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**The Electoral College and its Defenders: A Constitutional
Argument for the National Popular Vote Interstate
Compact**

Alfryd van Bruggen

In light of the Electoral College's role in determining both the 2000 and 2016 elections, the continued existence of the Electoral College has increasingly been called into question. In lieu of a constitutional amendment to replace the institution, some states have created an agreement known as the National Popular Vote Interstate Compact. The agreement lays out that once states representing a majority of electors join the compact, they will pledge all of their electors to whomever wins the popular vote. Naturally, subverting part of the Constitution in this way has drawn some legal criticism, and it is sure to draw even more should enough states adopt it. This paper addresses objections on three grounds: the Compact Clause, the Guarantee Clause, and the Voting Rights Act. The paper shows that none of these objections make the National Popular Vote Interstate Compact illegal or unconstitutional.

I. Introduction

The Electoral College is the institution used to elect the president of the United States of America by way of giving each state a number of electors equal to their congresspeople and senators, who then vote for a presidential candidate. In every state but two, all the electors are supposed to vote for whomever won the state's popular vote. Over the past two decades, the Electoral College has twice declared the winner of the presidential election to be the candidate who received fewer votes from the public. This has led to calls for the Electoral College to be replaced with the popular vote.

Replacing the Electoral College is a daunting task. Among other reasons, the Electoral College is enshrined in the Constitution, so removing it would require a constitutional amendment. However, there is one idea for replacing the Electoral College without the need to amend the Constitution. If enough states pledge their electoral votes to the winner of the popular vote, the Electoral College could effectively be

circumvented entirely. This plan is called the National Popular Vote Interstate Compact (NPVIC). Naturally, this has sparked significant debate among legal scholars as to whether or not the NPVIC is constitutional. Law Reviews at some universities such as Northwestern, Valparaiso, Columbia, and Brigham Young have published articles arguing that the NPVIC violates the Constitution for various reasons.^{1 2} In this essay, I intend to tackle three legal objections to this plan—the Compact Clause, the Guarantee Clause, and the Voting Rights Act—and prove that the NPVIC is constitutional.^{3 4}

II. The Electoral College

The Electoral College is established in Article II, Section 1 of the Constitution and is further refined in the Twelfth Amendment.^{5 6} The language in Article II, Section 1 outlines exactly how the Electoral College works: “Each State shall appoint, in such Manner as the Legislature thereof may direct, a Number of Electors, equal to the whole Number of Senators and Representatives to which the State may be entitled in the Congress.”⁷ These electors then vote for the President and Vice President according to the state’s popular vote, although states can tell electors how to vote.⁸ Every state except for Maine and Nebraska currently awards all of their electors to the person who received the most votes in the state.⁹

This makes the Electoral College different from the popular vote in two distinct ways. First, each state has the same number of Senators,

¹ Feeley, Kristin, *Guaranteeing a Federally Elected President*. Vol. 103, Nw. U. L. Rev., Available at SSRN: <https://ssrn.com/abstract=1121483> (2009).

² Turflinger, Bradley T., “*Fifty Republics and the National Popular Vote: How the Guarantee Clause Should Protect States Striving for Equal Protection in Presidential Elections*”. Val. U. L. Rev. Valco Scholar (2011).

³ Williams, N. R. *Why the National Popular Vote Compact is Unconstitutional*. BYU L. Rev., 5 (2012).

⁴ Gringer, D. *Why the National Popular Vote Plan Is the Wrong Way to Abolish the Electoral College*. Colum. L. Rev., 108, 1 (2008).

⁵ U.S. Const. art. II, § 1

⁶ U.S. Const. amend. XII

⁷ U.S. Const. art. II, § 1

⁸ *Chiafalo v. Washington*, 591 U.S. (2020)

⁹ *Distribution of Electoral Votes* (March 6, 2020), <https://www.archives.gov/electoral-college/allocation>.

regardless of its size or population, and as a result, smaller states have a larger portion of the electoral votes than their portion of the American population. Second, the number of votes for the losing candidate in each state is not reflected by the Electoral College. A candidate could receive more total votes and still lose the election by losing many states by a small margin and winning a few states by a large margin while the other candidate simply wins enough states to receive the majority of Electoral College votes. As a result, the Electoral College has delivered the presidency to a candidate with fewer total votes four times: Rutherford B. Hayes in 1876, Benjamin Harrison in 1888, George W. Bush in 2000, and Donald Trump in 2016.

The Electoral College has attracted criticism over the years for several reasons. Akhil Reed Amar, a constitutional law professor at Yale, has argued that the Electoral College was originally created as a ploy to increase the influence of slave states in the federal government.¹⁰ Rather than being a compromise between big and small states, Amar argues that the biggest divide in early American politics was the North and South. He backs this up by pointing out that Northerners and Southerners tended to support candidates from their own area, such as the elections between John Adams of Massachusetts and Jefferson of Virginia. By virtue of indirect elections, slaves could be counted in the number of votes given to a state without actually giving slaves the right to vote thus increasing the voting power of Southern states. Consequently, every president until Lincoln was either a Southerner or a Northerner who tolerated slavery.

Additionally, even if the Electoral College was intended to balance the power of large and small states, it failed to do so. Eight of the first nine presidents of the United States were from Virginia—the largest state in the Union at the time—and only three people from small states have ever been elected president.

Other opponents of the Electoral College take issue with who it disempowers. Because small rural states have more electoral votes per voter, and rural states tend to be predominantly white, the average

¹⁰ Amar, A. R., *Actually, the Electoral College Was a Pro-Slavery Ploy* (April 6, 2019), <https://www.nytimes.com/2019/04/06/opinion/electoral-college-slavery.html>.

impact of white voters on the presidential election is higher than any other racial group.¹¹

Due to the controversies surrounding it, reforming or abolishing the Electoral College is a popular idea in America, especially among Democrats after the 2016 election.¹² However, doing so would be quite a challenge. According to Article V of the Constitution, passing an amendment requires the votes of two-thirds of the members of both houses of Congress and the approval from three-fourths of the States.¹³

One way around the arduous process of amending the Constitution is The National Popular Vote Interstate Compact (NPVIC).

The NPVIC is an agreement between certain states and the District of Columbia to use the Electoral College to circumvent itself. According to the Supreme Court in *McPherson v. Blacker*, “the legislatures of the several states have exclusive power to direct the manner in which the electors of President and Vice President shall be appointed.”¹⁴ Proponents of the NPVIC argue that this means states can pledge their electors to the winner of the popular vote nationwide instead of statewide. The NPVIC is an agreement to do just that. Once the electors of the NPVIC member states reach half the total electors, each state in the compact must pledge all of their electors to the winner of the national popular vote, effectively replacing the Electoral College with the popular vote.

Once this comes into effect, it is bound to draw significant legal challenges. Indeed, there has already been much discussion as to the legality of the compact. The next section investigates three such challenges and demonstrates why these challenges ultimately do not prevent the NPVIC from becoming reality: the Compact Clause, the Guarantee Clause, and the Voting Rights Act.

III. Legal Challenges

¹¹ In the Electoral College White Votes Matter More (January 30, 2020), <https://cepr.net/in-the-electoral-college-white-votes-matter-more/>.

¹² Daniller, A, A majority of Americans continue to favor replacing Electoral College with a nationwide popular vote (January 28, 2021), <https://www.pewresearch.org/fact-tank/2020/03/13/a-majority-of-americans-continue-to-favor-replacing-electoral-college-with-a-nationwide-popular-vote/>.

¹³ U.S. Const. art. V

¹⁴ *McPherson v. Blacker*, 146 U.S. 1 (1892)

Part A: The Compact Clause

The first of the legal challenges that shall be investigated is arguing that the NPVIC violates the Compact Clause of the Constitution. The Compact Clause in Article I section 10 of the Constitution reads: “No State shall, without the Consent of Congress... enter into any Agreement or Compact with another State.”¹⁵ This essentially means that if two or more states want to enter into an agreement with each other, Congress must pass a joint resolution or act of Congress giving its approval and it must be signed by the president. However, in *Virginia v. Tennessee*, the Supreme Court stated that the Compact Clause applies only to “any combination tending to the increase of political power in the states, which may encroach upon or interfere with the just supremacy of the United States”, but not to “those to which the United States can have no possible objection or have any interest in interfering with.”¹⁶ What this means in practice is that the Compact Clause does not apply unless the compact makes the States more powerful relative to the federal government.

To determine whether or not the NPVIC violates the Compact Clause, we must establish if it alters the balance of power between the federal government and the States. American presidential elections are performed at the state level, not the federal level. The federal government has very little power to influence how these elections are carried out. Thus, altering the manner in which states pledge their electors does not deprive the federal government of any power it previously had, nor does it make the States more powerful in a way that infringes on the supremacy of the United States. One scholar has argued that the NPVIC would alter the balance of power between the States and the federal government by denying the House of Representatives the chance to decide the election in the event of an electoral tie.¹⁷ However, this has happened only twice, and has not happened in almost 200 years. It is unclear if such an insignificant and hypothetical case of diminishing

¹⁵ U.S. Const. art. I, § 10

¹⁶ *Virginia v. Tennessee*, 148 U.S. 503 (1893)

¹⁷ Schleifer, (14, May 2007). “Interstate Agreement for Electoral Reform,” pp. 739-740

federal power would require the NPVIC to receive Congressional approval is unsettled, but it would appear unlikely.

Another challenge to the NPVIC in the Compact Clause is the issue of altering the balance of power between states. This legal principle is less clearly stated by the Supreme Court, but it is evident from rulings such as *Northeast Bancorp, Inc. v. Board of Governors of the Federal Reserve System* that the Court views the purpose of the compact clause as protecting the rights of states outside of the compact. This case involved questioning the legality of a compact that allowed the merger of banks in New England, which would have been illegal without the compact. The plaintiffs argued that the compact was unconstitutional because it violated the compact clause, but the court held that it did not. In Justice William Rehnquist's opinion, he states "Petitioners also assert that the alleged regional compact impermissibly offends the sovereignty of sister States outside of New England. We do not see how the statutes in question either enhance the political power of the New England States at the expense of other States or have an 'impact on our federal structure.'"¹⁸ According to this view, the Compact Clause serves not only to protect the supremacy of the United States, but also to protect the interests of the other States.

