carisoprodol	25	1	0	1	0	0	1	1	0	0	0	1	1	31
Hydrocodone/ Apap	28	0	0	0	0	1	0	0	0	0	0	0	0	29
TOTAL	92	1	1	1	1	1	1	1	1	1	1	1	1	104

Table 3: Years in Practice

GROUP	N	Mean	Std. Deviation
Amoxicillin	44	24.07	10.98
Carisoprodol	31	23.74	14.05
Hydrocodone/Apap	29	21.31	11.71
TOTAL	104	23.20	12.11

Table 4: Gender of Respondents

Group	No Answer	Female	Male	Total
Amoxicillin	1	16	27	44
Carisoprodol	0	15	16	31
Hydrocodone/Apap	0	13	16	29
Total	1	44	59	104

Table 5: Pharmacy Practice Degree

Group/ Type	B.S. Degree	Pharm D
Amoxicillin	37	8
Carisoprodol	23	8
Hydrocodone/Apap	20	10
TOTAL	80	26

Hypotheses Testing

To test individual hypothesis, the items (questions) were grouped into the factors they represented in the literature. The means of item responses were computed. Items were grouped into the factors they represent and the response means computed for each category. Means and standard deviations for scales in each of the three groups are provided in Table 7. The reliability of each factor was assessed using Cronbach's alpha, as presented in Table 8.

Table 6: Group means* across all factors

		Irrelevant Factors	Suspicious Factors	Confirmatory Factors	Determinative Factors	DEA Factors	Other Factors
Group 1 Amoxicillin	Mean	3.71	3.82	6.08	5.15	5.49	2.57
	SD	1.22	1.46	1.24	1.32	1.13	0.99
Group 2 Carisoprodol	Mean	4.88	5.67	6.56	6.03	5.09	3.65
	SD	1.67	1.09	0.79	0.94	1.00	1.10
Group 3 Hydrocodone/apap	Mean	4.79	5.73	6.16	6.08	5.94	3.44
	SD	1.22	1.08	1.35	1.20	0.91	0.89

*Based on a 1-7 scale where 1=not relevant and 7= very relevant

Table 7: Reliability Results – Cronbach’s Alpha

Factors	Item Means	Min	Max	α	Item Numbers
Irrelevant	4.359	3.779	5.117	.574	1, 2, 22
Suspicious	4.906	4.356	5.712	.857	3, 4, 5, 24, 25
Confirmatory	6.247	5.740	6.673	.716	6, 7, 8
Determinative	5.671	4.760	6.583	.558	9, 23
DEA	5.739	3.490	6.750	.937	19, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39
Other	3.136	1.563	5.096	.905	10, 11, 12, 13, 14, 15, 16, 17, 18, 20, 21, 40, 41

Group factor means were compared using MANOVA. Two groups of medications (amoxicillin and hydrocodone/apap) were included in the hypotheses testing. The amoxicillin group and the hydrocodone/apap group were compared in pair-wise fashion to determine if the differences in response means represented significant differences. A significant difference (Hotelling’s Trace = 40.298, $F = 443.277$, $p < .05$) was found between the two groups. Significant differences, at the .05 level, were found in the response means between the amoxicillin and hydrocodone/apap groups in Irrelevant Factors, Suspicious Factors, Determinative Factors, and Other Factors (See Table 9). A summary of findings related to hypothesis testing is as follows:

Table 8: Average Difference between groups on each factor

	Mean Difference between Amoxicillin & Hydrocodone groups	Significance (at .05 level)
Irrelevant Factor Mean	1.088 *	.000
Suspicious Factor Mean	1.909 *	.000
Confirmatory Factor Mean	0.078	.801
Determinative Factor Mean	0.931 *	.003
DEA Factor Mean	0.454	.074
Other Factor Mean	0.867 *	.000

(* mean difference significant at the .05 level)

H1: Pharmacists attribute greater relevance to **irrelevant factors** when deciding the validity of a prescription for a prescription for CIII medications than to non-scheduled prescriptions.

H1 supported.

Pharmacists in the sample attributed more relevance to irrelevant factors when considering the validity of a hydrocodone/apap prescription than when considering the validity of an amoxicillin prescription.

H2: Pharmacists attribute greater relevance to **suspicious factors** when deciding the validity of a prescription for a prescription for CIII medications than to non-scheduled prescriptions.

H2 supported.

Pharmacists in the sample attributed greater relevance to suspicious factors when deciding the validity of a prescription for hydrocodone/apap than when considering the validity of an amoxicillin prescription.

H3: Pharmacists attribute greater relevance to **confirmatory factors** when deciding the validity of a prescription for a prescription for CIII medications than to non-scheduled prescriptions.

H3 not supported.

Pharmacists in the sample indicated that the confirmatory factors had the same relevance whether they were considering the validity of the amoxicillin prescription or the hydrocodone/apap prescription.

