Blinded by the White: Can Pharmacists See Fraud or Have Pharmacy Curricula Left Them in the

Dark?

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Keywords: focus groups, qualitative research, pharmacy fraud, health care fraud, pharmacoethics

# **Author Note**

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# **ABSTRACT**

**Objectives.** The primary aim of the study was to determine if working pharmacists recognize fraudulent situations and if so, what considerations took place in making pharmacoethical decisions.

Methods. Two focus group discussions involving working pharmacists were conducted in which short scenarios common in pharmacy practice were discussed to determine how participants reacted to moral and ethical decision-making and to understand which stakeholders (patients, employers, insurers, regulators) were considered. Participants were recruited from the alumni lists of two Colleges of Pharmacy. Both focus groups were recorded and transcribed. A grounded theory approach allowed participants' voices to develop themes. Based on the most frequently used words, transcripts were color coded transcripts when these words were used and six themes were developed around participant's responses when these words were used.

**Results.** Results showed that participants tended to satisfy the requests of the patients and may not consider other stakeholders/interests: their employer (corporation, pharmacy owner, hospital), managed care rules outside pharmacy practice regulations or financial considerations, reinforcing a patient centric focus. Participants also were confused about recently enacted legislation and participants had more allegiance to the practice of pharmacy rather than corporate policies or regulations. Criminological theory suggests that neutralizing conflicts, a lack of capable guardianship, combined with stressors and strains, can lead to fraudulent activities. Neutralizing techniques, lack of guardianship (supervision) and not dealing appropriately with strain were all exhibited by study participants.

Conclusions. Results suggested that pharmacists may struggle with identifying multiple perspectives that should be considered when deciding how to act on a pharmacoethical dilemma. Pharmacoethical decisions will be more critical in the future with the increased introduction of costly specialty medications with more severe adverse side effects. Pharmacy curricula, possibly involving more Problem Based Learning techniques, might enhance pharmacists' ethical decision making.

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### INTRODUCTION

Dispensing and providing counseling around pharmaceutical products, essentially the role of pharmacists, is important in the delivery of quality health care. The vast majority of day to day transactions are carried out with diligence and care, however, a small percentage, 7.29% <sup>1</sup>, result in fraudulent transactions. While small in relation to the \$3.3 trillion health budget in the United States<sup>2</sup>, the cost of pharmacy fraud is nonetheless estimated at \$48 billion<sup>3</sup>. Criminological theory informs us that stressors and strains, neutralization techniques and lack of controls (guardianship) can lead to white collar crime<sup>4</sup>. Is stress, neutralization and lack of controls leading well-meaning pharmacists to make decisions that result in fraud? The aim of this study was to better understand how pharmacists make decisions when conflicts exist and which stakeholders are most important. This research may then lay the groundwork for improvements in pharmacy school curriculum to better train pharmacists to avoid decisions that are detrimental.

In 2017, the Department of Justice arrested over 400 physicians, nurses and pharmacists in a \$1.3 billion false billing scheme, involving 41 judicial districts. Of the 400 defendants, 120 were charged for their roles in prescribing and distributing opioids and other dangerous narcotics.<sup>5</sup> Controlling pharmacy fraud is of vital importance to curb the opioid crisis in the United States. In June 2016, CVS Pharmacy Inc. paid \$3.5 million and entered into a three-year compliance agreement with the Drug Enforcement Administration (DEA) that requires CVS to maintain and enhance programs for detecting and preventing diversion of controlled substances. CVS pharmacists in New Hampshire and Massachusetts dispensed 523 forged prescriptions, all for highly addictive opioids<sup>6</sup>.

The role of the pharmacist in healthcare fraud is particularly important. While physicians and nurses can commit fraud through submitting claims in part (upcoding claims) or in total (phantom claims) that are false, pharmacy fraud often involves a product that can then be resold, illegally distributed or can be fatal. Among recent fraud cases, the 2012 fatal New England Compounding Center (NECC) scheme is an example of where pharmacists alone were responsible for 64 fatalities. In 2012, 753 patients in 20 states were diagnosed with a fungal infection after receiving injections of preservative-free

methylprednisolone acetate (MPA) manufactured by NECC. Of those 753 patients, the U.S. Centers for Disease Control and Prevention (CDC) reported that 64 patients in nine states died. The outbreak was the largest public health crisis ever caused by a pharmaceutical product<sup>7</sup>. Other fatalities caused by a pharmacist include the case of Robert Courtney, the pharmacist that diluted over 98,000 oncology prescriptions in Hays, KS, causing the death of at least one patient and who, when arrested in 2001, had amassed a fortune of \$18.7 million<sup>8</sup>.

Pharmacists and other healthcare professionals are not the beneficiaries of extensive education and training in ethics<sup>9</sup>. Such moral decision making involves imaginatively constructing possible scenarios, and knowing cause-consequence chains of events in the real world; it involves empathy and role-taking skills<sup>10</sup>. Lawrence Kohlberg's work in moral development, ironically, posed a moral conflict known as "Heinz's Dilemma" in which a pharmacist, a dying woman and her husband were pitted against each other over access to an expensive pharmaceutical product which could save the woman's life. Based on responses to the dilemma, Kohlberg developed six stages of individualistic moral development, each progressive stage embracing a wider social context with stage one being the self-serving stage and stage six incorporating the universal ethical principles of justice, reciprocity, equality and respect<sup>11</sup>.