So does the NPVIC violate this understanding of the Compact Clause? Some would argue that it does, saying that the compact's ultimate aim is to dismantle the Electoral College, thereby eliminating the relative benefit it grants to smaller, less populous states.¹⁹ By enacting the NPVIC and switching to a popular vote, the balance of power between large and small states would be shifted, thus requiring Congressional approval under the Compact Clause. However, this line of reasoning does not hold weight. A collection of States with the minority of electoral votes has never been entitled to decide the result of a presidential election. If enough states agree to the NPVIC for it to become active, they will comprise a bloc of States with enough power afforded to them by the Electoral College to decide the election by design. The NPVIC does not alter the balance of power between states,

¹⁸ *Northeast Bancorp, Inc. v. Governors, FRS*, 472 U.S. 159 (1985)

¹⁹ Neale, Thomas H.; Nolan, Andrew (October 28, 2019). *The National Popular Vote (NPV) Initiative: Direct Election of the President by Interstate Compact (Report)*. Congressional Research Service

it merely uses the current balance of power to achieve its goal. It is also worth noting that even if the NPVIC did violate the balance of power between States or the federal government, this would not make it unconstitutional. It would simply require congressional approval. Even in the most uncharitable interpretation of the Compact Clause, it would only add another hurdle but not an insurmountable one.

Part B: The Guarantee Clause

The second legal challenge to the National Popular Vote Interstate Compact discussed in this essay is the Guarantee Clause. Found in Article IV, Section 4, it reads “The United States shall guarantee to every State in this Union a Republican Form of Government, and shall protect each of them against Invasion; and on Application of the Legislature, or of the Executive (when the Legislature cannot be convened) against domestic violence.”²⁰ Several scholars have used it to object to the compact.^{21 22} Each state must be a Republic, which by definition must be responsive to its electorate. Some constitutional scholars have argued that this clause is intended to enshrine the idea of the “compound republic” into the constitution, as described by Madison in the Federalist Papers.²³ Presidential authority flows from the citizens of each state through their legislature to the federal government. According to opponents of the NPVIC, the compact violates the nature of the “compound republic” established by the Guarantee Clause and thus is incompatible with the Constitution.²⁴ However, this represents a fundamental misunderstanding of the compact in question. The NPVIC is inherently state-based legislation. Each state that signs on does so with the willing consent of its Republican government. In this way, the source of the President’s powers still flows from the citizens of each state, as it is still up to each

²⁰ U.S. Const. art. IV, § 4

²¹ Turflinger, Bradley T. (2011). "Fifty Republics and the National Popular Vote: How the Guarantee Clause Should Protect States Striving for Equal Protection in Presidential Elections". *Valparaiso University Law Review*. Valco Scholar

²² Feeley, Kristin, *Guaranteeing a Federally Elected President*. Northwestern University Law Review, Vol. 103, 2009, Available at SSRN: <https://ssrn.com/abstract=1121483>

²³ *Ibid*

²⁴ *Ibid*

legislature to select electors and decide whether or not to sign up to NPVIC. It would not undermine the Guarantee Clause for a state to select their electors based on the votes of the nation as a whole, so long as the citizens of that state consent to it through their representatives.

Part C: The Voting Rights Act

The third and final legal challenge is a conflict with the Voting Rights Act. In the *Columbia Law Review*, David Gringer writes, “[the NPVIC] may run afoul of another deeply contested area of law--sections 2 and 5 of the Voting Rights Act--as either minority vote dilution or retrogression in the ability of minority voters to elect the candidate of their choice.”²⁵ Currently, only one of the conflicts merits discussion, that of section 2. After Gringer’s article was published, the Supreme Court struck down section 4 of the Voting Rights Act as unconstitutional on the basis that it was operating on outdated facts. Congress could have updated the criteria in section 4 but failed to do so. While they did not directly rule on section 5, the elimination of section 4 renders section 5 inoperative. The Court leaves the possibility of updating the act, but for the time being, discussion on section 5 is irrelevant.²⁶ Violation of section 2, however, remains an important topic. It reads, “No voting qualification or prerequisite to voting, or standard, practice, or procedure shall be imposed or applied by any State or political subdivision to deny or abridge the right of any citizen of the United States to vote on account of race or color.” It has been argued that this section causes problems for the NPVIC in places such as California and the District of Columbia which have a higher percentage of minorities than the national average. By pledging all the electors of a state to the winner of the national popular vote, the NPVIC could be in conflict with this section, as it diminishes the power of racial groups to elect their own representatives.

In truth, while minorities may be less influential in selecting the president in certain states, instituting a national popular vote nationwide would actually increase the voting power of minority racial groups, as currently white voters are on average more influential in the electoral

²⁵ David Gringer. *Why the National Popular Vote Plan Is the Wrong Way to Abolish the Electoral College*. *Columbia Law Review*, 108(1) (2008).

²⁶ *Shelby County v. Holder*, 133 S. Ct. 2612 (2013)

college vote.²⁷ Thus, the NPVIC does empower minorities compared to the current political situation. Using the Voting Rights Act to defend a system that weighs the votes of white people, rather than the groups which the Act was designed to empower, is an interpretation that is certainly difficult to support. While this question is not settled, the Justice Department has previously shown that it agrees with the interpretation of the NPVIC and the Voting Rights Act given in this paper. In 2012, they declined to challenge California's assent to the NPVIC on the grounds of the Voting Rights Act.²⁸ It seems unlikely that the DOJ would decline to challenge the Compact in one state but challenge it later in another state, so the NPVIC is unlikely to be overturned due to the Voting Rights Act.

IV. Conclusion

Many legal questions have been posed that challenge the National Popular Vote Interstate Compact. Compliance with the Compact Clause, the Guarantee Clause, and the Voting Rights Act are all topics of contention regarding its constitutionality. However, each of these challenges is insufficient to strike down the legality of the NPVIC. The Compact Clause does not apply to the NPVIC because it does not alter the balance of power between the states and the federal government or the states and each other. Even if it did, this would not prove to be insurmountable if Congress and the President were amenable to the popular vote. The Guarantee Clause is compatible with the NPVIC because each state is still ultimately responsible for their citizens, even if their electoral votes are based on a nationwide vote. Finally, the Voting Rights Act cannot pose a challenge to the NPVIC because the clauses that could have themselves been struck down. In addition, the NPVIC actually further enfranchised minorities by making every vote equal. While this is not the only means to abolish the Electoral College, it would prove significantly easier to pass than a constitutional amendment, although an amendment would likely create fewer legal

²⁷ Lara Merling, *In the Electoral College White Votes Matter More*, Jan 30, 2020. <https://cepr.net/in-the-electoral-college-white-votes-matter-more/>

²⁸ U.S. Department of Justice, Civil Rights Division, Letter of T. Christian Herren, Jr., Chief, Voting Rights Section

challenges. Nonetheless, the National Popular Vote Interstate Compact is a legal way to circumvent the Electoral College.

This would deliver several tangible benefits for the American political system. For one, it would increase perceived legitimacy of American democracy. A majority of Americans support electing the president via popular vote, and it would avoid the chance of citizens losing faith in the political process when a candidate becomes president without a majority of votes.²⁹ Both of the recent occasions where the Electoral College delivered different results from the popular vote stirred national controversy that lingered for years in the public consciousness; this paper itself is evidence of this. Switching to a popular vote system would prevent this uprising of discontent from occurring again. Abolishing the electoral college would also simplify the democratic process, further restoring legitimacy. Having an archaic and convoluted electoral system makes voters feel disconnected from politics, as if the leadership of the country is determined by forces outside their control. The popular vote avoids this pitfall. Additionally, getting rid of the electoral college ensures every vote is as important as another. Currently, voters in smaller states receive more electors per voter than those of bigger states, and swing states are more politically relevant than others. Electing the president via the popular vote makes every voter equal. This also applies to race; the electoral college awards more weight to white voters and less to people of color as a result of how electors are allocated.³⁰ Replacing the electoral college would not only increase legitimacy in this regard, but also make appealing to people of color more politically attractive. Concurrently, the popular vote would also be one step in the direction of undoing white supremacy in this country. The National Popular Vote Interstate Compact would increase democratic legitimacy and help advance the cause of civil rights. There are no legitimate constitutional challenges in its manner of achieving these goals. If enough states ratify the compact, the popular

²⁹ Bradley Jones, *Majority of Americans continue to favor moving away from Electoral College*, PEW RESEARCH CENTER (Jan. 27, 2021) <https://www.pewresearch.org/fact-tank/2021/01/27/majority-of-americans-continue-to-favor-moving-away-from-electoral-college/>

³⁰ Lara Merling, *In the Electoral College White Votes Matter More*. (Jan. 30). <https://cepr.net/in-the-electoral-college-white-votes-matter-more/>

vote will become the law of the land and help revitalize American democracy.

Tort Doctrine on the Law of Dental Malpractice

Zihan Li

The authorship of law reviews and legal studies have neglected the subject of malpractice as an essential element of Tort Doctrine. Malpractice study in the field of dentistry is especially rare. The profession of dentistry is evolving, oral disease patterns are changing, and a more educated and consumption-oriented population is willing to spend on advanced dental treatments. The development of clinical sciences altered practice paradigms, and now the dentist can perform various specialized dental treatments. From a legal liability perspective, the complexity of treatments raises the possibility that dentists may provide care below acceptable standards. This review aims to provide general readers with an introduction to the basic concepts of dental malpractice law within the spectrum of tort doctrine, while also promoting patient awareness of legal rights, preventing dental litigations, and improving public welfare.

I. Introduction

The neglect of dental malpractice as a subject of legal study by public opinion, academia, and legal scholarship cannot be justified given its importance. The rule of law that applies to cases of medical-related malpractice is similar to that which applies to dental malpractice cases. Unlike medical practitioners, who typically provide care to patients who are hospitalized or in a clinical setting, dental practitioners typically perform procedures on conscious patients in an outpatient or office setting. Furthermore, dental procedures often involve the use of specialized equipment and tools that are not commonly used in other medical specialties. These unique characteristics of dental practice create a different set of risks and challenges compared to other medical specialties. For example, dental

procedures may require the use of anesthesia and are often not¹ performed by a board-certified anesthesiologist, which can have serious adverse effects if not administered properly. As a result, the standard of care for dental practitioners may differ from that of medical practitioners.