H4: Pharmacists attribute greater relevance to **determinative factors** when deciding the validity of a prescription for a prescription for CIII medications than to non-scheduled prescriptions.

H4 supported.

When evaluating the validity of a hydrocodone/apap prescription, pharmacists in the sample attributed greater relevance to determinative factors than when considering the validity of an amoxicillin prescription.

H5: Pharmacists attribute greater relevance to **DEA factors** when deciding the validity of a prescription for a prescription for CIII medications than to non-scheduled prescriptions.

H5 not supported.

Pharmacists in the sample considered DEA factors to have the same amount of relevance when evaluating the validity of an amoxicillin prescription and a hydrocodone/apap prescription.

DISCUSSION

Pharmacists were asked to rate the relevance of various pieces of information (or factors) as they related to the validity of the prescription. They were given scenarios that represented potential information available to pharmacists at the time of filling. Regardless of the scenarios, pharmacists used confirmatory, determinative, and DEA factors to determine the validity of a prescription. Irrelevant, suspicious, and other factors were considered less often. Although there are certain pieces of information used more commonly than others, pharmacists do consider different information depending on the prescription.

Three of the five hypotheses were supported, which indicates that pharmacists did deem certain types of information (irrelevant information, information that can be deemed suspicious and determinative information) to more relevant when filling a prescription for a controlled substance than for an antibiotic. This indicates that controlled prescription medications are held to a different standard when it comes to assessing their validity; and the different standard seems to manifest in the assessment of irrelevant, suspicious, and determinative factors. Two of the hypotheses were not supported indicating that pharmacists in the sample are likely to consider the DEA factors and confirmatory factors to hold the same amount of relevance regardless of whether the prescription is a controlled substance or an antibiotic. Therefore, factors that the DEA promotes as being relevant and factors that are published to be confirmatory in the assessment of a prescription appropriately carried the same level of relevance to the pharmacists in the sample.

Irrelevant Factors

H1: Pharmacists attribute greater relevance to irrelevant factors when deciding the validity of a prescription for a prescription for CIII medications than to non-scheduled prescriptions.
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<i>H1 supported.</i>

<p>The patient is aggressive in demanding the prescription immediately [irr] The dose of the prescription seems high [irr] The prescription was written for an off-label use [irr] (Cronbach's $\alpha = .574$)</p>

There was a significant difference in the relevance placed upon the grouping of information titled **irrelevant factors** for the pharmacists considering the validity of the controlled medication prescription when compared with the relevance placed by pharmacists in the group presented a non-scheduled medication. Published guides indicate that these factors are possibly used for screening potential problem prescriptions despite the fact that they are not directly relevant to the validity of the prescription. This raises the question as to how pharmacists ultimately use this information in deciding whether to fill a prescription for a patient. Research findings indicate that pharmacists are less willing to fill controlled substance prescriptions (Greenwald & Narcessian, 1999; Kim et al., 2000; Gee & Fins, 2003). The findings supporting hypothesis 1 indicate that this reluctance may manifest in the assessed relevance of irrelevant information – information that is not directly related to the validity of the prescription and may not be an appropriate indicator or surrogate for validity assessment.

Pharmacists were asked to consider each piece of information independently. Therefore, it is not clear whether this information alone would lead to a patient not receiving medication. Yet, it does seem that pharmacists will consider this information relevant and that is a important step toward those factors being included in their decision to fill or not fill a given prescription.

Suspicious Factors

<p>H2: Pharmacists attribute greater relevance to suspicious factors when deciding the validity of a prescription for a prescription for CIII medications than to non-scheduled prescriptions.</p>
<p>H2 supported.</p>
<p>Patient lost the medication and this is a replacement [sus] This medication accompanies another medication and the patient doesn't want the other filled [sus] From the profile, you see that the patient has had this medication before from another</p>

prescriber [sus] The patient refuses generic substitution [sus] The patient ask that the prescription not be run on their prescription drug insurance [sus] (Cronbach's $\alpha = .857$)
--

When the pieces of information named **suspicious factors** was presented to the two groups of pharmacists, again the relevance of the information by the group given the controlled scheduled medication stimulus was rated higher than that compared to the group given the non-controlled medication. While these factors may lead a person to be suspicious, they should have the same relevance regardless of prescription. The fact that pharmacists in this study indicate a greater relevance to these factors for the controlled prescription indicates that there may be a link between pharmacists assessed relevance of these factors and the reported difficulty that patients have in having filling valid controlled prescription medications.

These patient behaviors seem to have more relevance to pharmacists when filling a controlled substance prescription than when filling an antibiotic. From the present study, it is not clear whether this relevance is simply a clue that would drive pharmacists to consider other, more appropriate information, or whether it will change the likelihood that a prescription will be filled or not. The differential relevance of these factors, as compared to an antibiotic, do further support the likelihood that controlled substance medications are held to a different level of scrutiny than prescriptions for antibiotics.

