Pharmacist Malpractice Over the Last Decade in the United States

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Abstract

Background: The National Practitioner Databank is a database that lists all malpractice cases against healthcare professionals. There is no study considering the trends in pharmacy malpractice using official data from the National Practitioner Databank in recent times. Methods: In the current study, we used the National Practitioner Databank for period 2006-2015 to evaluate trends numbers of malpractice payments and adverse actions enforced against pharmacists in the United States. JMP was utilized to visualize and evaluate data. Results: During the decade of the study there were 646 malpractice payments made against pharmacists and 2015 represents the fifth consecutive year of increase in the annual number of malpractice payments against pharmacists. Contrastingly, numbers of adverse actions against pharmacists has experienced the fifth consecutive year of reduction. Hence, malpractice payments are trending upward while adverse actions against pharmacists are trending downward. Conclusion: Although the pharmacy profession implements multiple processes to protect patients from medication errors the number of malpractice payments against them continues to rise.

Key words: Malpractice, Malpractice Payments, Licensure, Adverse Action, Healthcare Delivery.

INTRODUCTION

Historically, a pharmacist who was identified and banned/limited from pharmacy practice could move to a different state and continue practicing because no nationally linked database tracked malpractice. However, in 1986, the United States Department of Health and Human services formed the National Practitioner Databank (NPDB).¹ They are the NPDB is a database that lists all malpractice cases against the same healthcare professional and its goal is to improve the quality of healthcare delivery.

Highly publicized cases of pharmacist malpractice include adulteration of drugs or fraud, including a pharmacist who was responsible for 69 deaths and over 700 cases of fungal meningitis due to providing contaminated steroids in their compounding pharmacy in 2012.² The pharmacist involved faces 25 counts of second-degree murder for this error. Unfortunately, pharmacists can make unintentional medication errors and go to prison as punishment. In a pharmacy
malpractice case in Ohio, a technician inadvertently used 23.4% sodium chloride when preparing a 2-year old patient’s chemotherapy.\[8\] The pharmacist did not catch the error and the 2-year old patient died. The pharmacist was charged for involuntary manslaughter and served 6 months in prison, 6 months house arrest, 3 years’ probation, and will never be able to practice pharmacy again.

Liability for pharmacists has changed dramatically in the last 40 years. The passing of the Omnibus Budget Reconciliation Act of 1990 (OBRA ’90) now requires prospective drug utilization review, requirements for record-keeping, and an obligation to offer the patient counseling.\[4,5\] Prior to the passing of OBRA ’90, pharmacist liability was limited to clerical issues, such as dispensing the wrong drug, wrong strength, providing inaccurate directions for use, or compounding errors. Nonetheless, whatever the physician prescribed, the pharmacist would dispense without question. Since the passing of OBRA ’90, pharmacists’ scope of practice has greatly expanded, with many states allowing pharmacists to use their “professional judgment” when dispensing prescriptions. This allows them the ability to refuse to fill certain prescriptions based on the potential for patient harm. With this increase in professional judgment comes an increase in potential liability.

There is no study considering the trends in pharmacy malpractice in recent times. Our study is an evaluation of the trends in pharmacy malpractice numbers and number of adverse actions taken against pharmacists over the last decade in the United States. NPDB data has a two-year lag; hence, in 2017 the most recent data available is from 2015.

METHODS

We utilized the NPDB to conduct the current study which is a retrospective analysis of non-identifiable, aggregate governmental data on the number of malpractice payments against pharmacists and the number of adverse actions taken against pharmacists over the last decade in the United States. NPDB data has a two-year lag; hence, in 2017 the most recent data available is from 2015.

All data regarding numbers of pharmacy malpractice payments and adverse actions were exported to the data visualization tool, JMP Pro.\[7\] The variables we evaluated were type of healthcare provider, the state the healthcare provider was working in, year the malpractice payment was made and the range of payment amount.

JMP Pro was used to enable data visualization, trends analysis, highlighting of the upper and lower limits and mathematical calculation of the standard deviation. The committee on human studies at University of Michigan Medical School provided IRB approval for this study (Study ID HUM00116742).

RESULTS

During the ten year period of the study there were 646 malpractice payments made against pharmacists, with the most malpractice payments in Florida (78, 12%) (Table 1). Additionally, there were 16,576 adverse actions enforced against pharmacists with Texas having the most at 1,221 (Table 2).

The upper limit of nationwide malpractice payments against pharmacists was in 2009 when there were 95 payments. The lower limit was in the next year – 34 in 2010. The year 2015 represents the fifth consecutive year of increase in the annual number of malpractice payments against pharmacists (see Figure 1).

In contrast, the number of adverse actions against pharmacists has experienced the fifth consecutive year of reduction (Figure 2). Year 2010 was the upper limit with 1,981 adverse actions and the most recent year was 2015.
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Rhee and Nalliah: Pharmacist Malpractice in the US

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<td>6 3 4 91</td>
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<td>Column Total</td>
<td>1716 1656 1655 1754</td>
<td>1981 1795 1601 1509 1505 1404 16576</td>
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The lower limit – 1,404 in year 2015. Hence, malpractice payments are trending upward while adverse actions against pharmacists are trending downward. The mean number of malpractice payments against pharmacists is 64.60 and this is a reasonable representation of the current situation as the last 3 years have been within 1 standard deviation from the mean. Contrastingly, the mean number of adverse actions was 1,657.60 and this is not a good representation of the current situation – the last year (2015) was three standard deviations below the mean. The last 2 years (2014, 2013) were two standard deviations below the mean.