There has been a rise in dental malpractice litigation in the past few years, and as patients become more consumption-oriented, they become more conscious of their rights and more willing to file lawsuits. A recent study suggests that dental malpractice suits are increasing, and the data show that 11.2% of malpractice payments in the United States are against dentists.² However, the number of malpractice payments against non-dentist health professionals is falling. In addition, the legal profession is expanding. In the United States, there has been an increase in lawyers practicing each year over the last decade. According to the American Bar Association's "2022 ABA Profile of the Legal Profession," there are currently about 1.3 million lawyers in the US.³ Despite the significance of dental malpractice as a legal issue, there is currently little in the way of comprehensive research on trends and insights related to dental malpractice lawsuits. While some studies have focused on analyzing malpractice claims in the medical field, research on dental malpractice is relatively scarce. This gap in knowledge is concerning given the potential consequences of dental malpractice for patients, practitioners, and healthcare systems. Without a thorough understanding of the factors that contribute to dental malpractice lawsuits, it is difficult to develop effective strategies for prevention and mitigation. To address this gap in knowledge, further legal studies are needed to examine trends and insights in dental malpractice lawsuits. Malpractice is a word that indicates a civil wrong as applied to professional legal liability disputes. Dental malpractice is defined as any omission by a dental professional during the treatment of a patient that diverges from accepted norms or the standards of care in the dental community and causes damage to the patient. Current dental

¹ Louis J Regan, *Doctor and Patient and the Law* (C.V. Mosby Company, 1956).

² R. P. Nalliah, "Trends in US Malpractice Payments in Dentistry Compared to Other Health Professions – Dentistry Payments Increase, Others Fall," *British Dental Journal* 222, no. 1 (January 2017): 36–40, <https://doi.org/10.1038/sj.bdj.2017.34>.

³ "Demographics | American Bar Association Profile of the Legal Profession"

malpractice law originated in 19th century English common law.⁴ Common law refers to the law and legal systems developed through the rulings of courts, which objected to laws developed solely through legislative statutes or executive orders. In the United States, dental malpractice law is under the jurisdiction of states; the structure and rules of law that oversee it have been established through decisions on lawsuits filed in state courts. Thus, dental malpractice laws can vary across different jurisdictions in the U.S. but with basic and similar legal standards. In addition, statutes passed by state legislatures and federal legislation, such as the 1946 Federal Tort Claims Act, have further influenced the framework of dental malpractice laws.

II. Common Law of Tort Doctrine

“Tort” is the medieval Latin word for “wrong and injustice,” and tort law is a rule of law that creates and provides remedies for civil wrongs.⁵ Tort Doctrine is the rule of law solely pivoting on interpersonal wrongs, principally between private parties. Distinct from the law of contractual duties, tort liabilities are not a voluntary *quid pro quo* - a reciprocal exchange of benefits or services, whereby each party agrees to provide something of value to the other in return for a corresponding benefit or service; they are also distinct from the law regarding criminal wrongs. In the case of criminal wrong, the standard of proof is "beyond a reasonable doubt"; the plaintiff must demonstrate that the defendant has satisfied each of the requirements of the tort action that is more probable than not. Beyond that, the state or the federal government is not necessarily a part of the tort action. In the United States, tort cases are heard before civil juries, and most of the time, tort suits are settled before reaching trial.⁶ Tort law protects people's physical integrity and health from intentional or omissive harm; it protects people's mental health and integrity from intentional harassment or violation and negligent infliction of psychological damage; it protects people's

⁴ Stuart M Speiser, *The American Law of Torts* (Thomson West, 1986).

⁵G Edward White and Inc Ebrary, *Tort Law in America : An Intellectual History* (Oxford ; New York: Oxford University Press, 2003).

⁶ Arthur Ripstein, “Theories of the Common Law of Torts,” ed. Edward N. Zalta, *Stanford Encyclopedia of Philosophy* (Metaphysics Research Lab, Stanford University, 2022)

reputation from defamation; it protects people to be free from unwarranted publicity (right to privacy) and false imprisonment; it also protects the integrity of property from intrusions like unauthorized use, damage, and trespassing (land). The law derived from tort doctrine partakes of two fundamental issues of law and ethics in civil life: how people should treat each other and whose liability it is when the damage occurs.

III. Tort Law in Dental Malpractice

The etymology of "malpractice" is rooted in the Latin words "male" and "praxis," which together indicate "bad, incorrect application." The World Medical Association defines malpractice as "injury caused to a patient due to a healthcare provider's failure to adhere to the standard of care, the lack of expertise, or improper and careless delivery of the treatment."⁷ Malpractice in dentistry refers to improper procedures carried out by dental professionals that cause damage to the patient. Although the legal definition of dental malpractice differs across jurisdictions, it typically relates to problems arising from neglect, misdiagnosis, or delayed diagnosis or treatment in dentistry.

Dental malpractice law, like medical malpractice law, is rooted in English common law and evolved via the decisions of state courts. Dental malpractice cases are prevalent in the United States but receive little public attention. Applying the tort doctrine to dental malpractice cases is meant to foster the involved parties to reach a settlement through extensive negotiation and concessions and resolve the issue without a jury trial. The vast majority of lawsuits involve the patients suing their dentist or provider for bodily damage purportedly caused by negligence. The injured patient must prove that their dentist's treatment was negligent and that this conduct resulted in harm to have the standing to file a lawsuit. Three legal components must be established to have standing. First, a duty of care between the provider and the patient must have been established. Second, an actual violation of said duty must have occurred. Third, harm must have resulted from the violation. If the jury ruling favors the plaintiff, the compensatory damages often account

⁷ "WMA - the World Medical Association-World Medical Association Statement on Medical Malpractice," n.d.,

for economic and noneconomic losses (pain and mental distress).⁸ In the eyes of many dentists, one of the most unpalatable elements of dentistry is the possibility of being sued for malpractice. Some believe that the fear of being sued forces the dentist to practice defensive decision making, recommending a diagnostic test or dental treatment that is not necessarily the best option for the patient but mainly protects the dentist against the patient as a potential plaintiff.⁹ The defensive method raises the cost of the visit and encourages overtreatment in dentistry. Overtreatment refers to a situation in which a patient receives more medical or dental treatment than necessary or appropriate for their condition. However, patients regularly incur financial loss, pain, and emotional distress due to the dentist's omissions. It is commonly considered that the possibility of legal sanctions encourages providers to be more cautious and invest in safety. These contrasting opinions clash when a lawsuit is filed.

IV. Duty of Care

In negligence cases, the pivotal question revolves around the potential breach of duty of care by defendants, which the tort doctrine scrutinizes through the lens of the actions a reasonable individual would undertake in analogous circumstances. The standard dentist-patient relationship is a contractual duty. Even if the dentist invites people to seek his service, the dentist is not legally required to accept them as her or his patients. Regardless of one's values or professional ethics, the law does not force the dentist to accept the patients just because she or he is licensed to practice dentistry.¹⁰ The law imposes obligations on the dentist and the patient only if the invited individual has been accepted as a patient.¹¹ The dentist then represents, directly or by implication, that

⁸ B. Sonny Bal, "An Introduction to Medical Malpractice in the United States," *Clinical Orthopaedics and Related Research* 467, no. 2 (November 26, 2008): 339–47, <https://doi.org/10.1007/s11999-008-0636-2>.

⁹ MSonal Sekhar and N Vyas, "Defensive Medicine: A Bane to Healthcare," *Annals of Medical and Health Sciences Research* 3, no. 2 (2013): 295, <https://doi.org/10.4103/2141-9248.113688>.

¹⁰ *Tvedt v. Haugen*, 70 N. D. 338, 294 N. W. 183; 132 A. L. R. 379 (1940); *Findlay v. Board of Sup'rs of County of Mohave*, 72 Ariz. 58, 230 P. 2d 526 (1951).

¹¹ *Stevenson v. Yates*, 183 Ky. 196, 208 S. W. 820 (1919); *Summerour v. Lee*, 104 Ga. 73, 121 S. E. 2d 80 (1961); *Allison v. Blewitt*, 348 S. W. 2d 182 (Tex. Civ. App. 1961); *Engle v. Clark*, 346 S. W. 2d 13 (Ky. App. 1961); see also, Ohio Rev. Code,

she or he possesses professional knowledge and competence; and the dentist will exercise care in using their skill and knowledge to achieve the clinical objective for which she or he is engaged. In addition, once the relationship is formed, the dentist is obligated to provide services until they are no longer required or until the patient is discharged. It would be unreasonable to expect a dentist to provide immaculate treatment and neglect the patient's own behavior. Consequently, according to the contributory negligence doctrine, that individuals have a duty to exercise reasonable care for their own safety and well-being.¹² When a plaintiff fails to fulfill this duty, they are deemed to have contributed to the harm they have experienced. Simply put, it is the patient's responsibility to provide an accurate medical history, alert the dentist of any unanticipated occurrences during treatment, and indicate whether she or he comprehends a proposed treatment. These responsibilities may play a role in defenses with contributory negligence or acceptance of risk, but they may also be relevant in assessing the dentist's performance.

Once a dentist-patient relationship has been established, some responsibilities take effect. If the duties of care are not satisfied, whether by omission or intention, and someone is hurt directly due to the dentist's breach of duty, the dentist is liable. The duty of care for the dentist is straightforward. The dentist must possess the updated knowledge and competence in the region in which she or he practices, and the dentist must apply that knowledge and skill as a reasonably sensible dentist would in the same community. This is in favor of the dentist since there is a presumption that the dentist possesses and employs the required knowledge and abilities. The plaintiff bears the burden of proving that the dentist lacked the expertise or did not employ it appropriately. In states that demand ongoing education for dental society membership or re-licensure, there is a legally questionable inference that the dentist may lack the required knowledge and skills if the dentist fails to complete the continuing education courses. It is

§§ 4715.01-4715.99, which is exemplary of the majority of the states' codes on this subject

¹² *Chubbs v. Holmes*, 111 Conn. 482, 150 A. 516 (1930); see also, *Anno.*, Contributory negligence or assumption of risk as a defense in actions against physicians or surgeons for malpractice, 50 A. L. R. 2d 1043 (1954); *Donathan v. McConnell*, 121 Mont. 230, 193 P. 2d 819 (1948).

simpler to demonstrate that the dentist did not employ the anticipated knowledge and ability than to demonstrate that he did not possess them.¹³

V. The Standard of Care

Standard of care is what standard a professional would use and what a reasonable person would do. A few examples of some common cases that violated the standard of care would be where there is some known procedure that is not done, such as failure to sterilize or irrigate a socket after extraction of a tooth, the injury due to the negligent use of an instrument, or the dentist drilling through someone's tongue instead of their tooth. In the tort doctrine, customary practice is the standard of care in dental malpractice cases and proving compliance with it typically nullifies the plaintiff's claim. Within the paradigm of customary practice, dentists are held to the standard of a reasonable practitioner in their field. Customary behavior is not conclusive in most tort cases, although it can be used to determine if a defendant behaved inappropriately.¹⁴

