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RESEARCH ARTICLE

Trends in Malpractice Payments and Adverse Actions against Pharmacists in the United States between 1990-2022

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ABSTRACT

**Background:** We evaluated malpractice payments and adverse actions against pharmacists in the United States. Malpractice is defined as professional negligence by act or omission. Adverse actions are actions administered by the board of registration in a health profession against a provider. The purpose of the study is to analyze the trends in malpractice payments and adverse actions for pharmacists during the period 1990-2022.

**Methods:** This is a retrospective study that utilizes the National Practitioner Data Bank (NPDB) data analysis tool for the period 1990-2022. This information was exported to a data visualization tool and trends were studied. Results: During the period of the study there were 2480 malpractice payments and 44,204 adverse action reports made against pharmacists. In the current study we found that there has been a 19.56% decline in the number of malpractice payments against pharmacists in the last 5 years from 46 in 2018 to 37 in 2022. Similarly, adverse action reports also show a downward trend from 2016 to 2022. Conclusion: Pharmacy profession implements multiple processes to protect patients from medication errors. As the volume of prescriptions increases in the US, there is an increased risk of error and subsequent litigation against pharmacists. Even though malpractice payments and adverse actions against pharmacists have continued to decline, the probability of an adverse action remains high for practicing pharmacists. As the role of pharmacist continues to evolve there is a need to keep up with the changes in the healthcare market.

## Introduction

Medications are powerful tools that, if used correctly, can prevent, or treat disease. If used incorrectly, there is a potential to cause great harm to people who take them. Incorrect use may be intentional misuse and diversion or accidental. As health care teams make pharmacological management decisions for their patients, it is essential to weigh the potential risks against the expected benefit of each medication to minimize the chance of harm to the patient. The pharmacist's expertise makes them central to this process and they must work collaboratively with dentists, physicians, nurse practitioners and all other prescribers to achieve the optimal outcome for their patient.

The scope of practice of a pharmacist varies in each state of the United States. However, it is a national requirement that pharmacists must complete six to eight years of post-high school education that includes training about diseases and the medications used to prevent and treat them.<sup>1</sup> Pharmacist education and training also includes assessing the health status of patients, providing education and counseling, managing diseases, and using healthcare technology.

Pharmacists are the health care team members with the most complete drug therapy knowledge, and they are best positioned to serve as the key coordinator of any drug therapies. This is particularly useful with complex patients who have multiple prescribers and more than one condition requiring treatment. It is also notable that pharmacists will have the opportunity to interact much more frequently with their patients than most prescribers of medication. Changes in conditions can thus be detected sooner by a vigilant pharmacist, including instances where patients would benefit from better adherence to their treatment plan.<sup>2</sup>

Close to 6,800 unique prescription medications and countless over-the-counter drugs are available in the United States.<sup>3</sup> To further complicate matters, there are thousands of health supplements, herbs, potions, and lotions used by the public regularly to treat their health problems. With the number of substances on the market, it is conceivable that mistakes can be made when practitioners prescribe or dispense drugs. Added to this is the high risk of interaction between substances. The U.S. Food and Drug Administration (FDA) receives more than 100,000 U.S. reports each year associated with a suspected medication error.<sup>4</sup> FDA reviews the reports and classifies them to determine the cause

and type of error. The reports come from drug manufacturers, and healthcare professionals and consumers through [MedWatch](#), the Agency's safety information and adverse event reporting program. Medication errors can occur throughout the medication-use system. Such as, when prescribing a drug, upon entering information into a computer system, when the drug is being prepared or dispensed, or when the drug is given to or taken by a patient. Serious harmful results of a medication error may include Death, Life threatening situation, Hospitalization, Disability and Birth defect.<sup>4</sup> Each year, in the United States alone, 7,000 to 9,000 people die due to a medication error.<sup>3</sup> Additionally, hundreds of thousands of other patients experience but often do not report an adverse reaction or other complications related to a medication. The total cost of managing patients with medication - related errors exceeds \$40 billion each year, with over 7 million patients affected.<sup>3</sup> In addition to the monetary cost, patients experience psychological and physical pain and suffering because of medication errors. Finally, a major consequence of medication errors is that it leads to decreased patient satisfaction and a growing lack of trust in the healthcare system.<sup>5,6</sup>

With the expanding number and complexity of medications, pharmacists' roles and responsibilities have expanded broadly beyond medication distribution. Pharmacists are providing patient care in almost all health care settings to help people of all ages get the most from the medications that are prescribed to them. Examples of pharmacists' patient care services include providing health and wellness screenings, managing chronic diseases, assisting patients with medication management, administering immunizations, and working with hospitals and health systems to improve patient care and reduce the number of patients who are readmitted to the hospital following their hospital stay.

Errors made by the pharmacist are usually judgmental or mechanical. Some of the most common causes of these errors are as follows -

1. High volume high stress pharmacies - some pharmacies are run like busy fast-food restaurants. They have to process thousands of prescriptions per day. Many pharmacies are national chains and demand high volume sales from their pharmacists. Some have to fill as many as 50 prescriptions per hour. High volume pharmacies can cause a lot of errors.<sup>6</sup>
2. Homophone-related error - many medications have similar names that sound alike.