In a review of several pharmacoethics textbooks, Kohlberg's model was not presented and other models were used that took a more reflective and insular role. Veatch, Haddad and Last, in *Case Studies in Pharmacy Ethics*, proposes a five-step model that included: sensing something was wrong, gathering information, identifying the problem, seeking a resolution and working with others to determine a course of action<sup>12</sup>. Another model proposed by Gettman and Arneson include the following steps: gather all medical, social and other facts; identify values in conflict; list the options available to you; choose the best solution; justify it and respond to possible criticisms<sup>13</sup>. The Hippocratic maxim of "first, do no harm" and the principles of beneficence, respect for the person and autonomous decision making and loyalty are heavily cited in pharmacoethics text books<sup>14</sup>. All of these principles place a high degree of emphasis on the patient.<sup>15</sup>

It is doubtful that Glenn Chin, the owner of NECC, who was convicted in October 2017 for racketeering, racketeering conspiracy, mail fraud and introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead<sup>7</sup>, or Robert Courtney, who admitted to intentionally diluting medications, graduated from pharmacy school with the goal of murdering their patients. As the prosecutor in the Courtney case, Mike Ketchmark, stated, "The road to hell leads one step at a time<sup>8</sup>." Fraud can occur when pharmacists fail to see or properly acknowledge ethical dilemmas in their practice. Little academic research has been conducted on health care fraud and more specifically fraud perpetrated by pharmacists<sup>16</sup>. Pharmacy fraud is a vulnerable area of health care fraud since pharmacists can work alone, unsupervised and often without peer review or reflective educational tools. Courtney, for example, worked in a nine foot by nine foot room unsupervised.<sup>8</sup> Even less academic research has been conducted using working pharmacists rather than pharmacy students and the focus of similar research has been aimed at testing pharmacy students' academic integrity<sup>16</sup>, <sup>17</sup>, <sup>18</sup>.

Only one similar study on pharmacy fraud was found, conducted by Zuzana Deans, as part of her Doctoral thesis at the University of Bristol, U.K., in which Deans conducted a quantitative survey and qualitative focus groups of pharmacists in the U.K. Deans concluded that pharmacists in the United Kingdom frequently face ethical dilemmas, approach these dilemmas in a commonsense way, often favoring patient needs and fearful of regulations<sup>19</sup>. In the U.K., pharmacists are more regulated than in the United States, fall under a single National Health System and are governed by one Royal Pharmaceutical Society. Each year, the Royal Pharmaceutical Society publishes "Medicines, Ethics and Practice: The Professional Guide for Pharmacists" as a guide for working pharmacists regarding ethical decision making and this text is also used in U.K. Colleges of Pharmacy, such as the College of Pharmacy at the University of Portsmouth<sup>20</sup>. Conversely, pharmacists in the United States are presented a confusing patchwork of regulations issued by the State Board of Pharmacy in the state in which they practice, Federal laws and Drug Enforcement Agency (DEA) regulations, while simultaneously being required to comply with corporate rules (if working in a hospital or for a pharmacy chain), insurance and Pharmacy

Benefit Manager (PBM) managed care requirements and reimbursement policies (i.e. formularies, restrictions and limitation of coverage rules) and patient plan design requirements (i.e. copays).

The primary aim of this study was to determine if working pharmacists in the United States recognize fraudulent situations and if so, how they learned to make pharmacoethical decisions and what considerations took place. Specifically, this research focused on which stakeholders were considered by pharmacists when presented with an ethical dilemma. Were pharmacists aligned with patients' needs with disregard for corporate rules or managed care requirements? Did pharmacists forgive their own financial considerations over their patients' finances?

Because this study took an inductive approach, a specific hypothesis was not tested. Rather, using the results of what the focus group discussions yielded, common approaches to solving for ethical dilemmas were identified. Furthermore, the results of this research will inform future inquiries into how pharmacists make ethical decisions.

# **METHODS**

As content development for the focus group discussions, short scenarios were prepared so that participants could respond to objective situations rather than asking general questions about fraud or asking about personally experienced situations that risked exposing criminality. Each of these scenarios was taken directly from a leading pharmacy law textbook, *Pharmacy Practice and the Law*<sup>21</sup>. Each of the scenarios involved breaking the law or committing a regulatory infraction and typically weighed time management and/or profitability over dishonest/illegal acts. A few of the scenarios were designed to test the pharmacists' own moral compasses. Each of these scenarios were then presented to the focus group participants and were included in a discussion guide with the following questions asked to the participants by the researcher:

- What would you do or have done in situations like this one?
- What have other pharmacists or technicians that you have worked with done in these situations?
- What would your company/owner/supervisor say or do in these situations is there any "company policy" around this situation?

Prior to conducting the focus groups, the scenarios were peer reviewed for comprehension levels by three pharmacists, two of which were also attorneys (not included in the study) to determine if the scenarios were understandable and relatable. These scenarios, along with probing questions about the scenarios, were used to develop an Interview Guide.

A Protocol Template was also developed which outlined the project's aims, participant information, known ethical concerns and strategies to manage these concerns such as confidentiality, risk/reputation and the use (or lack) of deception in the study. The Interview Guide and Protocol Template, along with Consent Forms, the Participant Information Sheet and University Invitation Letters were submitted to the researcher's University of Portsmouth, UK and two separate College of Pharmacy (COP) Universities' ethics committees, specifically, Midwestern University and Roosevelt University, both located in the Chicago, IL suburbs. All three Institutional Review Boards reviewed the materials, and the study was given a provisional favorable ethical opinion subject to some limited requirements which were met prior to conducting the focus group discussions.

Focus group participants were solicited by the Office of the Dean from both of the colleges using alumni email addresses. Inclusion criteria included pharmacists that practiced in community, hospital or managed care/mail order. Participants were excluded if they worked in academia or were known to the researcher. Participants were provided consent forms prior to participation and were instructed that they could revoke their consent at any time. Confidentiality of respondents was maintained throughout the process and only limited demographic information was collected. Other than a modest meal, no incentives were provided to focus group participants.

The focus group discussions were conducted on each separate College of Pharmacy campus in May and June 2017. Each focus group discussion lasted about an hour. In the first group, there were 15 participants; in the second, there were five participants. Participants were 85% female and had been practicing an average of 15 years. The majority of participants (55%) practiced in community settings; of the remaining, 30% practiced in hospitals and 15% in other settings. Discussions were audio and video

recorded, and transcripts were developed for analysis. Transcripts are retained and available in accordance with ethical requirements.

During the focus group discussions, participants were verbally and visually (through Power Point slides) presented with up to 15 scenarios (referred to as "cases") with different ethical dilemmas. The researcher posed follow-up questions accordingly to determine how participants made decisions in these cases. Follow up questions were asked to better understand which stakeholders (patients, pharmacists, employers, managed care, pharmacy regulators) were favored in the decision process.