Confirmatory Factors

H3: Pharmacists attribute greater relevance to confirmatory factors when deciding the validity of a prescription for a prescription for CIII medications than to non-scheduled prescriptions.
H3 not supported.
The patient refuses to let you call the doctor to verify the prescription [conf] The patient refuses a partial fill while you verify the prescription [conf] The patient refuses to show you identification [conf]

(Cronbach's $\alpha = .716$)

For the information deemed **confirmatory factors**, there was no significant difference between the pharmacists shown the controlled scheduled medication scenario and the pharmacists in the non-controlled medication group. This may seem to go against the trend seen from the previous factor groups, but the means of both groups are toward the higher relevance side of the 7 point scale (non-controlled group mean= 6.08, SD=1.24; controlled group mean=6.16, SD=1.35). This indicates that there were no significant differences between the two groups, and both groups placed a high level of relevance equally upon the pieces of information.

Perhaps, the behaviors presented in this group might be egregious enough that they transcend the controlled versus non-controlled nature of the question posed. The “patient refuses” statement that starts each item puts the patient directly between the pharmacist and their duties. This in itself might bring the validity of any given prescription into question, no matter the medication. The patient’s refusal behavior may also indicate an unwillingness to actively participate in assisting the pharmacist to properly do her job. As a result, this refusal of the patient may call into question the validity of the prescription regardless of class of medications being dispensed.

Determinative Factors

H4: Pharmacists attribute greater relevance to **determinative factors** when deciding the validity of a prescription for a prescription for CIII medications than to non-scheduled prescriptions.

H4 supported.

There is a note in the profile that this patient has presented a forged prescription before [det]
The patient uses “street drug” terminology to describe another medication he is taking [det]
(Cronbach's $\alpha = .558$)

Hypothesis 4 was supported. This again gives a significant difference in pharmacists assigning relevance of the information in determining validity of a prescription between the

groups that did and did not get the controlled drug as the differentiating medication. Pharmacists thought these two items, considered the **determinative factors** in the literature, to be more relevant for a controlled medication than for a non-controlled medication. These two items speak directly to potential drug abuse, with a forgery mentioned in one and “street drug” mentioned in the other. It would seem almost obvious that they would not warrant the same level of relevance for a non-controlled amoxicillin prescription than for a controlled hydrocodone medication.

This finding seems to indicate that pharmacists will consider a patient’s past behavior to be relevant to the validity of their future prescriptions. It also seems to indicate that pharmacists deem this past behavior to be more relevant to controlled substance prescriptions than amoxicillin prescriptions.

DEA Factors

H5: Pharmacists attribute greater relevance to **DEA factors** when deciding the validity of a prescription for a prescription for CIII medications than to non-scheduled prescriptions.

H5 not supported.

- Quantities differ from usual medical usage [dea]
 - The prescriber has very clear and legible handwriting. [dea]
 - Directions differ from usual medical usage[dea]
 - Dosages differ from usual medical usage [dea]
 - Sig codes do not match acceptable standard abbreviations [dea]
 - Prescription appears to be photocopied[dea]
 - Prescription directions are written in full with no abbreviations [dea]
 - Prescription written in different-color inks [dea]
 - Prescription written in different handwriting [dea]
 - There are apparent erasure marks on the prescription [dea]
 - A number of people appear simultaneously, or within a short time, all bearing similar prescriptions from the same physician [dea]
 - Numerous "strangers," people, who are not regular patrons or residents of your community, suddenly show up with prescriptions from the same prescriber [dea]
 - The prescription is written for significantly larger quantities compared to other practitioners in the area [dea]
 - The patient appears to be returning too frequently [dea]
 - Patient appears presenting prescriptions written in the names of other people [dea]
- (Cronbach’s $\alpha = .937$)

The relevance placed upon the **DEA factors** was not significantly different when comparing the controlled medication against the non-controlled medication. Again, as in the confirmatory factors, the means of both groups trended toward the “very relevant” side of the 7 point scale (non-controlled mean=5.90, SD=1.13; controlled mean=5.94, SD=0.91).

Determining the reasons the amoxicillin might have hovered close to the hydrocodone prescriptions in these factors might have to do with the widespread availability of the DEA resources to pharmacists. These factors are perhaps widely recognized as information to look for as recommended by the DEA. When determining the validity of a prescription, recognition of this information might trigger a questioning of validity of a prescription, without regard to the medication.

Also, many of the items speak to the physical prescription itself. Different color inks, different handwriting, potential photocopied prescription, etc. might give a pharmacist pause to question validity for any prescription regardless of the medication.