In recent years, the courts' approach to evaluating allegations of negligence has clearly shifted in favor of using the test of the standard of care provided nationwide rather than the community test-legal principle that assesses whether the conduct in question would be deemed reasonable and appropriate by an ordinary person within the relevant community or social group. A case in point is *Sanderson v. Moline*, 1972, in which the Washington State Court of Appeal reversed the trial court's judgment that the trial court improperly utilized the locality rule to establish the standard of care. A patient in Spokane County filed a malpractice suit against his dentist, alleging that his dentist failed to diagnose and treat their periodontal disease properly. The dentist's attorney falsely convinced the trial court that the expert witness within the Spokane area was where the patient could establish the only standard of care relevant to the case. Thus, the jury charge was prejudicial to the patient by dismissing the value of the patient's expert

¹³ Henry A. Collett, "Dental Malpractice: An Enormous and Growing Problem," *The Journal of Prosthetic Dentistry* 39, no. 2 (February 1978): 217–25

¹⁴ "Dental Malpractice," *Justia*, September 14, 2018, <https://www.justia.com/injury/medical-malpractice/dental-malpractice/>.

witness, who did not come from the Spokane area. The Appellate court reasoned that the Washington Supreme Court, in the far-reaching decision of *Pederson v. Dumouchel* 1967, abandoned the locality rule as it then existed in this jurisdiction:

The "locality rule" has no present-day vitality except that it may be considered as one of the elements to determine the degree of care and skill which is to be expected of the average practitioner of the class to which he belongs. A qualified medical or dental practitioner should be subject to liability, in an action for negligence, if he fails to exercise that degree of care and skill that is expected of the average practitioner in the class to which he belongs, acting in the same or similar circumstances (*Sanderson v. Moline* 1972).¹⁵ This rule gave the court a guideline when determining the standard of care; the geographic boundary should not be the limitation.¹⁶

Another crucial factor in the dental malpractice case is the standard for specialists. It is not a sign of a lack of empathy to refer patients to a dental specialist when providing treatment. It shows extreme caution and professionalism to refer patients to dental specialists who are better at delivering the necessary care. The referral also indicates that the dentist could not be capable or legally providing such treatment for the patient. For example, asthma patients are sent to pulmonologists for specialized care. After visiting the specialist, the patients must continue visiting their primary care provider or family physician. In dentistry, the same principle holds. A general dentist might refer a patient to an endodontist to discuss the possibility of root canal treatment when the patient is suffering from pain but does not want the tooth extraction. Dental malpractice claims may emerge from a dentist's inability to refer patients who need care outside the scope of their training, experience, or expertise. Concerns arise when more dental procedures are carried out by dentists who are not trained, experienced, or licensed. A specialist is held to the same standards as other dental specialists who practice in a related or identical community. For example, an oral surgeon must present superior skills and knowledge he

¹⁵ *Pederson v. Dumouchel*, 72 Wn.2d 73, 431 P.2d 973, 1967 Wash. LEXIS 784, 31 A.L.R.3d 1100

¹⁶ *Sanderson v. Moline*, 7 Wn. App. 439, 499 P.2d 1281, 1972 Wash. App. LEXIS 994

represents to the public as holding. In contrast, a general dentist is not required to acquire and use the knowledge and skills of third-molar (wisdom teeth) extraction like an oral surgeon.

VI. Rule of Law on Proof

The heart of a dental malpractice lawsuit consists of four essential components. The first is a duty of care that results from a patient-dentist relationship. Typically, it is simple to identify whether or not this relationship exists. Dentists must perform a high standard of care for their patients. This entails the safety protocols/measures that a dentist would have followed while caring for a patient within the same professional community. The plaintiff would need an expert witness unless the negligence were egregious to demonstrate this facet. The expert needs to be knowledgeable about the particular kind of procedure that relates to the claim. The third and fourth parts of the claim, known as breach and causation, will also require the expert's opinion. Any action (or inaction) by the dentist that deviates from the standard of care is referred to as a breach. If the dentist had not violated the duty of care, there would have been no harm to the patient; this inference process is known as causation. Damage is the final component of the claim, and they rely significantly on how much the patient was harmed. The jury commonly leans to award damage to the patient sympathetically if the patients have to afford high medical costs to treat the malpractice injuries. The patients may also be rewarded for non-economic harms like pain and mental distress; therefore, they should assess the severity of the injuries with an attorney before bringing litigation to determine whether it is worthwhile considering the potential legal cost. Burden of proof refers to the standard that a party seeking to prove a fact in court must satisfy the legal establishment of that fact. There are different standards for different circumstances. In civil cases, the plaintiff has the burden of proving their case by a preponderance of the evidence, which means the plaintiff only needs to demonstrate the fact is more likely than not. "Beyond a reasonable doubt" and "preponderance of the evidence" are different standards that require distinct methods of proof.¹⁷ The

¹⁷ David M. Studdert and Mark A. Hall, "Medical Malpractice Law — Doctrine and Dynamics," *New England Journal of Medicine* 387, no. 17 (October 27, 2022): 1533–37, <https://doi.org/10.1056/nejmp2201675>.

preponderance of the evidence is the evidentiary standard in a civil litigation burden of proof analysis. When the party with the burden of proof persuades the fact-finder (judge or jury) that there is a more than 50% possibility that the claim is true, the burden of proof is considered to have been satisfied under the preponderance test. In *Karch v. Karch*, 2005, the Superior Court of Pennsylvania interpreted that “preponderance of the evidence is defined as the greater weight of the evidence, i.e., to tip a scale slightly is the criteria or requirement for the preponderance of the evidence.”¹⁸ Additionally, in *Barbour v. Mun. Police Officers' Educ. & Training Comm'n*, 2012, the Commonwealth Court of Pennsylvania interpreted that “A preponderance of the evidence is the evidence that leads a fact-finder to find a contested fact to be more probable than its nonexistence. It is also within the exclusive province of the Commission, as a fact-finder, to determine the witnesses' credibility and resolve any conflicting evidence.”¹⁹ For most civil cases, the preponderance of the evidence standard is used by default. In these cases, the plaintiff usually sues the defendant for financial loss due to damage, injury, and medical bills caused by the tort action. After both parties have presented their evidence during a trial, the judge rules on the apparent facts; and then the jury resolves the remaining issues, including whether the defendant is at fault and, if so, how much in damages the plaintiff should be awarded. The plaintiff must demonstrate the aforementioned factors using the “more likely than not” method to establish liabilities. However, the plaintiff often struggles to achieve that due to the fact that dental procedures can be complicated and involve many different factors, and it can be challenging to demonstrate that a particular dental procedure was done improperly or that a dentist failed to meet the appropriate standard of care. The expert witness is a crucial part of any dental malpractice litigation. Dental experts who can attest to the standard of care the defendant should have adhered to are commonly used as reliable evidence in this situation. The testimony of an expert can be very helpful in persuading the court to rule in the plaintiff's favor. The expert witness is significant for several reasons: First, experts can give precise and succinct testimony regarding the

¹⁸ *Karch v. Karch*, 2005 PA Super 342, 885 A.2d 535, 2005 Pa. Super. LEXIS 3570

¹⁹ *Barbour v. Mun. Police Officers' Educ. & Training Comm'n*, 52 A.3d 392, 2012 Pa. Commw. LEXIS 193

relevant standard of care; Second, they can also assist the jury in comprehending the defendant's departure from that standard. Additionally, they can discuss how the plaintiff's injuries related to the degree of that deviation. The expert witness can distinguish between winning or losing dental malpractice litigation.²⁰ The plaintiff in a malpractice case needs expert testimony to support her or his allegations of negligence and proximate causation before they can bring his problem to the jury for judgment. The expert must inform the jury of the standard in the defendant's professional community and apply the profession's standards to the facts. Then, the jury can determine whether the defendant violated his duty of care.²¹ The jury can be expected to understand common sense, such as knowing that one should not run a red light, but may not be aware of technical or specialized knowledge, such as the standard practice. So, there needs to be sufficient education in a professional case to explain to them what the duty of the case was and how it was breached.²² The expert is essential to successful results by the parties to a suit involving dental malpractice; at the same time, they are the dental profession's public relations representative. Through the medium of a public trial, the expert informs the public precisely how high the standards of his profession are. The sacred role of the expert witness is to vindicate the dental profession's standard of care and ethics. The American Dental Association Principles of Ethics and Code of Professional Conduct (ADA Code) states, "dentists may provide expert testimony when that testimony is essential to a just and fair disposition of a judicial or administrative action."²³

VII. **Res Ipsa Loquitur**

The patient must provide evidence that the dentist violated the standard of care to prove a duty breach. The exact interpretation of the standard of care varies by jurisdiction and can be difficult to apply to each specific case. Res ipsa loquitur refers to the treatment a reasonable dentist in a similar situation would have given her or his patient. The

²⁰ *Id*

²¹ *Id*

²² *Id*

²³ American Dental Association and American, *Principles of Ethics and Code of Professional Conduct*, 2020.

legal concept of *res ipsa loquitur* is Latin for "the fact itself speaks" or "the fact speaks for itself". Extraction for the wrong tooth is an apparent breach of duty that "speaks for itself." Some violations of the standard of care are so evident that expert testimony is not necessary. In such circumstances, the trial is shortened. The court will likely grant a summary judgment to the movant, or the jury can easily move on to awarding damages because the violation of duty is evident.²⁴ When *res ipsa loquitur* is an available doctrine, there is no need for the plaintiff to put forth expert testimony to sustain his burden of proof; when "the fact speaks for itself," the plaintiff is assured that the jury will be able to consider his case. In *Whetstine v. Moravec*, 1940, an action at law for personal injury damages was alleged to have been caused by the defendant's negligence in permitting the root of a tooth to pass into the plaintiff's right lung while extracting their teeth. During the extraction procedure, several teeth were fractured by the defendant. Unbeknownst to the defendant and the plaintiff, a part of the tooth's roots slipped into the patient's lung. The moment the plaintiff left the clinic, he felt terrible chest pain. The patient's lung underwent an x-ray, but nothing was found. After the extraction, the patient felt severe discomfort and kept coughing for nine months. One day, the plaintiff coughed out a tip of the root from his lung. The appellate court reversed the trial court ruling that erred in ordering a summary judgment in favor of the defendant. The court interpreted and asserted the concept of *res ipsa loquitur* applied in the malpractice case; thus, expert testimony was not necessary.²⁵ It is common sense that when a tooth or its root is extracted, neither usually enters the trachea or the lungs. This incident happens quite infrequently. In the eyes of the court, this incident was so uncommon and exceptional that there was a high likelihood of negligence just by virtue of its happening.²⁶