Table 3 shows the number of retail prescriptions dispensed in 2015. California, by far, exceeded the volume of prescriptions that other states had (over 450 million prescriptions), with Florida (255 million), New York (251 million), and Texas (221 million) following. California had the second largest number of malpractice payments at 73, but is fifth in number of adverse actions at 684.
DISCUSSION

The current study has demonstrated that there has been a 221% increase in the number of malpractice payments against pharmacists in the last five years from 34 in 2010 to 75 in 2015. The United States (US) population is aging and people are living longer with more chronic diseases. Hence, the need for long term medication use is increasing. Food and Drug Administration data shows that there were 4,065,175,064 prescriptions filled in US pharmacies in 2015. This number is elevated from 3.3 billion in 2002 and 3.7 billion in 2006. According to the FDA, one patient dies every day due to medication errors, and 1.3 million people are injured every year. As the volume of prescriptions increases in the US, there is an increased risk of error and subsequent litigation against pharmacists which may, partially, explain the recent rise in malpractice payments.

Some US states maintain traditional pharmacist roles of dispensing the medication the physician has prescribed. Other states have broadened the “duty to warn” or counsel the patient utilizing their “professional judgment”. Brushwood and Belgado state: “it may be unrealistic to expect the courts to develop firm guidelines for accountability in pharmacy when the profession has yet to firmly define its responsibilities.” Unfortunately, this allows for multiple interpretations of the law, which increases liability risk to the pharmacist. Many states have passed laws requiring pharmacists to evaluate all prescription orders for accuracy, and therefore hold pharmacists liable for identifying errors on physician’s prescriptions. This essentially represents an expansion in the scope of practice for pharmacists who have more responsibility, which puts them at higher risk of malpractice payments.

Next, there has been a rapid broadening in the training

<table>
<thead>
<tr>
<th>State</th>
<th>Total Retail Prescriptions Dispensed in 2015</th>
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</thead>
<tbody>
<tr>
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</table>

Table 3: Total Retail Prescriptions Dispensed in 2015.
background of individuals licensed to prescribe medications in the US.\textsuperscript{15,16} There has been an expansion of the nursing profession to include various independent practitioners who are licensed to prescribe. High variability in prescribing practices may also increase the risk of prescribing/dispensing errors. Similarly, many foreign trained doctors practice in the United States – in fact, 50\% of internal medicine residencies are filled with foreign medical school graduates.\textsuperscript{17} Hence, there will be a broad variability in pharmacological training and prescribing habits. Subsequently, the larger amount of variability poses an increased risk of error for the pharmacist.

Pharmacy practice is experiencing a corporatization worldwide and there are several benefits to this.\textsuperscript{18-20} Firstly, broader capacity for after-hours access and better purchasing power which may enable less expensive drugs. However, corporatization means that a pharmacist is now associated with a larger organization with enormous resources. Hence, to the opportunistic litigator there is the chance to win larger compensations based on the retail pharmacy’s resources rather than the limited resources of the individual pharmacist. According to legal precedents, a larger healthcare organization can have responsibility for the actions of an individual provider through various pathways, including vicarious liability.\textsuperscript{21} Hence, litigation against a pharmacist who is part of a larger organization is an appealing action for the opportunistic lawyer, and this may partially explain the increase in malpractice payments against pharmacists.

The current study showed that the upper limit of malpractice payments against pharmacists was year 2009 with 95. Subsequent to this, year 2010 had the upper limit of adverse actions against pharmacists with 1,981. Perhaps as a consequence to the rise in adverse actions, malpractice payments numbers dropped in 2010 to the lower limit for the entire study period of just 34. This success continued in 2011 with only 36 malpractice payments. From this pattern it is clear that the number of adverse actions has, at least, some effect on reducing the number of malpractice numbers. The following trend, then, is a concern: the current study has demonstrated that, with the rise in malpractice payments over the last five years there has been a concurrent fall in adverse actions against pharmacists. From historical data uncovered in this study, it seems clear that an increase in adverse action places a downward pressure on malpractice numbers. As the number of malpractice payments increases, one would expect adverse actions to increase to help control those numbers. However, this study has revealed the very opposite trend.

**CONCLUSION**

Various factors are at play that may increase the risk of Pharmacists to litigation. Their scope of responsibilities are increasing, more of them are employed by large retail companies, they are dispensing more prescriptions each year, and the number and type of prescriber is growing while the prescriber’s educational background is become more complex and diverse. This study has revealed that adverse action has an impact on reducing malpractice payments; however, the last five years has seen a reduction in adverse actions while the number of malpractice payments grows. Although the pharmacy profession implements multiple processes to prevent patients from medication errors, ultimately pharmacists are still human. The healthcare system and healthcare practitioners must work together as an inter-professional healthcare community to protect patients from further harm without fear of litigation.

**ACKNOWLEDGEMENT**

None

**CONFLICT OF INTEREST**

The authors have no conflicts of interest to declare

**FUNDING**

There is no funding to declare

**ABBREVIATION USED**

NPDB: National Practitioner Databank; OBRA: Omnibus Budget Reconciliation Act; IRB: Institutional Review Board; FDA: Food and Drugs Administration

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