Other

Non-hypothesized data
Significant differences found between groups.
The patient is elderly The patient looks frail The patient is dressed in jeans and a t-shirt The patient is dressed in business attire The patient is female The patient is male The patient looks unkempt (messy hair, dirty clothes, etc.) The prescriber is from a different state than the patient. The prescriber is a pain specialist. The dose is at the upper limit of clinical guidelines for this medication. The quantity of medication prescribed seems higher than other prescriptions of this type. The patient has no prescription insurance The patient has visible bruises (Cronbach’s $\alpha = .905$)

In addition to the available information presented in published guides and other available resources, the pharmacists in the study were presented with other information that might be potentially available at the time of filling. These pieces of information speak mainly to demographics (elderly, dressed, gender) and also to pain-management specific patients (pain specialist, upper guidelines). The results were surprising. The mean for each group were to the lower side of the 7 point scale used for attributing relevance to the information in deciding the validity of the prescription (non-controlled, 2.57 SD=0.99; controlled, 3.44 SD=0.89), but did register on the scale as higher than completely “not relevant.” The scores were significantly different when compared to each other, meaning the controlled medication group gave higher relevance scores for the information provided.

The idea that demographics might play any part in helping a pharmacist determine the validity of a prescription is disturbing at first thought. There is a potential for a person holding a valid pain medication prescription to have the prescription undergo a different level of relevance when the pharmacist is deciding the validity of the prescription. Even if the relevance of the information was due to confirmatory reasons, as in “this patient type is not an issue for forgeries,” the competing idea that a group of people might get a prescription deemed invalid due to a relevance of demographics is disturbing. Hopefully, demographics are not the only information that a pharmacist uses to make a decision on validity and that collective information about the patient and the prescription itself will ultimately determine a pharmacist's judgment of its validity.

Again, in these scenarios the means for each group were significant when compared to each other, indicating there was more relevance placed on the controlled medication scenario, but both scores did fall on the lower end of the 7 point scale. Further research would be needed

to determine to what extent demographic information might actually contribute to a pharmacist determining the validity of a prescription.

Pharmacists have to process a lot of information. This study indicates that the medication will influence the information (or factors) that pharmacists deem to be relevant when considering the validity of prescriptions. This study asked pharmacists to consider each piece of information independently. More work is needed to fully understand whether these pieces of information are considered alone and how the information and its relevance ultimately influences pharmacists' decisions to fill patients' prescriptions.

Carisoprodol Analysis

This study compared an antibiotic to a schedule III controlled substance. In an attempt to begin to understand whether the controlled status influences the relevance that pharmacists place on specific pieces of information or if it is driven by the likelihood of a medication to be sought illegally by patients, carisoprodol, a muscle relaxant, was included in the study as a secondary analysis. This drug has abuse potential and was not a scheduled controlled medication in all but eighteen states (http://www.deadiversion.usdoj.gov/drugs_concern/carisoprodol.htm). Because of its mainly non-scheduled non-controlled status and its abuse potential, this drug was chosen to also be tested along with the non-controlled amoxicillin and the controlled hydrocodone. This drug was chosen originally to test a medication with abuse potential (carisoprodol) versus a drug that had a scheduled controlled status and abuse potential (hydrocodone) to study if pharmacists regarded a higher level of relevance with a scheduled versus a non-scheduled medication.

In most states, at the start of this study, carisoprodol was non-controlled but recognized for its abuse potential by many state pharmacy boards (Reeves & Burke 2008). Shortly before the release of this study, the Deputy Administrator of the DEA issued a proposed rule “to place the

substance carisoprodol, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, into schedule IV of the Controlled Substances Act (CSA)” (http://www.deadiversion.usdoj.gov/fed_regs/rules/2009/fr1117.htm).

Upon analysis it was found that the medications carisoprodol and hydrocodone had very similar profiles with regards to the relevance of the information available to a pharmacist at the time of filling. The carisoprodol group and the hydrocodone/apap group were compared in pair wise fashion to determine if the differences in response means represented significant differences. No significant differences (Hotelling’s Trace = .133, F = 1.172) were found between the two groups. No significant mean differences, at the .05 level, were found for any of the factor means between the carisoprodol and hydrocodone/apap groups. (Table 10)

Table 9: Mean response differences between the carisoprodol and hydrocodone/apap groups on each of the factors

	Mean Difference (Carisoprodol and Hydrocodone)	Significance (at .05 level)
Irrelevant Factor Mean	.089	.791
Suspicious Factor Mean	.061	.829
Confirmatory Factor Mean	.398	.165
Determinative Factor Mean	.046	.867
DEA Factor Mean	.048	.847
Other Factor Mean	.208	.428

The amoxicillin group and carisoprodol comparison had a very similar profile to the amoxicillin and hydrocodone/apap group. There were significant differences in the same factors for both sets of analysis. (Table 11)

Table 10: Mean response differences between the carisoprodol and hydrocodone/apap groups on each of the factors

	Mean Difference (Amoxicillin and Carisoprodol)	Significance (at .05 level)
Irrelevant Factor Mean	1.176 *	.000
Suspicious Factor Mean	1.848 *	.000
Confirmatory Factor Mean	.476	.063
Determinative Factor Mean	.885 *	.002
DEA Factor Mean	.406	.110
Other Factor Mean	1.075 *	.000

***Difference significant at the .05 level**

While not formally predicted or tested, these findings indicate that the relevance of information considered by pharmacists when determining the validity of prescriptions is likely to be influenced by the nature of the medication; specifically, the drug abuse likelihood or potential of the prescription.