VIII. Proximate Causation

The patient must show that the dentist directly caused them damage through action or inaction. Causation in a dental malpractice claim must be "cause in fact," meaning that the patient's injury would

²⁴ *Id*

²⁵ *Whetstine v. Moravec*, 228 Iowa 352, 291 N.W. 425, 1940 Iowa Sup. LEXIS 269

²⁶ *Id*

not have occurred but for the dentist's carelessness. Additionally, "proximate cause"—the notion that the harm was a predictable result of their negligence—must be proven. The issue of proximate cause and injury is often a key defense in cases involving failure to diagnose cancer. In *Dien v. Seltzer*, 2014, the plaintiff was referred by her family dentist to the defendant, an endodontist, for root canal treatment. The plaintiff's family dentist noticed an ulcer on the left side of her tongue and referred her to an oral pathologist. The oral pathologist found that the plaintiff tested positive for oral squamous cell carcinoma. The plaintiff accused the defendant of deviating from the accepted standard of care in failing to perform a screening for oral cancer and to referring her to the oral surgeon for biopsy and treatment, thereby contributing to her injuries. The court found the defendant liable for the injuries due to a causation relationship between the defendant's negligence and the development of oral cancer.²⁷ The range of testimonial experts available to both plaintiffs and defendants in the case of failure to diagnose oral cancer is significantly wider than it is for other dental malpractice suits. The selection for expert witness for proof of causation and damages is not restricted to those solely with dental expertise and board licensure, but instead include many types of medical care providers with expertise in various specialties, such as otolaryngologists, oncologists, pathologists, and other physicians.²⁸

IX. Application of the Standard of Care in Dental Specialities

Dentists no longer only clean plaque or remove teeth. A dentist may also provide patients with sophisticated endodontic, periodontic, orthodontic, and other general or specialized care with training and board certification. The hazard of malpractice associated with offering those complex procedures has increased. The possibility of a poor

²⁷ *Dien v. Seltzer*, 116 A.D.3d 910, 984 N.Y.S.2d 129, 2014 N.Y. App. Div. LEXIS 2680, 2014 NY Slip Op 2744, 2014 WL 1613001

²⁸ Joel B. Epstein et al., "Failure to Diagnose and Delayed Diagnosis of Cancer," *The Journal of the American Dental Association* 140, no. 12 (December 2009): 1494–1503, <https://doi.org/10.14219/jada.archive.2009.0100>.

outcome rises so the patient may pursue legal action.²⁹ A dental specialty is a particular focus within dentistry and oral health. There are 12 specialties recognized by the American Dental Association (ADA) and the National Commission on Recognition of Dental Specialties and Certifying Board (NCRDSCB). The 12 specialties are Dental Anesthesiology, Dental Public Health, Endodontics, Oral and Maxillofacial Pathology, Oral and Maxillofacial Radiology, Oral and Maxillofacial Surgery, Oral Medicine, Orofacial Pain, Orthodontics and Dentofacial Orthopedics, Pediatric Dentistry, Periodontics, and Prosthodontics.³⁰ Those specialties require additional knowledge and training after the completion of dental school. This may include a residency, a master's degree, or a doctorate (Ph.D. or M.D.) Since dental school offers rotations for the specialties in the dental school clinical training, in some states, general dentists can perform some of the same services that a specialist offers.³¹ To properly understand the dentist's legal duty, a study must be made of how the malpractice hazards and standard of care are applied to certain dental specialties.

X. Oral and Maxillofacial Surgery

Oral maxillofacial surgeons are the only dental specialists recognized by the American Dental Association who get at least four years of surgical training in a hospital-based residency program. They spend time in otolaryngology, plastic surgery, emergency medicine, and other subspecialties. Oral and maxillofacial surgeons treat patients with wisdom tooth problems, face discomfort, and misaligned jaws. They treat trauma victims with facial injuries, insert dental implants, treat patients with oral cancer, tumors, and jaw cysts, and conduct cosmetic surgery on the face. Their comprehensive expertise in anesthesia enables them to give great care in a safe and comfortable office

²⁹ Joseph P. Graskemper, "Dental Law in the United States of America," *Forensic and Legal Dentistry*, November 15, 2013, 89–98, https://doi.org/10.1007/978-3-319-01330-5_14.

³⁰ "Dental Specialties." n.d. www.cda.org. <https://www.cda.org/Home/Public-Health/Careers-in-Oral-Health/Dental-Specialties>.

³¹ *Id*

environment.³² According to research conducted by Shahid Beheshti University of Medical Sciences, oral and maxillofacial surgery is a dental field where errors most often occur.³³ Most dental malpractice cases involve expensive procedures like extraction and dental implants, same with malpractice involving oral and maxillofacial surgery. Teeth extractions are a practical aspect for analysis, with only oral surgeons being capable of carrying out the majority of extractions. The idea of extraction for jurisprudential reasons should not be viewed as merely the act of pulling the tooth out of its socket with force; rather, it encompasses a comprehensive process that includes diagnosis, post-operative care, and follow-up by oral surgeon. For example, failing to notify the patient that a root has been left in the gum is considered malpractice. An oral surgeon must exercise extra caution to avoid breaking off a burr (a cutting instrument), an elevator (a tool used to take the tooth from the gum socket), or allowing one to stay in the patient's gum.³⁴ The jury and court often scrutinize the oral surgeon's practice; teeth extraction procedures are the most common suits in which the oral surgeon or general dentists are named defendants.³⁵ Failure to notice that an instrument has been damaged or a failure to take reasonable precautions to prevent metal in a patient's gum, would constitute malpractice.³⁶ Additionally, oral surgeons can prevent losing the lawsuits by clearing any potential allegation for a claim that their equipment was not sterile in infection.³⁷ Any sign of infection following the surgery must be handled immediately. The courts have recognized that it is important to refer patients to a physician or a hospital setting if the oral surgeon becomes aware of facts that would raise suspicions of an infection.³⁸ Cancer misdiagnosis and delayed diagnosis can significantly affect patients' morbidity and mortality. The dentist should

³² "Dental Students | AAOMS," www.aaoms.org, accessed January 6, 2023, <https://www.aaoms.org/education-research/dental-students>.

³³ Mehrzad Kiani and Ardeshir Sheikhazadi, "A Five-Year Survey for Dental Malpractice Claims in Tehran, Iran," *Journal of Forensic and Legal Medicine* 16, no. 2 (February 2009): 76–82, <https://doi.org/10.1016/j.jflm.2008.08.016>.

³⁴ *Rawleigh v. Donoho*, 238 Ky. 480, 482, 38 S.W.2d 227-28 (1931).

³⁵ *Acton v. Morrison*, 62 Ariz. 139, 142, 155 P.2d 782, 783 (1945).

³⁶ *Id*

³⁷ See *Rising v. Veatch*, 117 Cal. App. 404, 3 P.2d 1023 (1931); *Specht v. Gaines*, 65 Ga. App. 782, 16 S.E.2d 507 (1941).

³⁸ *Haliburton v. General Hosp. Soc.*, 133 Conn. 61, 48 A.2d 261 (1946).

be on the lookout for head and neck cancer, oral pre-malignancies, and neoplasms. Dental care as an early oral cancer diagnostic has ramifications for the law and patient care. Dentists in all specialties must take in-depth patient histories; conduct thorough head, neck, and oral exams; and recognize the need for oral surgeons to perform biopsies of the abnormalities that could help spot potentially cancerous diseases early. In the case of *Minor v. Casten*, 1988, the plaintiffs appealed a judgment. The issue is the statute of limitation in a wrongful death and survival action based on dental malpractice. After Minor scheduled a dental appointment, he claims that his dentist told him to begin spraying Chloraseptic[®], a medicine used for temporary throat irritation relief, on a lesion on the roof of his mouth. His dentist never referred him to an oral surgeon or treated the spot as potentially cancerous. After doing a mouth biopsy on Minor, an oral surgeon discovered squamous cell cancer. Later, after being brought to the hospital, the right half of his tongue and a part of his jaw and neck were removed. Minor passed away soon after. Under the Louisiana Medical Malpractice Act (La. R.S. 40:1231.1 et seq.)³⁹, a malpractice claim must be filed within one year of the date of the alleged act, omission, or neglect, or within one year of the date the alleged act, omission, or neglect was discovered or should have been discovered. The statute also imposes an overall time limit, stating that a claim cannot be filed more than three years after the date of the alleged act, omission, or neglect. In the current case, the lawsuit was filed within the three-year window, which aligns with the statute's intent. Furthermore, the statute allows survivors to claim damages that the deceased experienced before their death. It also permits wrongful death actions, enabling survivors to seek compensation for their own losses resulting from the death. These actions can be filed within a year from the date of death. Therefore, the court ruled that the trial court's judgment was reversed, which favored the plaintiff.⁴⁰ In the cases that cancer diagnosis was delayed, which likely permitted the disease to progress to a more advanced stage and more intrusive treatment (chemotherapy) could result in increased morbidity or mortality. All dental professionals, regardless of their specialization, are trained to

³⁹ "Louisiana Laws - Louisiana State Legislature." n.d. Legis.la.gov. Accessed April 2, 2023. <http://legis.la.gov/legis/Law.aspx?d=108286>.

⁴⁰ *Minor v. Casten*, 521 So. 2d 465, 1988 La. App. LEXIS 312

recognize and be on the lookout for pathology in the head and neck. Delays in diagnosis are common allegations in malpractice involving patients with cancer, and such omission is unjustifiable.