Pharmacists make mistakes due to the similar sound of medicines that, usually, have totally different uses. For instance, in one case a pharmacy dispensed lindane instead of oral solution of lidocaine.<sup>7</sup> Lindane, is a lice poison which should only be used on skin and never taken in mouth.

3. Improper drug strength, dosage error - Another common pharmacy error is that when the pharmacist fills the prescription, they do so with the wrong strength dosage. Either too strong or too weak. This is another risk that often leads to hospitalization and health risks.<sup>8</sup>
4. Improper compounding error - Some patients may require a medication in a dose or dosage form that is not commercially available. Such medications must be specially prepared for the patient in a pharmacy and are referred to as compounded medications. In one such case an 18-month-old patient died after ingesting a prescribed, compounded oral liquid suspension that contained the wrong medication.<sup>9</sup>
5. Mislabeling instruction errors - Mistakes include frequency of taking the medication, too often or not often enough, how much to take, too much or too little, what not to take with the medication to prevent side effects, or the side effects that may be experienced from the medication.<sup>10</sup>
6. Contraindicated errors - Pharmacies occasionally fill a prescription that is "contraindicated," when a pharmacist has been filling a patient's prescription for a while, they should know what two different medications cannot be taken together.<sup>10</sup>
7. Dispensing drugs that are beyond the expiration date - This often causes the patient to receive a dosage that has become weaker over time due to its aging.
8. Substituting generic drugs without informing the patient - This usually can cause adverse side effects to the patients.

As health care becomes increasingly complex, utilizing the skills and expertise of all members of the health care team is a must. When it comes to helping patients manage medications, it is critical that pharmacists be part of the healthcare team. Pharmacists must have advanced education and hold a Doctor of Pharmacy degree. They must also be licensed, which requires passing the North American Pharmacist Licensure Exam (NAPLEX) and, in most states, the Multistate Pharmacy Jurisprudence Exam (MPJE). Pharmacists who administer vaccinations and immunizations must also be certified in most states. As of **May 2019**, there are more than 311,000 licensed pharmacists

working in the US. Pharmacists may enter into collaborative practice agreements with other health care providers, such as physicians and nurse practitioners. These collaborations can increase care coordination and access to more services and providers. For example, providers can delegate tasks to pharmacists such as chronic care management and medication refill authorization. Allowing pharmacists to prescribe certain medications is a growing trend among states seeking to increase access to important medications.

The role of pharmacists varies depending on the setting and state scope of practice laws. Adding to the variability in roles are changes to the healthcare system that may impact the way in which pharmacists practice and where they are employed, including mergers between pharmacy and insurance companies, the rise of telehealth as a health care modality. To date, no single source of information exists that best characterizes the increasingly complex nature of the pharmacist workforce. Without clarity, leaders in the field of pharmacy face challenges in educating health system leaders about the ways pharmacists can help transform care and advocating for ways to strengthen the pharmacist workforce. Pharmacists need to be better integrated into the healthcare teams and that doing so would allow them to practice at top of their license and result in better outcomes for patients. One study examining recently hospitalized patients taking at least ten medications found that patients who saw a pharmacist after being discharged had a lower risk of readmission compared to those who did not.<sup>11</sup> Ensuring the safe prescribing and dispensing of medication to patients is a core function of a pharmacist. Pharmacists ensure that patients not only get the correct medication and dosing, but that they have the guidance they need to use the medication safely and effectively.<sup>12</sup> The aim of the current study is to evaluate adverse actions and malpractice payments against pharmacists in the United States from 1990-2022.

## Methods

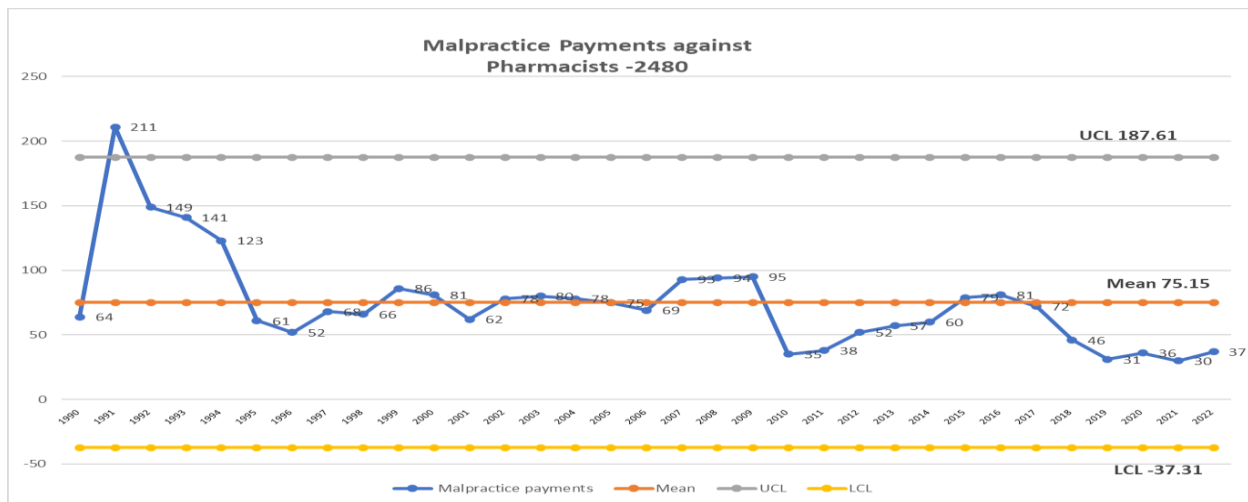
The National Practitioner Data Bank (NPDB) is a publicly available dataset that contains all the malpractice payments against pharmacists and the adverse actions taken by boards of pharmacy against individual pharmacists. Federal regulations permit certain entities to report into this database and some examples are state health boards, medical malpractice payers, professional societies, Drug Enforcement Administration (DEA) and the Health and Human Services office of the Inspector