Limitations

This study has a number of limitations that warrant careful interpretation of the findings. The sample size obtained for analysis is relatively small and did not allow for a confirmatory factor analysis. The minimum number of observations required for conducting a confirmatory factor analysis would be five times as many observations as the number of variables to have analyzed. In this study with forty-two variables the actual achieved was far fewer than the minimum required factor analysis (Hair et al., 2005).

Also, the study lacks generalizability. There was an overwhelming homogeneity of the groups with too many *independent pharmacists* in the sample to achieve a good cross representation of

all pharmacists. Finally, scenario-based surveys may not mimic accurately a real situation for a pharmacist.

The reliability coefficient, which measures the consistency of a scale, was poor for some of the factor groups. There was poor reliability in some of the factor groups. The **irrelevant factors** had a Cronbach's α of .574 and the **determinative factors** had a Cronbach's Alpha of .558. Cronbach's $\alpha >.5$ but $<.6$ are considered poor in reliability and internal consistency (Hair et al., 2005).

Conclusion

Pharmacists have access to various pieces of information at the time of filling prescriptions. As they determine the validity of the prescriptions that they fill, different pieces of information will be judged to be relevant. The findings from this study indicate that the relevance of the information will be influenced by the medication that is being filled.

References

Abood, R.R. (2011). *Pharmacy Practice and the Law, Edition 4*. Sudbury, Massachusetts. Jones & Bartlett Publishers.

AJHP. (1998). APhA adopts conscience clause, policies on pharmacists' role in care. *American Journal of Health-System Pharmacy*, 55(9), 878.

American Society of Health-System Pharmacists (ASHP). (2008). *ASHP Policy Positions 1982-2008*. http://www.ashp.org/s_ashp/doc1c.asp?CID=512&DID=7300#0610

Bessell, T.L., Silagy, C.A., Anderson, J.N., Hiller, J.E., & Sansom, L.N. (2002). Quality of global e-pharmacies: can we safeguard consumers?. *European Journal of Clinical Pharmacology*, 58(9), 567-572.

Brushwood, D., & Carlson, J. (1991). The Pharmacist's Responsibility to Evaluate Suspicious Prescriptions. *Food Drug Cosmetic Law Journal*, 46: 467-485.

Brushwood, D. (2001). Diagnosing a Fraudulent Prescription Order. *NABP Newsletter*, 30(7), 114-115.

Brushwood, D. (2002). The Pharmacist's Duty to Dispense Legally Prescribed and Therapeutically Appropriate Opioid Analgesics. *Pharmacy Times*, 68(1), 55- 63.

Brushwood, D. (2005). Defining Legitimate Medical Purpose. *American Journal of Health-System Pharmacists*, 62, 306-308.

Clark, D.J. (2002). Chronic Pain Prevalence and Analgesic Prescribing in a General Medical Population. *Journal of Pain and Symptom Management*, 23 (), 131-137.

Code of Federal Regulations Purpose of Issue of Prescription. 21 C.F.R. 1306.04. (1971)

Cohen, J. (1992). A Power Primer. *Psychological Bulletin*, 112(1), 155-159.

Davis, M.P., Srivastava, M. (2003). Demographics, assessment and management of pain in the elderly. *Drugs Aging*, 20(1), 23-57.

Dawson, R., Sellers, D.E., Spross, J.A., Jablonski, E.S., Hoyer, D.R., Solomon, M.Z. (2005). Do patients' beliefs act as barriers to effective pain management behaviors and outcomes in patients with cancer-related or noncancer-related pain?. *Oncology Nursing Forum*, 32(2), 363-374.

Drug Enforcement Agency. (2004). *Pharmacist's Manual: An Information Outline of the Controlled Substances Act of 1970*. Washington, DC: U.S. Government Printing Office.

Drug Enforcement Agency. (2010). *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act*. Washington, DC: U.S. Government Printing Office.

Doucette, W.R., Mays-Holland, T., Memmott, H., & Lipman, A.G.(1997). Cancer Pain Management: Pharmacist Knowledge and Practices. *Journal of Pharmaceutical Care in Pain & Symptom Control*, 5(3), 17 – 31.

Faul, F & E Erdfelder (1992). GPOWER: A priori, post-hoc, and compromise power analyses for MS-DOS [Computer Program]. Bonn FRG: Bonn University, Department of Psychology.

Fink, J.L., Vivian, J.C., & Bernstein, I.B.G. (2005). *Pharmacy Law Digest 2006: The Definitive Source for Pharmacy Law Information*. St. Louis, Missouri. Lippincott Williams & Wilkins.