XI. Dental Anesthesiology

Depending on the patient's treatment, the dentist must decide whether to administer local or general anesthesia. For minor oral procedures, local anesthesia is preferred over general anesthesia because it is less expensive. Local anesthesia also allows the patient to remain awake and is less risky than general anesthesia. In general anesthesia, several advantages emerge, such as easing patient discomfort and accelerating surgical procedures. Using anesthetics should be done with the utmost caution as they are toxic. Because of this, the dentist should prioritize the patient's safety before selecting or approving a certain type of anesthesia. The dentist, however, can not guarantee the success of each anesthetic treatment. In *Langis v. Danforth*, 1941, the dentist owes the duty of care to the patient after the anesthesia is performed. In this case, while the patient was still affected by the anesthesia, the patient left the office without being discharged since the patient was unwatched.⁴¹ Then, the patient fell out the window, suffering injuries for which the dentist is liable.⁴² A notable issue is whether administering anesthesia in pediatric dentistry is a standard of care. In dentist clinics around the nation, children who need their teeth pulled or cavities filled occasionally undergo sedation to reduce their anxiety and facilitate their collaboration. Children rarely go much farther into a deep sedation state. If the dentist omits the sign that a young patient is in a deep sedation state, they might stop breathing or die. The dentist or dental assistant must closely monitor the patient's vital signs and be able to determine changes in their condition. Under the tort doctrine or in the eyes of the court, the fact that the patient died is insufficient to prove a claim for malpractice brought about by the administration of an anesthetic. The dentist's violation of one of her or his duty of care must be demonstrated. For instance, in *Sanzari v.*

⁴¹ *Langis v. Danforth*, 308 Mass. 508, 33 N.E.2d 287, 1941 Mass. LEXIS 718

⁴² Allen L. Perry, *Malpractice in Dental Anesthesiology*, 13 *Clev.-Marshall L. Rev.* 319 (1964)

Rosenfeld, 1961, the dentist was found liable for the patient's death because he failed to abide by the manufacturer's brochures instructions. The administration of anesthesia in combination with Xylocaine and epinephrine by dentists has been observed to result in an increase in the patient's blood pressure. However, it is noteworthy that the use of epinephrine is contraindicated in cases where the patient suffers from hypertension, a condition that was duly highlighted in the brochure provided to the patient. The rapid attainment of the bursting point of blood vessels in hypertensive patients is triggered by the heightened blood pressure levels, a phenomenon that necessitates only a minor quantity of epinephrine to induce. Consequent to such vascular rupture, cerebral infarction or hemorrhage - commonly referred to as stroke - may ensue. According to the expert testimony, Mrs. Sanzari's hypertension condition was worsened by the dentist's injection of an epinephrine-containing anesthetic, which led to a brain hemorrhage and her death.⁴³

XII. Endodontics

Clinical endodontic surgeries involve highly technique-sensitive procedures. Endodontic-related cases in various specialties of dentistry witness the most frequently filed malpractice claims. This is due to the fact that endodontic treatment procedures involve operative and surgical procedures using a variety of medications and techniques. Endodontic procedural malpractice can involve preoperative errors such as misdiagnosis; intraoperative errors like treatment mistakes, perforations, anatomical injury, and hypochlorite-induced nerve damage; and postoperative errors including infections, bleeding, tooth cracks, inadequate referrals, improper medication, paresthesia, and retained fractured instruments. In the case of *Magos v. Feerick*, 1996, the dentist was found liable for a dental malpractice allegation due to his patient's root perforation caused by his error. The plaintiff went to the defendant (a general dentist) for damaged tooth repair. The defendant performed root canal therapy and cemented the tooth with permanent crowns. Shortly after the visit, the plaintiff began experiencing pain and discomfort in the gums above where the crowns

⁴³ *Sanzari v. Rosenfeld*, 34 N.J. 128, 167 A.2d 625, 1961 N.J. LEXIS 199

were cemented. According to the plaintiff's testimony, "the pain and discomfort included swelling, bleeding, and discoloration of the gums accompanied by a foul odor." However, the defendant only suggested the plaintiff massage her gums and rinse her mouth with Listerine mouthwash. Due to the continued pain and discoloration of her gums, the plaintiff visited another dentist who discovered that she had open margins surrounding the permanent crown. Soon, the dentist discovered that both front teeth had been perforated at the root under the gumline. The appellate court reversed the trial court ruling, and the court entered judgment in favor of the plaintiff in her dental malpractice allegation and awarded damages.⁴⁴ In the case of *Rorick v. Silverman*, 2015, the dentist faced liability for the malpractice allegation due to deviating from the standard of care and leaving a fragment of a broken instrument in the patient's tooth. The plaintiff alleged that the defendant performed root canal treatment on her and that she "began to experience headaches and also experienced tooth decay and infections with these same teeth and eventually lost two of these teeth." She then received treatment from another dentist, who found her symptoms stemmed from the defendant's negligent performance of root canal treatment. The defendant had not completed the root canal treatment completely or correctly according to the standard of care and had left a piece of a file in one of her teeth. After her treatment with the new dentist, the plaintiff no longer suffered from the headaches she had suffered over the previous eleven years. The court's judgment was entered in favor of the plaintiff in her dental malpractice allegation, and damages were awarded.⁴⁵ A research paper analyzed 650 endodontic-related malpractice lawsuits in the United States from 2001 to 2021; 86.6% of the defendants were general dentists; 43.75% of the cases favored the plaintiff, 55.2% of the cases favored the defendant, and 1.04% of the cases were settled without going to trial. The court rulings that favored the plaintiffs were based on allegations involving root (root canal and cementum) perforation, failure to use a rubber dam, root canal therapy performed on the wrong tooth, and paresthesia caused by infections. Plaintiffs who alleged postprocedural cases had a notably higher winning rate than non-

⁴⁴ *Magos v. Feerick*, 690 So. 2d 812, 1996 La. App. LEXIS 3052, 96-0686 (La.App. 3 Cir. 12/26/96)

⁴⁵ *Rorick v. Silverman*, 2015 U.S. Dist. LEXIS 170649

postprocedural cases. 77.08% of the litigations consisted of intraprocedural malpractice claims, which consist of the most common reason for litigation in endodontic therapy. In the study, the plaintiffs won 75% of the litigation attributed to postprocedural infections. Thorough irrigation of root canals is important to reduce infection, and failure of the dentist to abide by the standard of care and surgical protocols is the main cause of malpractice suits. The paper indicates that in 72.7% of cases the court rules in favor of the plaintiff, which indicates a high proportion of the cases the dentists lost.⁴⁶ Failure to use a rubber dam may result in the ingestion of endodontic instruments, which constitutes malpractice and potentially technical assault. S.C. Barnum invented the rubber dam in 1862.⁴⁷ The rubber dam enables the dentist to work in an aseptic field and apply gold foil and mercury restorations for dental fillings. The rubber dam's most crucial function in endodontic surgeries is to avoid the ingestion and aspiration of tooth debris and root canal tools and provide a field free of saliva and microbes. In a joint survey conducted by Veterans Administration Hospital in San Francisco and Loyola University Dental School in Chicago, the survey discovered that "37% dentists never or rarely apply the rubber dam for endodontic surgeries, 20% applied it occasionally, and 43% always applied it."⁴⁸ It is shocking that there are still a significant number of dentists who are not using the rubber dam. Yet, the incidence of ingestion or aspiration of reamers, files, and broaches has increased significantly since the twenty-first century. The reasons given by dentists who are not using the rubber dam according to the survey are mostly laziness. The fact is that the rubber dam can be applied in a minute; furthermore, the surgery will proceed more smoothly because there is no saliva. When dentists weigh the simplicity of applying the rubber dam against the risk of a patient swallowing the instrument, it is almost incredible that they

⁴⁶ King-Jean Wu et al., "Endodontic Malpractice Litigations in the United States from 2000 to 2021," *Journal of Dental Sciences*, November 2022, <https://doi.org/10.1016/j.jds.2022.11.008>.

⁴⁷ Louis I. Grossman, "Prevention in Endodontic Practice," *The Journal of the American Dental Association* 82, no. 2 (February 1971): 395–96, <https://doi.org/10.14219/jada.archive.1971.0052>.

⁴⁸ Robert E. Going and Vincent J. Sawinski, "Frequency of Use of the Rubber Dam: A Survey," *The Journal of the American Dental Association* 75, no. 1 (July 1967): 158–66, <https://doi.org/10.14219/jada.archive.1967.0187>.

would subject their patient to such hazard and expose themselves to malpractice litigation.⁴⁹ With a high level of technique sensitivity, endodontics is the most involved specialty in dental malpractice litigations.⁵⁰ Patients who are dissatisfied with a service tend to initiate legal lawsuits. According to reports, pain after root canal treatment affects 9.6% to 12% of patients.⁵¹ Thus, probably 10% of patients who undergo root canal treatment are potential plaintiffs. In the present study, 55.2% of endodontic litigation favored dentists in the US.⁵² General dentists refer complicated cases to endodontists and treat them carefully to avoid paresthesia, root canal perforation, and infections. Dentists should always diagnose and treat patients correctly, share the procedure plan with the patient, and use rubber dams routinely and timely to prevent malpractice claims.⁵³

XIII. The Statute of Limitation

The statute of limitations will not start to run until the patient is informed of the omission that caused harm; therefore, it is necessary and ethical to inform the patient of any unfavorable outcomes immediately after the dental procedure. The dentist breaks a sacred duty of care by intentionally remaining silent, which engages in not only malpractice but also fraud and technical assault. In the case *Morrison v. Acton*, 1948, the defendant removed the plaintiff's wisdom teeth. After the extraction, the plaintiff suffered infections and paresthesia. Years later, another dentist removed considerable scrap of metal instruments from the plaintiff's jawbone, and the plaintiff's symptoms were relieved. In this

⁴⁹ *Id*

⁵⁰ Alice Aquino ZANIN, Lara Maria HERRERA, and Rodolfo Francisco Haltenhoff MELANI, "Civil Liability: Characterization of the Demand for Lawsuits against Dentists," *Brazilian Oral Research* 30, no. 1 (2016), <https://doi.org/10.1590/1807-3107bor-2016.vol30.0091>.

⁵¹ N. Polycarpou et al., "Prevalence of Persistent Pain after Endodontic Treatment and Factors Affecting Its Occurrence in Cases with Complete Radiographic Healing," *International Endodontic Journal* 38, no. 3 (March 1, 2005): 169–78, <https://doi.org/10.1111/j.1365-2591.2004.00923.x>.