General. 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 and adverse actions enforced against pharmacists between 1990-2022.<sup>13</sup> Adverse actions recorded include loss of state licensure/certification, loss of clinical privileges or panel membership, exclusion from professional society, loss of drug enforcement administration privileges, Department of Health and Human Services, Office of Inspector General exclusion. All data regarding numbers of pharmacy

malpractice payments and adverse actions were exported to the data visualization tool to analyze the trends, 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) and we used descriptive data to present the information.

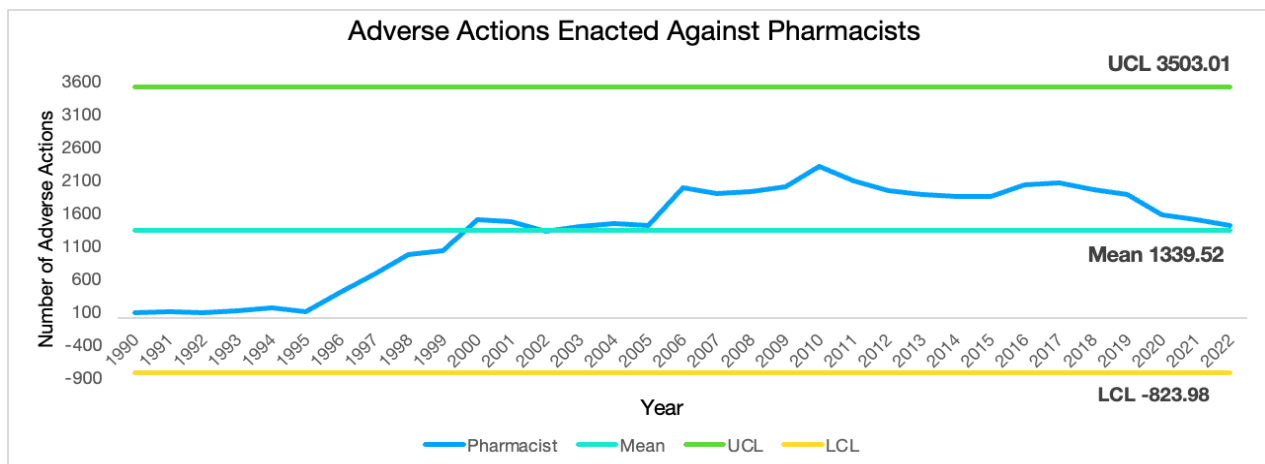
## Results

### Malpractice Payment Reports Against Pharmacist



**Figure 1:** A total of 2480 malpractice payment reports against pharmacists were found in our data. The total amount paid in malpractice payments was \$262.47 million (inflation adjusted). Highest number of payments were reported in the year 1991(211 reports) and the lowest in the year 2021 (30 reports). There was an average of 75.15 malpractice payments. Higher range was 187.61 and the lower range was -37.71.

### Adverse Actions Enacted Against Pharmacists



**Figure 2.** shows total no. of Adverse Action reports against Pharmacist 44,204. Highest no. of the adverse actions was reported in 2010 (2297) reports. Lowest no. of adverse action reports is reported in 1990 (84) reports.