Fiske, S., & Neuberg, S. (1990). A continuum of impression formation from category-based to individuating processes. In M. Zanna (Ed.), *Advances in experimental social psychology* (Vol. 23, pp. 1-73). San Diego, CA: Academic Press.

Gilson, A.M., Ryan, K.M., Joranson, D.E., & Dahl, J.L. (2004). A Reassessment of Trends in the Medical Use and Abuse of Opioid Analgesics and Implications for Diversion Control: 1997–2002. *Journal of Pain and Symptom Management*, 28(2), 176-188.

Green, C., Todd, K.H., Lebovits, A., Francis, M. (2006). Disparities in Pain: Ethical Issues. *Pain Medicine*, 7(6), 530-533.

Greenwald, B.D., & Narcessian, E.J. (1999). Opioids for managing patients with chronic pain: community pharmacists' perspectives and concerns. *Journal of Pain Symptom Management*, 17(5), 369-75.

Guharoy, R., & Noviasky, J. (2005). Ethical beliefs and professional duty. *American Journal of Health-System Pharmacy: AJHP: Official Journal of the American Society of Health-System Pharmacists*, 62(18), 1864-1866.

Hair, J.F., Anderson, R.E., Tatham, R.L., & Black, W.C. (2005). *Multivariate data analysis* (6th edition). Englewood Cliffs, NJ: Prentice Hall

Joransen, D.E. (1993). Guiding Principles of International and Federal Laws Pertaining to Medical Use and Diversion of Controlled Substances. In J.R. Cooper, D.J. Czechowicz, and S.P. Molinari (eds.), *Impact of Prescription Drug Diversion Control Systems on Medical Practice and Patient Care* (Washington, D.C.: U.S. Government Printing Office, National Institute on Drug Abuse.).

Joranson D.E., & Gilson A.M. (2001). Pharmacists' Knowledge and Attitudes Toward Opioid Pain Medication in Relation to Federal and State Policies. *Journal of the American Pharmacists Association*, 41(2), 213-220.

Kaiser Family Foundation and Health Research and Educational Trust. (2005) *Employer Health Benefits 2005 Annual Survey*, Section 9, at <http://www.kff.org/insurance/7315/index.cfm>.

Kaiser Family Foundation. (2005). *Prescription Drug Trends-Fact Sheet, November 2005 Update*. www.kff.org/insurance/upload/3057-04.pdf

Kaiser Family Foundation. (2007). *Overview of Medicare Part D Organizations, Plans and Benefits By Enrollment in 2006 and 2007*. www.kff.org/medicare/7710.cfm

Kanner, R. (2001). Opioids for Severe Pain Little Change Over 15 Years. *Journal of Pain Symptom Management*, 21(1), 3.

Kanner, R.M., & Portenoy, R.K. (1986). Unavailability of narcotic analgesics for ambulatory cancer patients in New York City. *Journal of Pain Symptom Management*, 1(2), 87-89.

Kim, K.S., Glajchen, M. & Portenoy R.K. (2000). Unwillingness to Fill Opioid Analgesic Prescriptions by Local Pharmacies *Journal of Pain and Symptom Management*, 20(3), 160-162.

Kuehn, B.M. (2007) Opioid prescriptions soar: Increase in legitimate use as well as abuse. *JAMA*, 297(3), 249–251.

Longo,L.P., Parran,T., Johnson, B., and Kinsey, W. (2000). Addiction: Part II. Identification and management of the drug-seeking patient. *American.Family Physician*, 61(8), 2401–2408.

MacIntosh, C., Weiser, C., Wassimi, Reddick, J., Scovis, N., Guy, M., and Boesen, K. (2009). Attitudes toward and factors affecting implementation of medication therapy management services by community pharmacists. *Journal of the American Pharmacists Association*, 49(1), 26-30.

Morrison, R.S., Wallenstein, S., Natale, D.K., Senzel, R.S., Huang, L.L. (2000). “We don’t carry that.” Failure of pharmacies in predominantly nonwhite neighborhoods to stock opioid analgesics. *New England Journal of Medicine*, 342(14), 1023–1026.

National Center on Addiction and Substance Abuse at Columbia University (CASA). (2005). *Under the Counter: The Diversion and Abuse of Controlled Prescription Drugs in the U.S.* Columbia University.

National Institutes of Health (2000). *National Institute on Drug Abuse, Principles of Drug Addiction Treatment: A Research-Based Guide*. Bethesda, MD.
www.nida.nih.gov/PODAT/PODATindex.html

O'Bryant, C.L., & Crandell, B.C. (2008). Community pharmacists' knowledge of and attitudes toward oral chemotherapy. *Journal of the American Pharmacists Association*, 48(5), 632-639.

Paice, J.A., Toy, C., Shott, S., (1998). Barriers to Cancer Pain Relief: Fear of Tolerance and Addiction, *Journal of Pain and Symptom Management*, 16(1), 1-9.