The transcripts were uploaded into NVivo11 (QSR International, Burlington, MA) to explore and analyze response themes. For example, the four most used words were "patient," "know," "like" and "think." By coding these four words, six themes were developed using the NVivo topic coding analysis tool. Actual transcription selections were highlighted and attached to the themes.

Because little academic research has been done testing pharmacists' decision making, the aim of this research was to gain an additional understanding of the reasoning process associated with pharmacists' decision making which can best be achieved through observation and interpretation of these actions (Interpretivism). Creswell states: "If a concept or phenomenon needs to be explored and understood because little research has been done on it, then it merits a qualitative approach<sup>22</sup>." A grounded theory approach to the analysis of the transcripts was used in this study so as to "tell the story" of the results of the focus group from the view of the participants<sup>23</sup> rather than prove or disprove a hypothesis. Focus group discussions were selected because they provided a forum for observation and interpretation that one-on-one interviews cannot achieve – specifically "blame" was deflected which allowed participants to state they have known of other pharmacists committing fraudulent acts, rather than admitting their own criminality<sup>24</sup>.

# **RESULTS**

Table 1 summarizes the scenarios presented and the general reactions from both focus group discussions. With few exceptions noted below, there was little difference in the reactions between the

two focus groups. Table 2 illustrates the six themes resulted from the NVivo analysis and the cases where the theme was supported.

Theme One: If the patient was known to the participant, and it was perceived as not involving a dangerous drug, participants were more likely to fulfill the request without regard to regulations.

This theme appeared in the discussions in Case One, where a woman leaving on vacation wanted a birth control prescription filled without a valid prescription order. The first focus group did not want to fill the prescription and instead tried to defer the issue (Theme Three, discussed below). Specific participant quotes when presented with Case One from the second focus group are:

"Yeah, I mean if it is a regular customer that has come to this pharmacy for several years and/or you have a relationship with that doctor, I would fill one month and then, later...;" and,

"I worked at an independent pharmacy and we would do it all of the time for people and called the doctor the next day;" and,

"I would have filled it, it's also a non-controlled drug, so that makes a little bit of a difference, she was a regular customer, those are all things I would have taken into consideration and if I had a relationship with the physician."

Case Four, which involved the dispensing of a generic (which was more cost effective) versus a brand drug (which was the patient's preference) and solicited comments that support patient preference. Specifically, one participant stated: "Yeah, make them happy (by filling the brand). So, they will always trust you."

Case Seven, involving completion of Prior Authorization forms for the physician at the patient's request elicited the following response:

"If I could safely fill out the form then I would do it. I wouldn't have a problem and I would let the patient know that this is the process we're going through."

Case Eight, which involved filling a prescription that was out of scope of the prescriber, also supported the patient-centric theme. One participant stated:

"I think it depends. I had a dentist that wrote a script for a three-day supply of medication for his grandson, not related to dental care at all. The grandson had been visiting and had left their medication in Colorado. We ended up filling it because he said he was just trying to get him the three-day supply so that he can get home and get his bottle."

Theme Two: Participants expressed a desire not to deal with the ethical dilemma by deferring the issue to another pharmacy or tried to ignore the conflict.

The response to Case One (woman wanting birth control without an order) by one participant was to totally ignore the situation and "make it go away:" "she can call another doctor, go to an emergency room, there are other options."

Case Two involved manufacturer misbranding. Participants chose to discuss the drug that was improperly in the medication (penicillin) and interactions caused by the drug in a portion of the population instead of the actual conflict. Some participants began discussing other well-known misbranding/tampering cases involving tainted Tylenol, which had little bearing on the case presented. In the same case, a participant wanted to "prove" the misbranded drug came from "their" pharmacy, even though there was no doubt:

"I would prove it first that what they took is actually what they got from us, because I mean there's cameras in every pharmacy, what went in the bottle was actually what they took and it came from us. Then we'd get to the misbranded part of it."

Case Nine involved a hospital physician ordering the dispensing of a drug against the hospital pharmacist's clinical judgement to a woman already admitted and in labor. A participant stated the following, deferring the issue completely and somewhat unrealistically:

"As a dispensing pharmacist, I honestly would not have dispensed that, and I have had very strong conversations with physicians about things that I felt would harm the patient. And my end result was ... Well, the physician would say, "Well you know what, this is what I want, then you have to dispense it." And I would say, "You know what, there are a million pharmacies in the

city of Chicago. It will not be dispensed to your patient in this pharmacy, but you can certainly try to find a pharmacist that will fill it."

Theme Three: Documenting the rationale for conflicting issues is a way to mitigate risks occurred frequently.

Using the NVivo word count analysis, "document," "documentation" and "documented" occurred 31 times. NVivo can produce a report which shows the researcher how frequently and specifically where in the transcript words or derivation of words are used, making it useful in interpretation and assigning meaning to a participant's statement. Participants understood the conflict but believed that taking a course of action against better judgment could be overcome by simply documenting a concern. Documenting the willingness to act fraudulently, even if one understands the conflict, does not forgive the fraudulent or unethical behavior.

Cases Two, Three, Four and Nine resulted in the most frequent discussions around documentation to mitigate risk. The following paraphrased quote, from Case Two, best summarized Theme Three, as a reaction to dispensing a misbranded prescription:

"If you counsel the patient on the prescription (because it's mandatory) and explain that there is a cross sensitivity between the penicillin and cephalosporin even if the patient has a documented allergy to the penicillin and you document you counselled the patient, you've covered yourself, you've documented it. Then it is a liability of the manufacturer. Because you covered yourself, you did your job, you educated the patient, and if the patient might get an anaphylactic reaction, you have covered yourself. You also document that you called the doctor so that you are comforted that you did your job."

Theme Four: The participant's own professional judgment overrode any policies or corporate directives that may have been issued.