Malpractice payments vs Adverse actions against Pharmacists

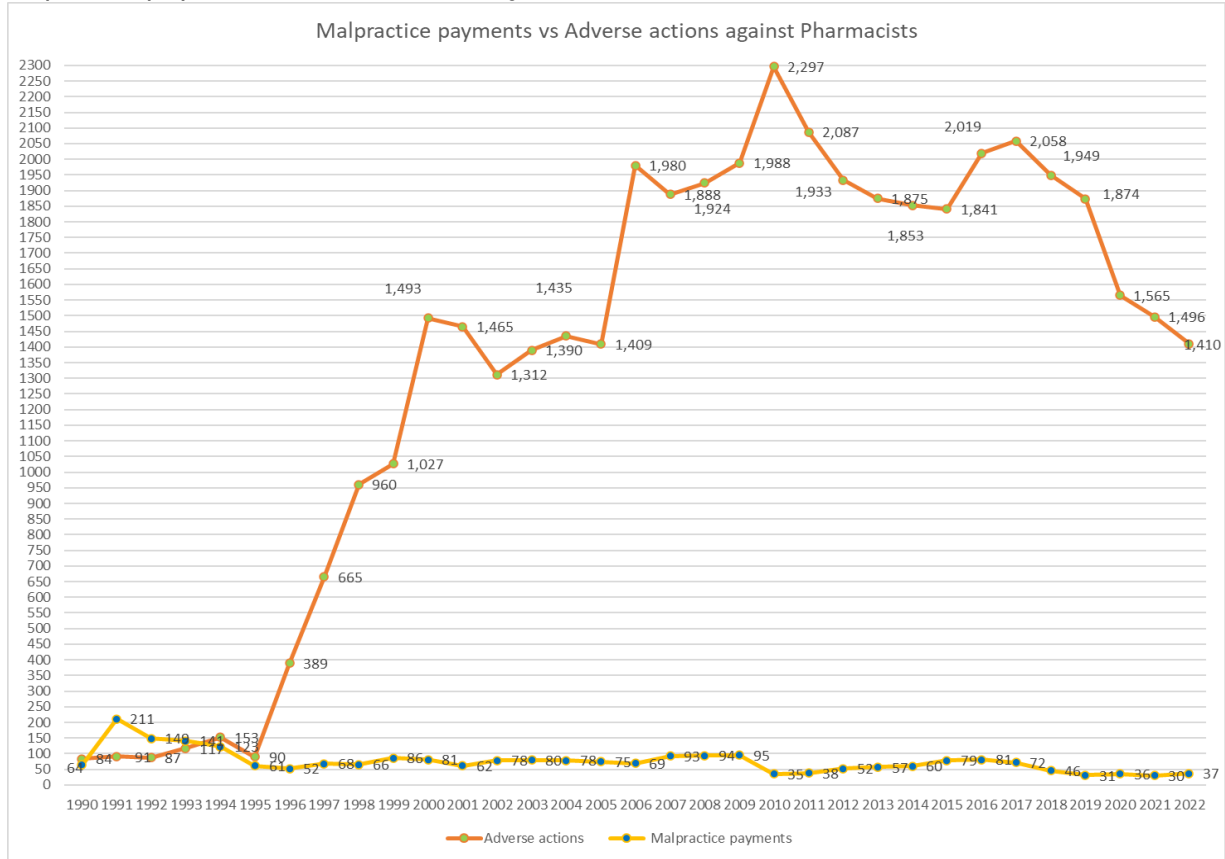


Figure 3. Shows the trends in malpractice payments in comparison to the adverse actions against pharmacists.

Adverse Actions Against All Healthcare Professions

Adverse Actions against All Healthcare Professionals

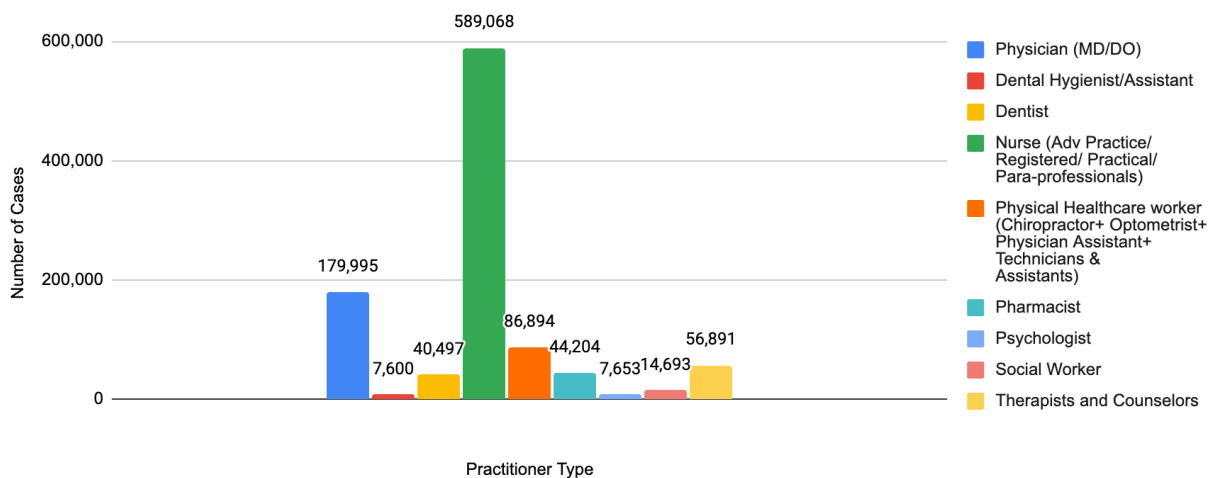
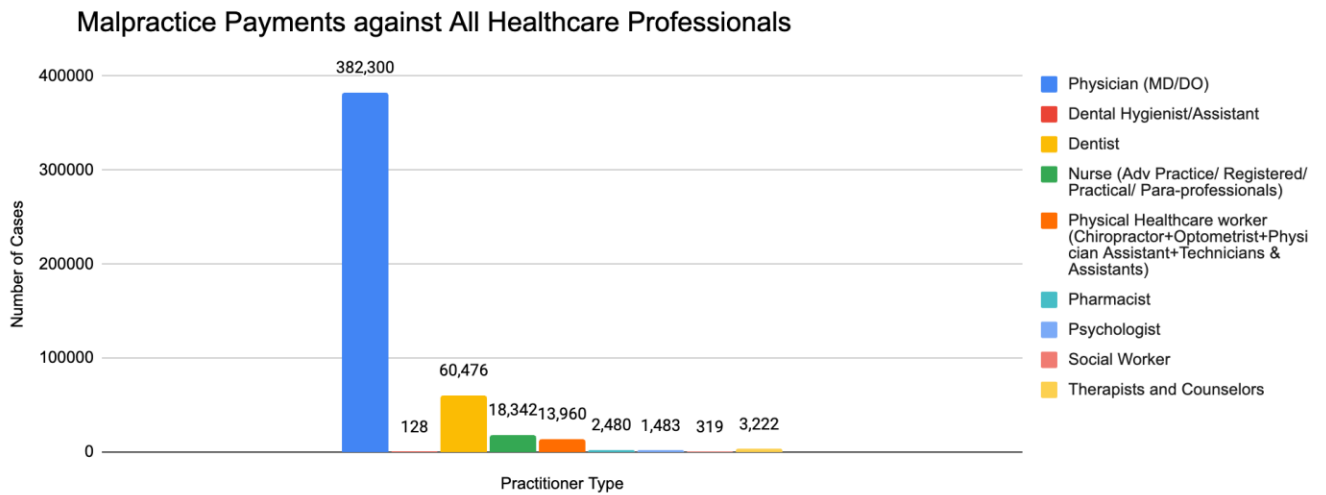