Palos G.R., Mendoza T.R., Cantor S.B., Aday L.A. & Cleeland C.S.(2004). Perceptions of analgesic use and side effects: what the public values in pain management. *Journal of Pain and Symptom Management*, 28(5), 460–473.

Pletcher, M.J., Kertesz, S.G. KohnM.A., & Gonzales, R. (2008). Trends in Opioid Prescribing by Race/Ethnicity for Patients Seeking Care in US Emergency Departments. *JAMA*, 299(1), 70-78.

Portenoy, R.K, (1993). Therapeutic Use of Opioids: Prescribing and Control Issues. In J.R. Cooper, D.J. Czechowicz, and S.P. Molinari (eds.), *Impact of Prescription Drug Diversion Control Systems on Medical Practice and Patient Care*. Washington, D.C.: U.S. Government Printing Office, National Institute on Drug Abuse.

Portenoy, R.K., & Lesage, P. (1999). Management of Cancer Pain. *The Lancet*, 353, 1965-1700.

Reeves, R., & Burke, R. (2008, February). Is It Time for Carisoprodol to Become a Controlled Substance at the Federal Level?. *Southern Medical Journal*, pp. 127-128. Retrieved from Academic Search Premier database.

relevance. (2009). In Merriam-Webster Online Dictionary. Retrieved June 06, 2009, from <http://www.merriam-webster.com/dictionary/relevance>

Rosenblum, A., Marsch, L.A., Joseph, H., & Portenoy, R.K. (2008) Opioids and the Treatment of Chronic Pain: Controversies, Current Status, and Future Directions. *Experimental and Clinical Psychopharmacology*, 16(5), 405–416.

Scott, S.A.(2005). The Prescription. In: Remington: The Science and Practice of Pharmacy. 21st Edition. P.Beringer, P.K Gupta., A .DerMarderosian, J.E.Hoover, L.Felton, N.P.Popovich (eds.). Philadelphia PA: The University of the Sciences in Philadelphia.

Simoni-Wastila, L., & Tompkins, C. (2001). Balancing Diversion Control and Medical Necessity: The Case of Prescription Drugs with Abuse Potential. *Substance Use & Misuse*, 36(9&10), 1275–1296.

South, S.M., & Smith, M.T. (2001). Analgesic Tolerance to Opioids. *Pain: Clinical Updates IX* (5), 1-9.

The Controlled Substances Act. 503(b) 21 U.S.C § 353 (1970).

The Controlled Substances Act. 503(b) 21U.S.C. §§801-907 (1970).

Thomas, T. (2007). Providing pain relief for patients in the emergency department. *Nursing Standard*, 22(9), 41-45.

Trescot, A.M., Boswell, M.V. Atluri, S.L., Hansen, H.C., Deer, T.R., Abdi, S., et al. (2006). Opioid guidelines in the management of chronic non-cancer pain. *Pain Physician*, 9(1), pp. 1–39.

useful. (2009). In Merriam-Webster Online Dictionary. Retrieved June 06, 2009, from <http://www.merriam-webster.com/dictionary/useful>

Zeller, J.L., Burke, A.E., Glass, R.M. (2008). Acute Pain Treatment. *JAMA*, 299(1), 128.

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Academic Experience

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Delta RX Associates 1997 - 2003
Pharmacist Consultant for Mental Health Medication Therapies
Dallas, TX
Los Barrios Unidos Community Clinic 1999 - 2002
Pharmacist in Charge, Head of Formulary Committee
Patient Education Advocate, Individual Translation Specialist
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Amber Pharmacy Dallas 1997 - 1999
Pharmacist in Charge, General Manager
Organ Transplantation Medication Consultant
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Eckerd Pharmacy 1993 - 1995
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Presentations

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“Changing the Face of Pharmacy: Real-World Strategies to Improve Medication Adherence”

Presented at the NCPA 109th Annual Convention and Trade Exposition, Anaheim, California

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“Changing the Face of Pharmacy – A Call to Action”

Presented at the NCPA 108th Annual Convention and Trade Exposition, Las Vegas, Nevada

October 2006

Presenter:

“President Select: A Seminar on the Healthcare Proposals of the 2008 Presidential Candidates.” Seminar presentation to the Department of Pharmacy Administration, University, MS. Spring 2008.

“Fish is Fish: Learning Styles and Patient’s Perceptions.” Seminar presentation to the Department of Pharmacy Administration, University, MS. Fall 2007.

“Mississippi Medicaid: Maximizing Benefits: Ninety vs. Thirty-one Days Supply.” Seminar presentation to the Department of Pharmacy Administration, University, MS. Spring 2007.

“The Equal Employment Opportunity Commission and Pharmacists.” Presentation to pharmacy students in Pharmacy Management class, University, MS. Fall 2006.

“Risk Management and Security.” Presentation to pharmacy students in Pharmacy Management class, University, MS. Fall 2006.