When participants were concerned with what course other stakeholders wanted them to take, which may have put their license in jeopardy, they almost always "solved for" themselves versus the policy. Participants viewed their lifelong commitment to be a pharmacist more important than a "temporary" job,

as exemplified in the following exchange between the researcher and a participant in response to Case Ten, where a compounding pharmacy owner asks a pharmacist to solicit patients and forgive copays:

Participant: No.

Researcher: You're not-Participant: Don't touch it.

Researcher: ... going to go to jail. So, you would essentially walk out of the pharmacy

and say-

Participant: I'm sure I'd be losing my job that day.

Researcher: Yeah. You'd lose your job, but ... Okay. All right.

Participant: It would be worth it.
Participant: But keep your livelihood.

Participant: Keep my license.

Other situations that invoked a similar response were when participants were asked to recommend a more expensive drug as a preferred status on a formulary (Case Five). While the participants realized that this does occur, most participants believed that "the hospital might get a discount on purchasing that specific medication, through the wholesaler...that makes the cost of the expensive medication the same as a lesser cost medication" in the same therapeutic category. Participants were reluctant to admit that they, themselves, would place a higher cost drug as a preferred drug, even though they realized this happens.

In a more direct way, participants were specific about corporate policies versus their own judgment, mainly due to fear that the pharmacist would be sanctioned instead of the company:

"Well, I think you should know that, it's your judgment. I don't think you need a policy to tell you. It's your professional judgment."

"But I don't know if there is a certain policy to say, as a pharmacist, it's your job to ensure what you are making for a patient is accurate and is not going to harm the patient."

"I think the policies come into play after the fact, when reporting and what we have been discussing (filling misbranded medication), and not before you dispense the product."

"It's not going to be whoever you work for, they're going to come after the pharmacist, because it's your initials on it (verifying the prescription order). So, at the end of the day, it's the judgment of the pharmacist, not necessarily the company that you work for."

"Our company has partial fill procedures for out of stock items, but not out of refill items. So generally, it's a judgment call, because it is the pharmacist that would get in trouble. This would be something that would result maybe in a citation from the Board of Pharmacy, and that would usually go towards the pharmacist. Generally, you would assume in a case like this that the area manager is not involved in pharmacists' wrongdoing, so it's very unlikely that the company would actually get in trouble."

Theme Five: A cost/benefit analysis/profitability was not as important as getting the patient the medication prescribed and/or requested by the patient.

Participants had no issue with letting a patient have a more expensive brand than a generic or over the counter drug, if the patient was willing to pay more: "I think at the end of the day, it's patient choice. I mean, yeah, great, you would make more money on the generic versus the brand, but at the end of the day, if the patient feels more comfortable taking the brand over the generic, and they're willing to pay that extra \$15, go for it." The lack of concern for cost, however, was tempered by efficacy: "I would consider the option of whichever one is less expensive to the patient, if that's what the patient seems to want ... And then whatever is in his benefit."

Participants did not have as much concern for making profit over what the patient wanted: "A pharmacy is a self-standing entity, so whatever money you make, you make just from prescriptions. So, I think it's a decision of, "Well do I boost my script count and my income, or my earnings? Or do I do what's best for my patient? And I think honestly what's best for the patient is to just let them buy the OTC version."

Participants had a keen perception of "how bad" third party reimbursement was and that being profitable was almost futile: "But, honestly, even if you think about the pharmacy making money at that point, insurance reimbursement is so bad, you know, it's probably a wash with over the counter, with store brand."

One participant recognized the tradeoff of patient satisfaction long term, over what could be made financially from one prescription transaction: "I think any ethical pharmacist would be first concerned

about patient safety and efficacy but in the long run, you've gotta think about whether this patient is dissatisfied with the way then you're treating them, then you are going to lose *all* their business."

# Theme Six: Participants were confused about newly enacted legislation.

Both focus group participants had an average of 15 years' experience, meaning that most participants had graduated from pharmacy school around the early 2000's. Case 10 involved compounded drugs, solicitation of patients and forgiving of copays, as well as conflicting information about sterile and non-sterile products. There have been many changes to the laws surrounding compound drugs, in part due to the NECC situation<sup>7, 25</sup>. The case was presented in the hope that the participants would break down the controversy in this case, as some of the requests are now legal, such as the solicitation of patients, which is considered a constitutional right, under the Drug Quality and Security Act of 2013<sup>25</sup>. However, in this case, the facility is determined to be an "outsourcing facility" which is a term meant to cover sterile compounds (compounds made for infusion), yet the drug discussed is a topical (non-sterile) product. Forgiving copays, which is contrary to a "managed care" rule, was inserted into the example to determine if the participants would "see" that managed care rules had a place in the discussion.

The reaction to Case 10 was that participants did realize that waiving the copays was "illegal." However, participants thought that solicitation of patients "for something they may not need" was also illegal. Lastly, the participants did not mention the outsourcing facility designation or the sterile versus non-sterile designation of the medication. In general, the consensus to this situation was to "run for the hills."

In Case Thirteen, participants discussed whether controlled drugs were required to be locked in a separate cabinet or could be dispersed throughout the pharmacy. Participants debated as to whether CII and CIII, IV and V or if just CIII, IV and V can be interspersed. Federal law allows all controlled drugs to be interspersed, but only in retail pharmacies and institutional practitioners, and solely for the reason of avoiding theft<sup>26</sup>. In Illinois, only CIII, IV and V may be interspersed<sup>27</sup>. The conflict between Federal law and Illinois law might have been a cause of the confusion.

Participants from one group did not believe that completing Prior Authorizations forms on behalf of a physician was "illegal" whereas participants from group two differed, perhaps because Prior Authorization form rules are not codified, but are part of the rules of each patient's managed care or PBM provider. Stated one participant:

"Okay this is what I do every day. Most likely you'll do the prior authorization. We do prior authorizations for the doctors but again like late at night and getting approved instantly is most likely not going to happen. I have seen occasionally that PAs get approved instantly but that's very, very rare. But I would have no problem and it's actually what we do, we do all the prior authorizations for our physicians. Specialty meds like Enbrel I wouldn't see an issue with that."