⁵² *Id*

⁵³ Mothanna Alrahabi, Muhammad Sohail Zafar, and Necdet Adanir, "Aspects of Clinical Malpractice in Endodontics," *European Journal of Dentistry* 13, no. 03 (July 2019): 450–58, <https://doi.org/10.1055/s-0039-1700767>.

dental malpractice litigation, the jury rendered a verdict in favor of the plaintiff. Sufficient evidence of a breach of the standard of care and causal connection between the alleged negligence and the plaintiff's injury supports a malpractice verdict. The court ruled that the defendant's silence and non-disclosure of the true condition of the plaintiff's jaw and teeth were fraudulent concealments, and it halted the running of the statute of limitations until the plaintiff discovered the breach of trust; thus, the case was not barred by the statute of limitations.⁵⁴ In the case of *Hotelling v. Walther*, 1942, the defendant—a general dentist—left a root in the plaintiff's gum after the extraction for a year without knowing it. The plaintiff's tooth socket was infected and exuded much greenish pus until an oral and maxillofacial radiologist performed an x-ray image and disclosed two parts of the roots in a highly infected area surrounding the tooth socket. The dentist was liable for a continuing tort, for which the statute of limitations did not begin to run until the last treatment (the x-ray).⁵⁵ In *Warner v. Ross*, 2006, the defendant pulled a wisdom tooth from the plaintiff's mouth and later the plaintiff learned that the extraction caused nerve damage for her. Two years later, she filed a dental malpractice lawsuit. After summary judgment—a legal ruling that is made by a judge that the case can be resolved without a trial—was granted to the defendant, the plaintiff sought review. In affirming, the court determined that there was a two-year statute of limitations for medical malpractice claims under 27 V.I. Code Ann. § 166d(a) (2005).⁵⁶ The appellate court affirmed the trial court's judgment and interpreted that it was unreasonable for the patient to rely on the dentist's assurance that the symptoms would subside. The court was justified to affirm summary judgment in the defendant's favor based on the circumstances of this case. In accordance with public policy, disputes should be resolved quickly.⁵⁷ It would be unjust to the dentist in this situation if liability could be placed on an occurrence that took place more than two years before a lawsuit was filed. The majority of state legislatures have established that two years

⁵⁴ *Morrison v. Acton*, 68 Ariz. 27, 198 P.2d 590, 1948 Ariz. LEXIS 76

⁵⁵ *Hotelling v. Walther*, 169 Ore. 559, 130 P.2d 944, 1942 Ore. LEXIS 98, 144 A.L.R. 205

⁵⁶ 27 V.I.C. § 166d

⁵⁷ *Warner v. Ross*, 164 Fed. Appx. 218, 2006 U.S. App. LEXIS 646

is an acceptable amount of time to initiate a malpractice claim, and this ruling respects this legislative framework.⁵⁸

XIV. Conclusion

This review aims to give readers a general understanding of dental malpractice within the tort doctrine. Contemporary tort doctrine relating to malpractice has developed in accordance with the principles of English common law. Court rulings, law interpretations, and legislation have contributed to developing dental malpractice litigation frameworks. Most cases analyzed in this review demonstrate that dentists need more knowledge about malpractice and related legal regulations. The practical way to reduce dental malpractice and the subsequent lawsuit is to make dentists aware of their legal, administrative, professional, and ethical duty of care, and implore them to reflect that duty to their practice. Dentists should strengthen their professional skills, learn healthcare laws, and update their clinical practices through continuous education. Constant communication with other dental professionals within the same community can help them benchmark the standard of care. Additional legal studies are required to address the current state of dental malpractice. Dental malpractice cannot be solved easily or quickly. However, future reforms should continue to work toward creating an economically viable system that adequately compensates those hurt by malpractice, and discourages opportunistic lawsuits against dentists.

⁵⁸ Peter M. Sfikas, "Statute of Limitations Precludes Dental Malpractice Claim," *The Journal of the American Dental Association* 137, no. 5 (May 2006): 668–69, <https://doi.org/10.14219/jada.archive.2006.0265>.

The Rite of Rights: An Examination of Socio-Cultural Precedent in Japanese Law

Kristine Pashin

Almost any experience can be contextualized in the concept of culture. Culture is woven into the very fabric of our being, serving as a crucial part of humanity's evolution. Nevertheless, while culture is an amalgamation of the human habits of a community, law shapes how members of a society envision themselves and interact with one another (Geertz 230).¹ Law and culture cannot be separated, as a change in one would distort the interconnected nature of its counterpart. As an epitome of communitarianism, Japanese society's views of the moral world encompass principles of human rights, justice, and fairness through a lens that emphasizes the importance of "human interdependence (*amae*), connection (*en*) and the mutual responsibility of caring (*kikubari*)" (Inoue 527–528).² Thus, Japanese jurisprudence is centered on the use of law as a mechanism of communitarianism, centralizing the Japanese legal system on people's natural sense of morality and exerting hegemonic power.

Yet, all law remains a matter of myth and narrative. Cultural theory can only be grasped imperfectly when reproduced into law, as culture is a social construct often passed through various historical translations. Upon their interpretation and application in different communities, customs are bound to evolve as they are culturally and historically conditioned. In a similar manner, rules and laws do not have any "empirical existence that can be significantly detached from the world of meanings that defines a legal culture; the part is an expression and a synthesis of the whole"

¹ CLIFFORD GEERTZ, *LOCAL KNOWLEDGE: FURTHER ESSAYS IN INTERPRETIVE ANTHROPOLOGY* 230 (1983).

² Tatsuo Inoue, *The Poverty of Rights-Blind Communitarity: Looking Through the Window of Japan*, 1993 *BYU L. REV.* 517, 527-528 (1993).

(Nelken and Feest 3).³ The term “legal culture” is defined as the “legal consciousness, attitudes, values, beliefs, and expectations about law and the legal system” in its sociological context by legal scholars, a facet of its broader definition as a determination of “living law” (Peng 81).⁴

The Japanese legal system is intrinsically tied to the cultural identity of the nation. Thus, people’s ideas and expectations of justice and morality shape Japan’s rule of law. As the ritual of rights evolved in Japan, in response to socio-cultural and historical changes — from uprisings of the peasantry class to Western legal influence — significant legal change occurred alongside the transformation of the conventional view of rights in Japan.

I. Foundations of the Japanese Legal System

Aside from legal vocabulary that is concerned exclusively with the technical level of the law, legal comparativists emphasize the distinctiveness of each nation’s legal system by analyzing the interaction between law and social change. Though the foundation of modern Japanese law is based in the Meiji Era during a time of Western influence, early Japanese law was entirely based on Japanese custom (Stevens 1259).⁵ While matters of criminal and public law were influenced by pre-1868 traditional Chinese law, Japanese commercial society followed an entirely indigenous legal system. Moreover, there were no career lawyers in Japan or even any form of legal counseling, though a popular legal-commercial concept that arose alongside the nationwide rice trade was the idea of a law merchant. Law merchants developed makeshift legal rules for banking, regulation of commodities and exchanges, and corporate formation in trading guilds. In general, these informal legal systems in commerce intersected with Japanese social values, exerting “a strong, virtually overwhelming, pressure on the people to resolve their

³ DAVID NELKEN & JOHANNES FEEST, ADAPTING LEGAL CULTURES 3 (2001).

⁴ Shin-yi Peng, *The WTO Legalistic Approach and East Asia: From the Legal Culture Perspective*, 1 ASIAN-PAC. L. & POL’Y J. 78, 81 (2000).

⁵ Charles R. Stevens, *Japanese Law and the Japanese Legal System: Perspectives For the American Business Lawyer*, 27 THE BUS. LAW. 1259, 1259 (1972).

problems by themselves and without the aid of a third party” (Hahn 518).⁶ Throughout the Tokugawa Era (1503-1868), the doctrine of *wa* (social order and harmony) served as a state orthodoxy in commercial disputes and day-to-day social interactions to prevent these disagreements from reaching any formal stage of litigation (Hahn 519).⁷ Distinctions between social status led to tensions regarding the preservation of life, property, and honor, but the early Japanese legal framework allowed individuals to engage in a broad range of social interactions with the assurance that, if conflict arose, they would be given an equal chance to adequately defend their interests and reach a balanced agreement before any formal legal action.

The lives of the feudal *daimyō* and their porters were equal in essential value. A rich merchant protects his million *ryō* no more than the candy vendor protects his four mon, each as their own personal property . . . What was distressing for the peasants was also distressing for the lord of the manor; what was sweet for the lord was also sweet for the peasants (Fukuzawa and Dilworth 11).⁸

The conventional notion of “society” is encapsulated by the national and sovereign body, which re-orientates the socio-legal perspective to fit the needs of a particular nation. Japanese society prioritized social harmony, thus allotting an equal measure of rights-like entitlement for each individual. Japan’s legal institutions were transformed to fit into the working of the sovereign state amidst new forms of social conflict and political domination (Nelken and Feest 103).⁹ In this period, the ethical and philosophical teachings of Confucianism were the primary processes of dispute resolution. Conciliation was merely a social control mechanism, showcasing the emergence of a legal order whose origins were significantly outside the Greco-Roman and Hebraic-Christian traditions that govern the modern, westernized rule of law that emphasizes the entitlements of

⁶ Elliot J Hahn, *An Overview of the Japanese Legal System*, 5 NW. J. INT’L L. & BUS. 517, 518 (1983).

⁷ *Id.* at 519.

⁸ YUKICHI FUKUZAWA & DAVID A. DILWORTH, AN ENCOURAGEMENT OF LEARNING 11 (2013).

⁹ NELKEN & FEEST, *supra* note 3, at 103.

the individual (Von Mehren 534–535).¹⁰ In Western cultural tradition, rights-like entitlements clearly reflected Western interests, serving as a weapon of cultural hegemony during times of imperialism. Social upheaval instigated by the peasantry class of Japan during the Tokugawa period, from 1603 to 1868, stimulated the potential idea of “rights” into the Japanese legal and socio-cultural vocabulary, urging a vehement defense in favor of individual rights and privilege-based entitlements (Feldman 22–23).¹¹ In Tokugawa Japan’s rigid, feudal society, peasants were viewed with disdain in the eyes of the elite and denied access to education, freedom of movement, and occupational choice.

Those people whom we call peasants are no better than cattle or horses. The authorities pitilessly compel them to pay heavy taxes . . . The arrogant behavior of these officials is like that of a heartless driver of some horses or ox; after loading it down with a great weight he proceeds to rain blows upon it; then when it stumbles he becomes more and more angry, cursing it loudly and striking it even with greater force – such is the fate of the peasant (Norman 326).¹²

Protests consequently erupted alongside various filings for legal appeals, amidst 3,000 to 7,000 peasant rebellions throughout the entire Tokugawa period. Confucian thought, which emphasized a natural hierarchy of higher and lower beings to maintain the legitimacy of Japanese imperial rule, linked the consciousness of Tokugawa peasants with the web of obligations between peasants and lords. This peasant-lord dynamic characterized a similar legal framework to that of the *shōen* system, where autonomous estates or manors were the core of economic organization in medieval Japan. The *shōen* system allowed villages to become self-governing units, with a nobleman presiding over each estate/*shōen* and the several different parties living within it. Even though peasants had little power to enforce their rights, they were correct in understanding the early

¹⁰ Arthur Taylor Von Mehren, *Conciliation and Japanese Law*, 25 J. ASIAN STUD. 534, 534–535 (1966).