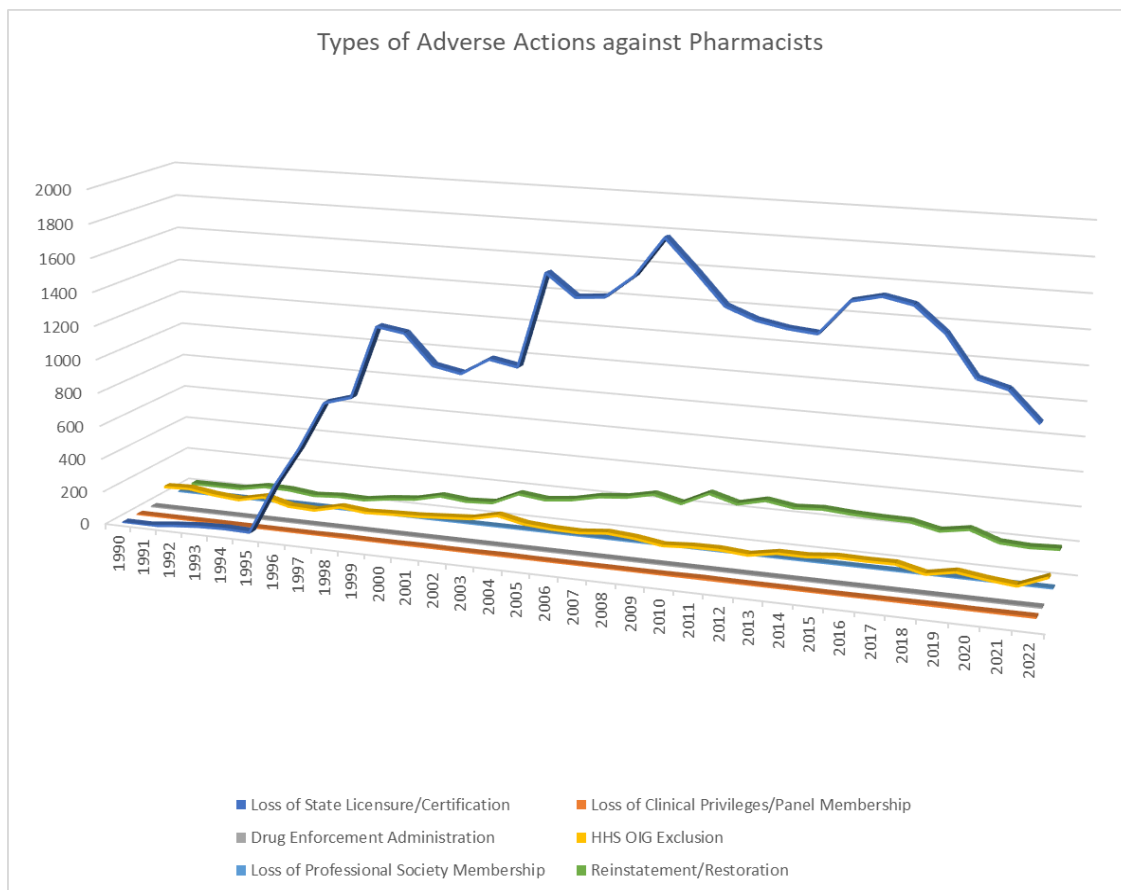
Figure 4. provides information regarding adverse actions and by practitioner types across the US. Pharmacists have relatively less adverse actions (44,204) compared to other health professionals. Physicians (MD and DO) (179,995) had more adverse actions than dental professionals including dentists and dental hygienists/ assistants (48,097). Nurses (Adv Practice/ Registered/ Practical/ Para-Professional) have the highest number of adverse actions (589,068).