Participants in group two took the approach that the pharmacist and physician could fill out the form together:

"There's an independent physician whom I have a very good relationship with, occasionally she will authorize me to do things on her behalf. So, we'll have a conversation, we'll complete it pretty much together. Like if it's check marks, I'll call her and say, "You know this is what they want. Do you want me to fax it to you?" And she'll say, 'No, just read it to me, check off this stuff, and fax it.' I think that, with authorization, is acceptable. But certainly not like pretending that you're a physician representative."

Case Four presented a situation where none of the group participants had concerns with filling an over the counter drug in place of the prescription drug. However, this was actually a change in the prescription order which should have been verified by the prescriber. None of the participants "saw" the illegality in this case.

### Cases Ten and Fourteen

Two cases were interjected into the focus group discussions which were fairly obvious that illegal activity was being asked of the participants and were presented to test the participants' own moral compasses. Case 10, as previously discussed, involved a compounding pharmacy with kickbacks going

to the prescriber. Participants quickly picked up that the kickbacks between the pharmacist owner and the prescriber were illegal (under 42 USC § 1320a-7b(b)). Stated one participant, "And there are kickbacks, basically, because Dr. Sam is receiving a kickback for writing the prescriptions that Dr. George is now making money off of. So multiple legal issues. That's the problem." However, the issue in the case is that the participant would have to quit his/her job if refusing to supervise the situation.

In Case 14, participants were asked to dispense "extra" controlled drugs so that the patient and pharmacist could split the proceeds from the sale of the controlled drugs, on the same day the pharmacist found out that the pharmacy's son was admitted to an expensive college but that the family did not have the money for the son to attend the college. Participants' reaction included "NO!", "Not happening, my friend" and "I would find a different way to make that money, like work an extra shift every week" or "Right, or I would just take a loan in my name and let it be my debt when the kid graduates. I mean, it's a lot of money, but…". Both of these cases, and the participant reaction, will be discussed in the following section, along with the criminological theory associated with long term financial strains.

# **DISCUSSION**

Results suggested that pharmacists may struggle with identifying multiple perspectives that should be considered when deciding how to act on a pharmacoethical dilemma. All of the themes that developed are problematic. These themes point to three leading criminological theories, which in turn inform us that there is a greater tendency to commit fraud. Specifically, neutralizing techniques (justifying or ignoring the situation), lack of capable guardianship/controls (ignoring policies and requirements to get the job done) and stressors/strain theory (quitting jobs under financial stress) can be observed from the participants' reactions.

In Case One, which involved filling the "emergency" prescription for oral contraceptives, participants never questioned the age of the patient or if the patient was a smoker, both reasons to consult with a physician before filling for oral contraceptives. One group would not have filled the prescription, the other group would have filled it, which indicates that there is conflict with this relatively simple and often presented situation. In Case Four, involving dispensing of an OTC versus a prescription drug,

participants failed to see that allowing a patient to obtain a medication other than the order was prescribed for – a brand instead of an OTC - was in essence, refusing to fill the prescribed medication. In this case, the prescriber should have been consulted with annotation on the prescription order that the medication had been switched/filled as an OTC.

Struggles with the pharmacoethical dilemmas continued when participants wanted to ignore the "real" issue and instead discussed extraneous issues. Case Two, involving misbranded/tainted medications and Case Nine, involving a physician demanding the dispensing of medication that ultimately ended in an induced heart attack in the actual situation<sup>28</sup>, elicited the strongest desire to not discuss the issue at hand, or parse the issue into "who benefits most" from the situation. None of the participants suggested calling the manufacturer to determine if there had been other cases of the tainted drug in Case Two, and rather proceeded into a discussion of the probability of anaphylaxis shock with an allergic reaction of penicillin versus cephalosporin. In Case Nine, one participant went as far as to want to tell the physician to "find another pharmacy" to fill an inpatient medication for a woman admitted into the hospital in labor.

Both ignoring the issue and not seeing others' importance in decision-making can lead to criminality. Edwin Sutherland's theory of white collar crime (Differential Association Theory), posits that crime is learned from and in association with other criminals.<sup>4</sup> Thus, if it is considered "acceptable" by pharmacists to fill prescriptions without valid orders, for whatever reasons, then learning that is acceptable will become the new normal. If it is acceptable to fill a birth control prescription without consulting with a prescriber, who may have additional information about the patient such as age and smoking, is it then acceptable to similarly fill other types of prescriptions?

Further, ignoring the issue is a technique of the Neutralization Theory, a theory developed by Gresham Sykes and David Matza. Sykes and Matza posit that criminal acts are often "justified" by the perpetrator.<sup>4</sup> Neutralization was apparent in many of the focus group participants' discussions. Most notably, participants justified dispensing more expensive medication if others (the patient, insurance companies) were willing to pay for it. Participants also were willing to commit acts that were fraudulent

(like dispensing a misbranded drug) if they rationalized it was acceptable because they documented that they told the patient and physician that there could be an adverse effect. Participants were willing to complete Prior Authorization forms, which should be completed by physicians (because diagnosis and prognosis is outside the scope of a pharmacist), including in some cases, signing the form on behalf of the physician. Pharmacists rationalized this behavior because it was the most expedient way to get their jobs done ("I do this all day long").

Ethical decision making involves imaginatively constructing possible scenarios, and knowing cause-consequence chains of events in the real world; it involves empathy and role-taking skills.

Participants rarely got out of the role of "pharmacist" to see the view of other stakeholders. Policies issued by the participants' employers held little weight in the overall decision-making process when compared to the pharmacists' long-term identification as a pharmacist and desire to retain an unsanctioned license to practice. Participants clearly saw themselves as harmed and personally accountable for their behavior and their employers rarely sanctioned for their behavior. Perhaps more legal cases, like the one cited above where CVS Pharmacy Inc. was sanctioned \$3.5 million for the action of its employees, will change this perception.