“SSRI’s and Suicide: A Seminar.” Seminar presentation to the Department of Pharmacy Administration, University, MS. Spring 2006.

Projects

CMS Medicare Prescription Continuity of Care System (PCCS) Project
Medication Quality Measures and Hospitalizations
Delta Pharmacy Patient Care Management Services (Outcomes Evaluation)

Licensure and Certification

Pharmacy Licensure

Mississippi

May 2003

Texas

July 1993

Pharmacy Based Immunization Delivery

October 1996

Appendix A

Scenario: Amoxil®

When filling prescriptions, there are many pieces of information available about patients and about the prescriptions. Sometimes information is not available. When it is available, it can sometimes be used to help determine the validity of a given prescription.

Please assume that a patient, whom you have never seen before, presents a prescription for Amoxil® (amoxicillin) 500mg . Please rate each of the following items on its value to you in deciding if the prescription is valid for dispensing.

In doing so, please a) assume that the following pieces of information are available for the Amoxil® prescription, b) consider each piece of information independently of one another, and c) indicate how relevant you believe each piece of information to be in determining the validity of this prescription.

Scenario: Soma®

When filling prescriptions, there are many pieces of information available about patients and about the prescriptions. Sometimes information is not available. When it is available, it can sometimes be used to help determine the validity of a given prescription.

Please assume that a patient, whom you have never seen before, presents a prescription for Soma® (carisoprodol) 350mg . Please rate each of the following items on its value to you in deciding if the prescription is valid for dispensing.

In doing so, please a) assume that the following pieces of information are available for the Soma® prescription, b) consider each piece of information independently of one another, and c) indicate how relevant you believe each piece of information to be in determining the validity of this prescription.

Scenario: Lortab®

When filling prescriptions, there are many pieces of information available about patients and about the prescriptions. Sometimes information is not available. When it is available, it can sometimes be used to help determine the validity of a given prescription.

Please assume that a patient, whom you have never seen before, presents a prescription for Lortab® (hydrocodone/acetaminophen) 5/500mg . Please rate each of the following items on its value to you in deciding if the prescription is valid for dispensing.

In doing so, please a) assume that the following pieces of information are available for the Lortab® prescription, b) consider each piece of information independently of one another, and c)

indicate how relevant you believe each piece of information to be in determining the validity of this prescription.

1 = Not relevant 2 3 4 5 6 7 = Very relevant

1. The patient is aggressive in demanding the prescription immediately [irr]
2. The dose of the prescription seems high [irr]
3. Patient lost the medication and this is a replacement [sus]
4. This medication accompanies another medication and the patient doesn't want the other filled [sus]
5. From the profile, you see that the patient has had this medication before from another prescriber [sus]
6. The patient refuses to let you call the doctor to verify the prescription [conf]
7. The patient refuses a partial fill while you verify the prescription [conf]
8. The patient refuses to show you identification [conf]
9. There is a note in the profile that this patient has presented a forged prescription before [det]
10. The patient is elderly [att]
11. The patient looks frail [att]
12. The patient is dressed in jeans and a t-shirt [att]
13. The patient is dressed in business attire [att]
14. The patient is female [att]
15. The patient is male [att]
16. The patient looks unkempt (messy hair, dirty clothes, etc.) [att]
17. The prescriber is from a different state than the patient. [p att]
18. The prescriber is a pain specialist. [p att]
19. The prescriber has very clear and legible handwriting. [dea]
20. The dose is at the upper limit of clinical guidelines for this medication. [th att]
21. The quantity of medication prescribed seems higher than other prescriptions of this type. [th att]
22. The prescription was written for an off label use [irr]
23. The patient uses "street drug" terminology to describe another medication he is taking [det]
24. The patient refuses generic substitution [sus]
25. The patient ask that the prescription not be run on their prescription drug

insurance

26. The medication quantities differ from usual medical usage [dea]
27. The directions for use differ from usual medical usage [dea]
28. The medication dosages differ from usual medical usage [dea]
29. The sig codes do not match acceptable standard abbreviations [dea]
30. The prescription appears to be photocopied [dea]
31. The prescription directions are written in full with no abbreviations [dea]
32. The prescription is written in different-color inks [dea]
33. The prescription is written in different handwriting [dea]
34. There are apparent erasure marks on the prescription [dea]
35. A number of people appear simultaneously, or within a short time, all bearing similar prescriptions from the same physician [dea]
36. Numerous "strangers," people, who are not regular patrons or residents of your community, suddenly show up with prescriptions from the same prescriber [dea]
37. The prescription is written for significantly larger quantities compared to other practitioners in the area [dea]
38. The patient appears to be returning too frequently [dea]
39. The patient appears presenting prescriptions written in the names of other people [dea]
40. The patient has no prescription insurance [att]
41. The patient has visible bruises [att]
42. The patient has a known history of opioid addiction [att]