Malpractice Payments against All Healthcare Professionals



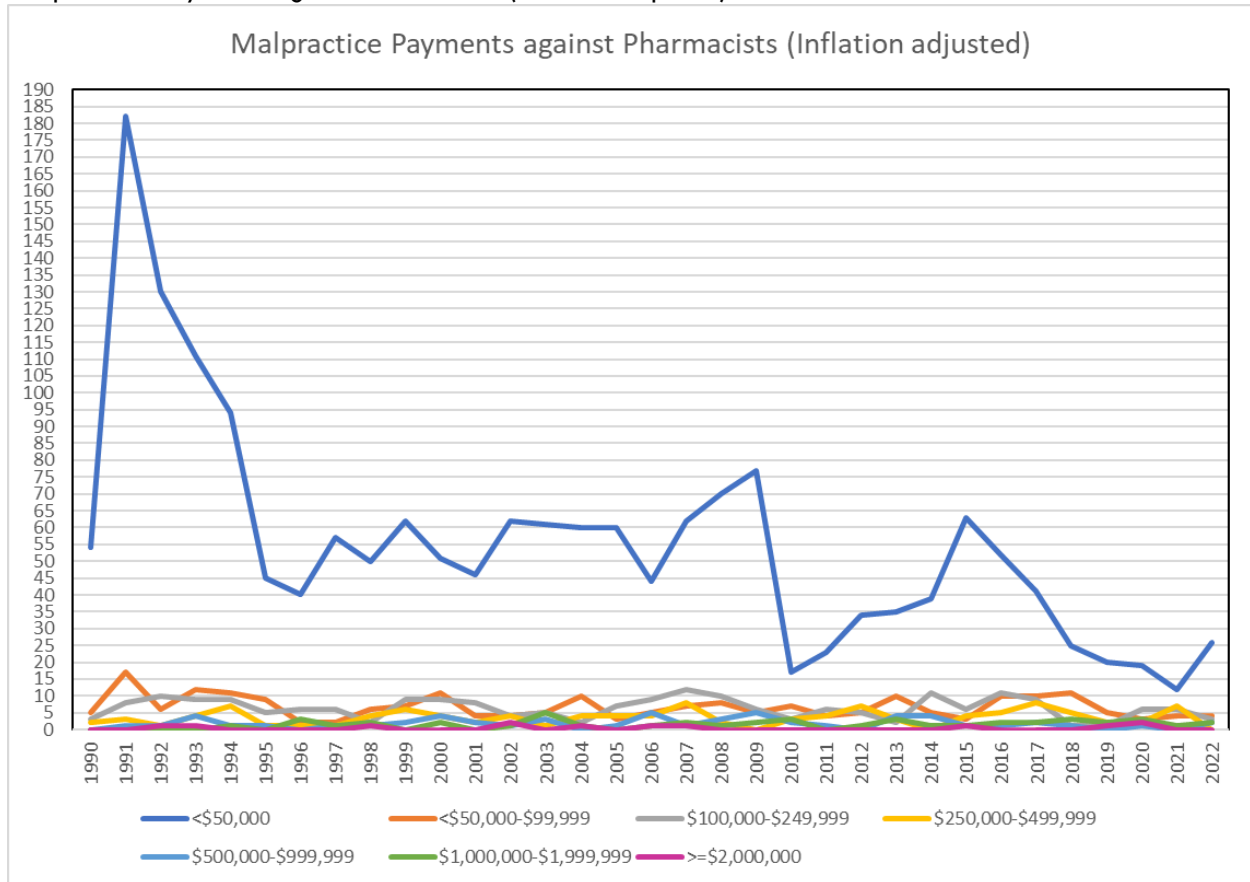
**Figure 5.** provides information on Malpractice payments. Pharmacists have less malpractice payments (2480) compared to other health professionals. Physicians (MD and DO) (382,300) had the highest malpractice payments against them. Dental professionals including dentists and dental hygienists/ assistants had (60,604) reports and nurses (Adv Practice/ Registered/ Practical/ Para-Professional) (18,342).

Type of Adverse Actions on the Practitioner



**Figure 6.** shows the type of adverse actions against Pharmacists. The most common adverse action has been loss of State licensure/Certification (36,666). No pharmacist has been reported to have lost their Clinical Privileges/Panel or Professional Society membership. In 2022, a case of adverse action by the Drug Enforcement Administration was reported. 2,582 pharmacists have had HHS OIG Exclusion and 4,930 Reinstatement/Restoration.