Regulators were displaced over patient demands, as in Case One, and in Case Eight, where one participant had filled a prescription for a dentist's family member outside the scope of the dentist's practice simply because the patient (the dentist's grandson) had left the medication at home. In that same case, another participant also stated, when asked if the participant would fill a prescription order for birth control written by a dentist, that, "I might fill it for one month. So, let's say they wrote a birth control pill for a year. I might fill it for one month and then tell the patient, 'You know what, next time, I am going to void all of these refills and you will need to see an OB/GYN or a primary care physician. Bring me a prescription for the next time'." She rationalized this decision by incorrectly stating, "On the other hand, taking birth control medication may not hurt a patient even if they are pregnant. So, you know, it depends on what it is, because some drugs might cause issues, but a lot of birth control medication won't."

Managed care entities, and the rules imposed, were also displaced over a patient-centric focus. Most of the participants found ways to get Prior Authorizations forms completed, even though most managed care entities require the physician, not the pharmacist, to complete the forms, stating the patient's diagnosis, prior treatment and prognosis. Determining these factors is outside the scope of a pharmacist. Community pharmacists did not want to complete the forms, but hospital pharmacists often did, going as far as to say from one participant that completing Prior Authorization forms is her sole job responsibility. Participants were also not clear on who sets what rules, such as copays and preferred drugs on a formulary, or how those decisions are made. This was most evident in Case Five, where it was unclear to participants how more expensive drugs got on a formulary. Stated one participant, "Yeah, there is usually some reason (why expensive drugs are on the formulary) but then, that's why these people get paid a lot of money...."

Marcus Felson and Lawrence Cohen developed the Routine Activities theory which states that lack of capable guardianship leads to criminal activities<sup>29</sup>. Essentially, without proper supervision or controls, crime will occur, because there will always be an element of motivated offenders and suitable targets. When pharmacists ignore regulators, corporate policies and managed care rules, pharmacists are removing the capable guardianship. In these cases, there is greater tendency for fraudulent activities to occur. As stated above, Robert Courtney worked unsupervised in a small office while diluting 98,000 prescription orders. For these reasons, it is important for a pharmacist to consider the role that these rules have and work within these rules when making pharmacoethical decisions.

Cases Ten and Fourteen, in which participants were faced with obvious fraudulent situations, yielded predictable results. Participants refused to get into situations which involved kickbacks or dispensing non-prescribed narcotics ("head for the hills!"), although as evidenced by cases cited in this article, pharmacists do dispense non-prescribed narcotics (CVS Pharmacy) and get involved in kickback situations. Sitting in a focus group, answering a researcher's questions, it is easy to dismiss situations that would get one in obvious legal concerns.

Criminological theory developed by Albert Cohen and Robert Agnew (the Strain Theory) informs us that when individuals cannot obtain success goals such as money or status in a profession, they experience strain or pressure<sup>4</sup>. Individuals are likely to respond to strain through criminal activities. The strains leading to crime activities (such as losing a job or new onerous financial burdens like college tuition) may not only be blocked by the inability to overcome the cause of the strain (i.e. keeping a job or paying tuition) but also by the presence of noxious stimuli and the taking away of valued stimuli<sup>4</sup>. This introduction or temptation of crime (noxious stimuli) can happen daily for pharmacists through patients and employer demands or by personal financial concerns. The taking away of valued stimuli, that is a way to cope with or make better pharmacoethical decisions or application of rules and policy, can lead pharmacists astray. As prosecutor Mike Ketchmark, stated, "The road to hell leads one step at a time."

Concern arises with the study results in Cases Ten and Fourteen. Participants "saw" the ethical dilemma in Cases Ten and Fourteen, but then quickly rejected the "temptation" to commit a crime. One wonders if the long-term results of taking a second job to pay for a son's college tuition or work extra shifts further erode the ability to stay off the "path to hell." Working pharmacists, who experience burnout, will have a decreased commitment to the practice of pharmacy. The high demand job and unpleasant interpersonal interactions decrease effective organization commitment<sup>30</sup>.

While this was a small-scale study involving only qualitative research, the results of the study were similar to those of the Dean study, in which pharmacists in the U.K., like those in this study, took a pragmatic approach to solving pharmacoethical dilemmas. Similar to the Dean study, there appears to be less "formal pharmacists' awareness, knowledge and understanding" into the formal ethical decision-making process, resulting in struggling to make such decisions.<sup>19</sup>

The findings of this study are not of a quantitative nature, and thereby are not statistically valid. The opinions and reactions of 20 pharmacists practicing in the Chicago area does not provide generalizability to the greater population of all practicing pharmacists. A quantitative survey, for example, conducted in several rural, urban and suburban geographic locations, involving a greater and statistically valid sample size, is warranted to further explore the topic of pharmacoethical decision

making and is needed to draw better conclusions. Further, this study revealed little understanding between the effect of a pharmacist's own moral code and beliefs compared to decisions that benefit the patient, one's employer, regulators and managed care providers.

However, the aim of the study, which was to determine the rationale of working pharmacists and the ability to recognize fraudulent situations and if so recognized, how they learned to make pharmacoethical decisions and what considerations took place, was achieved. Blatant situations were obvious and recognizable. However, gray areas, such as misbranding and filling without valid orders for "known" patients provided struggles and challenges for the study participants. Unexpected results included the participant's lack of knowledge or confusion about recently passed legislation on compounds and the storage of controlled drugs, which in some cases conflict between state regulation and Federal law.

It is not conclusive that participants' struggles with pharmacoethical decision-making is based on missing elements in pharmacy curricula. However, there is little focus on pharmacoethical decision-making in pharmacy curricula and for the most part the focus is on the patient and that, indeed, was the finding of this study. A larger quantitative study should be undertaken in the future, tying reliability and validity to educational goals and improved decision-making. Enhancements to curricula could include Problem-Based Learning (PBL) techniques, which have been used in medical schools for over two decades<sup>31</sup>. In PBL, students are presented with cases in which they must work out the correct answer to the problem, often by themselves or in small groups. The challenge of PBL for the student is to integrate experience, knowledge and skills to the application of a new scenario to solve clinically related problems. PBL is often called three-dimensional thinking because it takes prior knowledge, a current scenario and a desired outcome to learn a new technique. Problem-Based Learning takes place through three types of reflection: reflection in the anticipation of the event, reflection in the midst of action and reflection after the events. According to Boud, there are seven steps to reflective learning: returning to the experience, attending to feelings, association, integration, validation, appropriation and lastly, outcomes and actions<sup>32</sup>.