Malpractice Payments against Pharmacists (Inflation adjusted)



**Figure 7.** shows medical malpractice payments against pharmacists from 1990-2022 across the US. The trend shows that it was at its peak in 2006 with the amount of  $\geq \$2,000,000$  where the amount of  $\$1,000,000- \$1,999,999$  was higher in 2003. In 2022, compared to other payment categories  $\$1,000,000- \$1,999,999$  was highest and  $\geq \$2,000,000$  and  $\$250,000- \$499,999$  were lowest.

**Table 1**

State	Employed Pharmacists (May 2022)	Malpractice payments (1990-2022)	Adverse actions (1990-2022)	State	Employed Pharmacists (May 2022)	Malpractice payments (1990-2022)	Adverse actions (1990-2022)
Alabama	5650	63	1497	Montana	1300	9	129
Alaska	520	1	82	Nebraska	2210	17	380
Arizona	7730	42	784	Nevada	2760	22	620
Arkansas	3180	16	476	New Hampshire	1220	2	277
California	34100	191	2460	New Jersey	9360	74	1048
Colorado	4990	62	1342	New Mexico	1820	21	310
Connecticut	2990	17	467	New York	19930	79	1362
Delaware	970	5	132	North Carolina	11110	61	663
District of Columbia	880	8	63	North Dakota	1010	5	51
Florida	22420	157	2127	Ohio	13170	155	1495
Georgia	10320	113	611	Oklahoma	3810	21	536
Hawaii	870	5	66	Oregon	3660	14	1566
Idaho	1580	14	451	Pennsylvania	15190	87	2139
Illinois	12560	65	1472	Rhode Island	1280	10	184
Indiana	6710	147	1015	South Carolina	5150	38	813
Iowa	2790	33	420	South Dakota	1220	15	38
Kansas	3290	55	591	Tennessee	7780	76	799
Kentucky	5320	79	1387	Texas	23600	163	2909
Louisiana	5010	104	1155	Utah	2890	16	569
Maine	1360	8	536	Vermont	550	10	169
Maryland	5780	38	721	Virginia	7250	44	2307
Massachusetts	7400	32	859	Washington	7150	23	1131
Michigan	10200	55	3147	West Virginia	2360	21	292
Minnesota	6630	32	352	Wisconsin	5450	42	589
Mississippi	3220	44	587	Wyoming	510	5	190
Missouri	7280	47	750	Puerto Rico	2170	14	88



## Discussion

In the current study we found that there has been a 19.56% decline in the number of malpractice payments against pharmacists in the last 5 years from 46 in 2018 to 37 in 2022. Figure 1. shows that total no of malpractice payments against pharmacists from 1990-2022 were 2480. The highest number of reports were recorded in 1991 (211) and the lowest in 2021 (30). The US population is aging 14 and people are living longer and with more chronic diseases. The median age for the US is 38.8 15 and 16.8% of the population is above the age of 65 16. Evidence shows that the use of prescription medication is increasing.<sup>17</sup> Due to the coronavirus pandemic, the usage of prescription drugs has risen, resulting in changes in the way individuals acquire their medications. Approximately 66% of adults in the United States use prescription drugs (Health Policy Institute, 2021) 18, and the country consumed around 30% of the global supply of opioids in 2015 (Politifact, 2017).<sup>18</sup> There are more than 20,000 prescription drugs that are approved for marketing (FDA, 2020).<sup>18</sup> 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.

Figure 2. shows a total number of adverse actions against pharmacists 44,204 reports. In our study, we found Michigan reported the highest number of adverse actions against pharmacists 3147 reports. Lowest no of adverse action reports was submitted by South Dakota 38 reports. Table 1 As seen in figure 4 the highest number of adverse actions reports amongst all health professions were against nurses 589,068 reports and adverse action reports against physicians (MD & DO) were 179,995. The lowest number of adverse action reports were against podiatrists 4,361.

Pharmacists and physicians have separate duties when medications are prescribed and dispensed, and this can vary slightly from state to state. Traditionally, pharmacists have been viewed as protected from the duty to warn patients about their prescribed medications, this duty has historically rested upon physicians and drug companies. However, some courts have recently ruled that pharmacists do have a duty to warn, particularly in cases in which there are known contraindications or clear errors in the prescription (for example, excessive dosing, as demonstrated in the cases above).<sup>19</sup> Also, in Florida, pharmacists are required to double-check prescriptions for

certain controlled substances, such as opioids and benzodiazepines, before dispensing them to patients. In Illinois, pharmacists are required to verify the accuracy of prescription orders by reviewing the original prescription or a facsimile of the prescription, checking the identity of the patient, and confirming the dosage, route of administration, and duration of therapy.