Such reflective learning takes in all stakeholders, imaginatively puts pharmacists "in the shoes" of all stakeholders and then allows a decision to be made that derives the best outcome for the most concerned.

### CONCLUSION

The results of this small-scale study reveal that pharmacists struggle with pharmacoethical decisions and there may be a need for more pharmacoethical educational curriculum and coping tools, as well as ongoing training on how to make pharmacoethical decisions. Causality between the findings of this study (that participants struggled) and the greater need for curricula based pharmacoethical decision making tools needs to be established. If established, these curricula and training tools should provide background into the philosophical tenants of ethical decision making, such as Kohlberg's stages of moral development. Using Boud's Experienced-Based Learning theory, students would be presented with real life but carefully chosen scenarios which allow students to use knowledge and test each student's ability to handle these "real life" situations.

Pharmacoethical decisions will be more critical in the future with the increased introduction of costly specialty medications with more severe adverse side effects. As costs increase for prescription drugs, and taxpayers' ability to pay for health care decreases, pharmacists will be at the center of the decision-making process for access and rationing of health care services. Pharmacy curricula, supported by the philosophical tenants of ethical decision making and experienced based learning, conducted over at least one semester, may provide a better educational experience for pharmacy students and prepare pharmacists for the career long struggle of making pharmacoethical decisions.

Greater emphasis on better choices for pharmacists may reduce the \$48 billion dollars a year spent in pharmacy fraud by American taxpayers and corporations. Making the right decisions will keep pharmacists not so blinded or focused on the immediate patient need but instead shine a brighter light on all stakeholders involved.

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Table 1. Case Scenarios Presented and Group Discussion Feedback

Table 1. Case Scenarios Presented and Group Discussion Feedback	
Case	Feedback
1. A female patient visits your pharmacy at night and needs a refill on her birth control prescription, which she had been taking for two years. She has no refills remaining, the physician is unavailable, and she is flying on a 6 am flight with her husband for a two-week trip out of the country. Assume you are in a state that does not allow for emergency refills.	Most would fill the prescription. Two would not have filled it. One pharmacist wanted to send her to another pharmacy.
What would you do?  2. You received a bottle of cephalosporin capsules. Unknown to you, the capsules also contain small amounts of penicillin. You dispense the capsules to a patient that is allergic to penicillin and then suffers an anaphylactic shock. Was the drug misbranded and should you face sanctions?	It is not the responsibility of the pharmacist to inspect the capsules. Most discussed allergies of cephalosporin and penicillin without addressing the real issue. Counseling the patient mitigated risk.
3. You are working in a hospital pharmacy and receive ampules of a commonly stocked drug contained in a pink solution. Previously, the drug had always been in a colorless solution. You instruct the pharmacy technician working for you, who questioned the change in color, to mix and dispense the drug for IV administration. The drug was contaminated and injured the patient. How would you handle this situation?	Documenting the situation mitigated risk. Judgment overruled policies.
4. A patient presents you with a prescription for Spondicin 20mg, a prescription only drug. As the patient is waiting for the prescription to be filled, the patient notices that Spondicin 10mg is available over the counter and asks you how can it be that one strength is prescription only and the other is over the counter. The patient wants to purchase double the quantity of the OTC medication which is less expensive than his copay through his company's insurance plan. What would you do?	None saw that Spondicin was not an over the counter (OTC) or prescription medication. None would have destroyed the prescription order or phoned the prescriber. All would have let the patient purchase the OTC.
5. You are a member of a managed care formulary evaluation committee. The committee's task is to evaluate whether to include on the formulary a newly marketed drug. The drug is more expensive than the other drugs in the class and is rated by the FDA as type 5 (new formulation or new manufacturer) and S (standard, not priority or orphan). Would you include the drug on the formulary or not?	Most did not want to add the new drug.
6. As a pharmacist, you inform a patient that the patient's copay will be \$15 less if the patient gets the generic drug rather than the brand prescribed. The patient is concerned about the quality. As a pharmacist, your company/you will make more money on the generic drug than	Most would let the patient get the brand drug.

the brand version based on the reimbursement polices of pharmacy benefit manager of the	
patient. Do you insist on dispensing the generic or do you allow the patient to be dispensed	
the brand even though it costs the patient more and lowers your profitability?  7. It is late at night and a patient presents a prescription for Enbrel. The patient has been	Most would complete the prior
taking Enbrel for many years with no adverse side effects. However, when the prescription is sent to the pharmacy benefit manager, the message returned is the medication now requires a Prior Authorization. The physician is not available and the patient insists on obtaining the	authorization for the physician and submit to the PBM. One pharmacist stated that she would fill without a
medication. You complete the Prior Authorization form for the physician and send the	prior authorization and deal with the
information to the Pharmacy Benefit Manager so that the prescription will adjudicate. Is this acceptable?	cost implications later.
8. You receive a prescription written by a dentist for an antibiotic written "take TID for urinary infection." Would you fill this prescription and why?	Most realized out of scope but realized most dentists would not write an indication. In the second group, some would fill it.
9. You are a hospital pharmacist making rounds with Dr. Jake. One of Dr. Jake's patients	Most agreed pharmacist had liability,
has just been admitted to the hospital in premature labor. Unable to reduce the contractions,	but most would document objection.
Dr. Jake consulted with you about administering terbutaline sulfate. The drug has been FDA	
approved only for use in bronchial asthma but was also being widely used as a tocolytic agent	
because it relaxes smooth muscles. You have reservations because the labeling states	
terbutaline:is indicated for the prevention and reversal of bronchospasm in patients with	
bronchial asthma and reversible bronchospasm associated with bronchitis and emphysema.	
Terbtaline sulfate should not be used for tocolysis. Serious adverse reactions may occur after	
administration of terbutaline sulfate to women in labor. In the mother, these include	
increased heart rate, transient hyperglycemia, hypokalemia, cardiac arrhythmias, pulmonary edema and myocardial ischemia. Nonetheless, you deferred to Dr. Jake as the prescribing	
physician as to the best course of therapy. After 48 hours of dosing, the contractions stopped.	
Shortly thereafter, the patient suffered a heart attack, delivered a healthy baby, and underwent	
open heart surgery. The patient sued you and Dr. Jake. Who do you think has the most	
liability in this situation?	
10. You are recently employed by Super Compounding Pharmacy, Inc. which is a registered	Most said they would "run for the
"outsourcing facility." Your new supervisor, Dr. George, the Pharmacist in Charge of the	hills" and leave employment.
facility, requests you and a technician to work together. Dr. George has obtained a list of	
patients and corresponding insurance identification information. Dr. George asks the	