In *Brooks v Wal-Mart Stores, Inc*, the court ruled against a pharmacist who had filled a prescription for an excessive dose of prednisone (80 mg four times daily).<sup>20</sup> The dose was confirmed with the physician at the time. The patient subsequently developed *Nocardia pneumonia* and cerebral aspergillosis. Although the physician is responsible for warning of side effects, the pharmacist must “exercise his [or her] own judgment as to whether any dosage prescribed, even if confirmed by the prescriber, would be harmful” and has an obligation to not fill a prescription he or she deems harmful.<sup>21</sup> In our study we found that the highest number of malpractice payments were reported by the state of California (191) reports and lowest was in Alaska (1). Table 1 One reason is that California has the highest number of pharmacies and employed pharmacists when compared to any other state.<sup>22,23</sup> Another interesting finding was that malpractice payments against pharmacists have remained zero for the states of Washington, Idaho, Nevada since 2017, and in the states of Colorado, Arizona, Montana, Kansas, Massachusetts, Connecticut since 2018 and the state of Michigan since 2020.

There is variation amongst the jurisdictions regarding the type of activities that a pharmacist can complete, but only 4 states - Colorado, Idaho, Maine, Indiana allows a pharmacist to manage drug therapy without authorization from a physician. Prescription adaptation can be defined as pharmacists modifying medication regimens from the original prescriber to improve a patient’s health outcome, either independently or in collaboration with the original prescriber (e.g., physician, nurse practitioner). This can include modifying the quantity of a prescription (e.g., changing a 30-day supply to a 60-day supply) or switching a patient to a different medication that has the same effect as the previously prescribed drug (i.e., therapeutic substitution).

The adaptation cannot change the type of medication or the outcome that the original prescriber intended. Some states have used this as a way to help patients in rural areas to avoid unnecessary travel to the doctor’s office to modify

a prescription.<sup>24</sup> Most states now have laws that leverage pharmacists and their practice to expand access to care even further, through practice agreements with physicians and by delegating certain aspects of pharmacy practice to technicians. Forty-two states and the District of Columbia allow pharmacists to administer vaccinations, with 16 of those states allowing the pharmacist to do it independently, with no physician authorization required. Forty-seven states and the District of Columbia allow pharmacists to manage a patient's drug therapy. Twenty states including Colorado, District of Columbia, Florida, Georgia, Indiana, Kentucky, Louisiana, Mississippi, Montana, New Jersey, North Carolina, North Dakota, Ohio, Rhode Island, Texas, Tennessee, Utah, West Virginia, Wyoming explicitly allow pharmacists to perform certain activities independently. These include dispensing medication, substituting name brand drugs with generic forms, counseling patients, compounding drugs, reviewing patient profile for adverse results and correct drug dosage and refilling prescriptions in emergency conditions.<sup>24</sup> With the increased responsibilities that a pharmacist holds, some of these states have seen a rise in adverse actions against pharmacists while malpractice payment reports continue to show a downward trend.<sup>13</sup>

Pharmacists are doing well when compared to other health professions. As seen in figure 4 the highest number of malpractice payment reports were against physicians (MD & DO) 38,2300 and lowest number of malpractice payments were against dental hygienist/assistant 128 reports. Another study titled "Pharmacist Malpractice Over the Last Decade in the United States" demonstrates an increased number of malpractice payments against pharmacists from 2010-2015. <sup>25</sup> However, our study shows that this trend has declined in the last 5 years.

As Americans consume more prescription medications and as the duties of pharmacists expand, there is a potential increased risk of error which may increase the risk for litigation. According to our study, in figure 6 the most common adverse

action against pharmacists was loss of state licensure and certification. In 2022, a case of adverse action by the Drug Enforcement administration was reported. According to figure 7, the malpractice payment against pharmacists between \$100,000 - \$199,999 was the highest in 2022. It may be due to an increase in corporatization of the pharmacies. For opportunistic litigators there is the chance to win larger compensations based on the retail pharmacy's resources rather than the limited resources of the individual pharmacist. The current study shows that the adverse action reports decreased from 2016 (52,573) reports to 2022 (37,257) reports. Similarly, malpractice payments also show a downward trend from 2016 (11,532) reports to 2022 (9,778) reports. The following trend is of concern.

Currently, pharmacists are largely reimbursed based on volume (meaning that dispensing more drugs results in higher revenue for the pharmacy), shifting their roles to deliver more value-based and preventive care may contribute to reductions in litigations and health care spending.

### Conclusion

In this study we found that even though malpractice payments and adverse actions against pharmacists have continued to decline, the probability of an adverse action still remains high for practicing pharmacists. As pharmacists' scope of practice keeps expanding in lieu of rising provider shortages and changes in healthcare owing to the pandemic the chances of litigation continue to stay high. As patient care evolves with new therapies and digital healthcare technology solutions the role of pharmacists will continue to evolve along with other members of the healthcare team. It is important that practicing pharmacists stay aware of these changes through continuing education with accredited organizations and proof of credentials for any expansion in their scope of practice. The pharmacy profession should continue to adopt practices and systems similar to other health care providers to support pharmacists to be able to serve their patients without the fear of litigation.

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