technician, which you are told to supervise, to make calls to the patients on the list asking if	
the patients would like medication at no cost to them (i.e. the copays will be waived). The	
medication is a pain gel made from ketamine and a base lotion. Once the technician secures a	
patient that wants the mediation, she is to call Dr. Sam, a physician, who will write the order	
and give it to you to dispense. Dr. George and Dr. Sam are brothers and split the profit from	
the pain gel. What is your reaction to this situation?	
contract whereby in local promotional television ads, Dietco would tout Blevco as the place	did not want any part in it. One
to purchase the product. In those ads, unknown to Blevco, Dietco has engaged in false and	pharmacist wanted to report the
misleading ads. You work at Blevco and realize, as patients are lining up in your pharmacy	situation to the FDA.
to buy the medication that the ads are based on false and misleading information.	
12. You receive a prescription from a physician employed at a large county hospital. The	Most would use the hospital's DEA
prescription was written on a prescription form that contained the DEA registration number of	even for a controlled drug.
the hospital but not the physician. You call the physician who told you that he had no DEA	
number and that he just uses the hospital number. Would you fill the prescription? Would	
you answer change if the prescription was for a controlled drug?	
13. You are a new pharmacist at XYZ Pharmacy. You notice that the pharmacy keeps the C-	Most agreed that they needed to be
II drugs on the shelves interspersed with other drugs. All of the pharmacies where you	kept in a safe. That is incorrect.
worked in the past keep the C-II drugs in a safe. You tell your new supervisor that it was	Controlled drugs can be retained
your understanding that C-II drugs are to be kept in a safe. The supervisor explains that that	throughout the pharmacy.
pharmacy has been broken into several times and the robbers took the safe, knowing that the	
C-II drugs were kept in a safe so keeping them interspersed with the other drugs prevents	
robbers from taking the C-II drugs. Should you report this drug retention method to the State	
Board of Pharmacy?	
14. You recently were informed that your son got into a great university but did not qualify	None would get into the scheme with
for the scholarship that you were hoping he would receive. Tuition and room and board will	the customers, ignoring personal
be over \$50,000 a year. You will not be able to pay the tuition and do not want your son to	relationship stakeholders.
be heavily in debt when he graduates. That very same day, a couple that has been using your	
pharmacy for years and who you know well, and who regularly receives prescriptions for	
controlled substances for lower back pain tell you that they would make it worth your while if	
you would simply dispense to them 10 more tablets than what was prescribed. What would	
you do?	
misleading ads. You work at Blevco and realize, as patients are lining up in your pharmacy to buy the medication that the ads are based on false and misleading information.  12. You receive a prescription from a physician employed at a large county hospital. The prescription was written on a prescription form that contained the DEA registration number of the hospital but not the physician. You call the physician who told you that he had no DEA number and that he just uses the hospital number. Would you fill the prescription? Would you answer change if the prescription was for a controlled drug?  13. You are a new pharmacist at XYZ Pharmacy. You notice that the pharmacy keeps the C-II drugs on the shelves interspersed with other drugs. All of the pharmacies where you worked in the past keep the C-II drugs in a safe. You tell your new supervisor that it was your understanding that C-II drugs are to be kept in a safe. The supervisor explains that that pharmacy has been broken into several times and the robbers took the safe, knowing that the C-II drugs were kept in a safe so keeping them interspersed with the other drugs prevents robbers from taking the C-II drugs. Should you report this drug retention method to the State Board of Pharmacy?  14. You recently were informed that your son got into a great university but did not qualify for the scholarship that you were hoping he would receive. Tuition and room and board will be over \$50,000 a year. You will not be able to pay the tuition and do not want your son to be heavily in debt when he graduates. That very same day, a couple that has been using your pharmacy for years and who you know well, and who regularly receives prescriptions for controlled substances for lower back pain tell you that they would make it worth your while if you would simply dispense to them 10 more tablets than what was prescribed. What would	pharmacist wanted to report the situation to the FDA.  Most would use the hospital's DEA even for a controlled drug.  Most agreed that they needed to be kept in a safe. That is incorrect. Controlled drugs can be retained throughout the pharmacy.  None would get into the scheme wit the customers, ignoring personal relationship stakeholders.

15. You receive a prescription for methadone. Upon calling the prescriber, you learn that the	Most would not fill the prescription.
purpose of the prescription was to maintain the addiction. The physician informed you he	
was treating the patient under the Drug Addiction Treatment Act but was not knowledgeable	
about the requirements to do. Would you inform that prescriber that methadone cannot be	
prescribed under these conditions or fill the prescription as ordered?	

Table 2. Six Themes Evident in Given Cases

Theme	Cases Theme Appeared
If participants knew the patient, and the medication was perceived low risk and an	Case One, Case Four, Case Seven, Case Eight
emergency, participants were more likely to fulfill the request without regard to	
regulations.	
Some participants deferred the issue to other pharmacies or tried to ignore the issue.	Case One, Case Two, Case Nine
Documenting rationale for conflicting issues can mitigate risks.	Case Two, Case Three, Case Four, Case Nine
Professional judgment may override corporate policies.	Case One, Case Three, Case Seven, Case Ten, Case
	Eleven
Cost/benefit analysis was not as important as getting the patient the medication	Case Four, Case Five, Case Six, Case Seven
prescribed.	
Participants were confused about recently enacted regulations.	Case Four, Case Six, Case Eight, Case Twelve, Case
	Thirteen