¹¹ ERIC A. FELDMAN, *THE RITUAL OF RIGHTS IN JAPAN: LAW, SOCIETY, AND HEALTH POLICY* 22-23 (2000).

¹² E. H. NORMAN, *ORIGINS OF THE MODERN JAPANESE STATE* 326 (1975).

practice of Japanese legal disputes. The series of obligations that bound rulers and subjects together manifested the limits of Confucian traditions, ideating Japan's first "rights" in the form of the "quasi-political right of subsistence" (Feldman 24–25).¹³

II. The Early Construct of Rights

Japanese legal history cannot be fully understood without understanding the complexity of the construct of rights in Japan. The history of imperial Japan is "a history of the way courts enforced claims to scarce resources... a history of property rights" (Ramseyer 163).¹⁴ The first rules of law with regard to "rights" emerged in the eleventh and twelfth century in Japan under the shōen system that structured medieval economic organization. As this societal structure developed, the peasant and proprietor relationship did too. Legal authority was exercised to establish rules that emphasized "mutual dependence and empowerment" in regard to profit, land use, and occupancy. For example, when conflicts arose between peasants and other individuals, peasants were instructed to use petitions (*hyakushō mōshijō*) as a way of listing their grievances, implying an expectation of assistance on the part of the proprietors with problems like excessive rent (Keirstead 94–95).¹⁵ Though occurrences like these may not have encompassed all elements of the modern definition of "rights," they contained its key characteristics. These essential components included a standardized definition of "rights" for common people in society and a shared understanding of these entitlements' purpose of achieving societally-beneficial aims. Since they were established through a form of social governance, the rights-like correlations in the shōen system viewed rights as privileges that could be claimed with justification.

Another aspect of the shōen system, known as *shiki*, demonstrates an early example of Japanese legal rule under the Kamakura Shogunate from 1192 to 1333, through formal judgment on a disputed matter. The term "shiki" refers to the network of rights

¹³ FELDMAN, *supra* note 11, at 24-25.

¹⁴ J. MARK RAMSEYER, *ODD MARKETS IN JAPANESE HISTORY: LAW AND ECONOMIC GROWTH* 163 (2008).

¹⁵ THOMAS KEIRSTEAD, *THE GEOGRAPHY OF POWER IN MEDIEVAL JAPAN* 94-95 (1992).

that gave an individual proprietorship of and allowed them to gain income from cultivated land (Haley, *Authority Without Power* 42).¹⁶ The highly developed legal system of the new military government, the Kamakura Bakufu, “gave direction to the whole group and administered justice on the basis of local customary law rather than the old Chinese-type codes of the imperial court” (Reischauer and Jansen 53).¹⁷ This shift in the number of rights allotted to the individual mirrored the socio-political shift in Japan from a system of centralized rule to feudalism, blurring the boundaries of legal policy fueled by cultural customs.

Though *shiki* maintains a strong resemblance to the sociological interpretation of “rights,” the word itself cannot be translated to bear the same definition. The Kamakura period was constituted by a rights-conscious Japanese society, but there was a lack of Japanese legal vocabulary to express European legal concepts that legal scholars now typify as the basis for “modern” rule of law which emphasizes justice, equality, and representation for the individual.

III. From “*regt*” to “*kenri*”

Most accounts of the translation of Western legal texts begin with Mitsukuri Rinshō, and his grandfather, Mitsukuri Genpō, who was the pioneer in translating European legal codes into Japanese (Feldman 17).¹⁸ The definition of “right” in Japanese legal procedure began to take hold in 1839 when Mitsukuri Genpō was instructed by the Japanese government to translate the Dutch legal codes. In Dutch, the word “*regt*” is the combined meaning of the English terms “right” and “law.” In a similar manner, by combining the word “*tadashii*,” meaning correctness and justice, with “*ritsu*,” meaning law or regulation, to form the word “*seiritsu*,” Mitsukuri Genpō considerably advanced the discussion of law and natural rights in Japan; this was the first Japanese translation of the

¹⁶ JOHN OWEN HALEY, *AUTHORITY WITHOUT POWER: LAW AND THE JAPANESE PARADOX* 42 (1996).

¹⁷ EDWIN O. REISCHAUER & MARIUS B. JANSEN, *THE JAPANESE TODAY: CHANGE AND CONTINUITY* 53 (1995).

¹⁸ FELDMAN, *supra* note 11, at 17.

European terminology for “rights” (Feldman 18).¹⁹ To expand on his prior research, he became an official translator for the *bakufu* — the military government of Japan between 1192 and 1868 — during Matthew Perry’s visit in 1853 (Calman 272–273).²⁰

Years later, as a result of the American-Japanese Treaty of Commerce of 1858, the 200-year seclusion of Japan abruptly came to an end. In the ensuing years, violence directed towards foreigners and sympathetic officials erupted in Japan. While Shogun Jemochi tried to handle these uprisings, he was unable to rally enough forces to quench the capital of anti-foreign sentiment. Following his death in the fall of 1866, one of his advisors, Keiki, assumed the position as the fifteenth Shogun in January 1867. Within a month, Emperor Kōmei passed away, leaving his heir, Emperor Mutsuhito, better known by his reign name of Meiji, to serve as the head of state (Yanaga 42–45).²¹ The Meiji era forced dynamic cultural change via westernization, which influenced the modernization of Japanese jurisprudence into a legal system that abides by Western rule of law. The singular purpose of Meiji’s reign, illustrated by his Restoration Rescript that was issued in January 1868, was “to place Japan in a position where it might assume its rightful place in a strong family of nations” (Scott 326).²²

Despite an earlier interest in the Dutch legal theory of rights, it was French law rather than Dutch law that first had a considerable Western influence on Japanese law. When the Japanese emperor’s government was looking for a potential legal model in the early 1870s, France was considered to have the most developed codified legal system. In 1870, France had modernized their legal system, moving to a civil law system (referred to as the civil code) and codifying several branches of law, including commercial and criminal law. In an effort to protect Japan’s economic and political interests with Western imperialism on the rise, Japan’s first Minister

¹⁹ *Id.* at 18.

²⁰ DONALD CALMAN, *THE NATURE AND ORIGINS OF JAPANESE IMPERIALISM: A REINTERPRETATION OF THE GREAT CRISIS OF 1873* 326 (1992).

²¹ CHITOSHI YANAGA, *JAPAN SINCE PERRY* 42-45 (1975).

²² Geoffrey R. Scott, *The Cultural Property Laws of Japan: Social, Political, and Legal Influences*, 12 *WASH. INT’L L.J.* 315, 326 (2003).

of Justice, Shinpei Etoh, authorized a study of the French legal system. Taking into account the French legal system, Japanese legal scholars were directed to further expand Japan's criminal code (*ritsu*) and administrative and civil codes (*ryō*) that were built from Confucian and Chinese legalist principles. In this period, similar to his grandfather, Mitsukuri Genpō, Mitsukuri Rinshō became an important figure in Japan's Ministry of Justice when he was commissioned in 1870 to translate the French Civil Code into Japanese for possible adoption in Japan (Tanaka 163).²³ However, after conducting his preliminary research, he was at a loss as to how the French expression *droits civil* (civil rights) could be translated into the Japanese legal vernacular, as described in the following situation:

Whereupon at that time I translated the words *droits civil* as *minken* [people's powers or authority] there was an argument over what did I mean by saying that the people have power [*ken*]. Even though I tried to justify it as hard as I could, there was an extremely furious argument... (Tanaka 305).²⁴

Since many Japanese failed to accept the concept of people having rights, Mitsukuri Rinshō decided to use "*kenri*" as the Japanese equivalent of the French phrase "*droits civil*." The word "*kenri*" is a derivation of the combination of the Chinese characters "*kenni*," meaning authority, power, dignity, and prestige, and "*kensei*," meaning power and influence (Feldman 17–20).²⁵ Though the term "*kenri*" still remains relevant in the legal sphere of modern-day Japan, the attempt to literally translate the French Civil Code and apply it to the Japanese legal system was unsuccessful. This disjuncture between Japanese legal language and nineteenth-century Western legal concepts exemplified the relationship between law and its context, where the "language-in-use is closely tied to the expression of the shared beliefs of that tradition" (MacIntyre 384).²⁶ Legal concepts cannot simply be translated to fit a new host; rather,

²³ HIDEO TANAKA, *THE JAPANESE LEGAL SYSTEM: INTRODUCTORY CASES AND MATERIALS* 163 (2000).

²⁴ *Id.* at 305.

²⁵ FELDMAN, *supra* note 11, at 17-20.

²⁶ ALASDAIR MACINTYRE, *WHOSE JUSTICE? WHICH RATIONALITY?* 384 (1998).

different kinds of law relate to different kinds of community bonds that can only be formed by traditional identity, shared beliefs, and affective involvements.

IV. The “Modernization” of the Japanese Legal System

As national systemic influence changed, the French legal tradition declined, in favor of the Germanic civil tradition, as a result of theoretical controversies (Scott 329).²⁷ This historic development was of great significance to the formation of the Japanese civil law tradition, which concerns itself with the dynamics between members of a community, emphasizing human interdependence (*amae*) and the mutual responsibility of caring (*kikubari*). The 1889 Meiji Constitution was one of the first “modernized” legislative provisions for fundamental rights, modeled after Western governmental structure. In effect, it created a system of parliamentary supremacy, except concerning institutions directly subject to imperial command or the judiciary. This system determined that the constitutionally mandated “rights of subjects” could be restricted by legislative, but not administrative, action (Franklin and Baun 99).²⁸ Amidst this struggle for power and political reform, one of the most prominent movements of the Meiji era, the Movement for Freedom and Popular Rights, was founded by Itagaki Taisuke, a rōnin that was absorbed by the rapidly growing government bureaucracy, and other such masterless samurai. There were hundreds of affiliated local organizations that each boasted a member count in the hundreds of thousands (Feldman 27).²⁹ One manifesto of the movement clearly draws inspiration from the three principal examples of unalienable rights mentioned in the United States Declaration of Independence:

We, the thirty millions of [*sic*] people in Japan, are all equally endowed with certain definite rights, among which are those of enjoying and defending life and liberty, acquiring and possessing property, and obtaining a livelihood and pursuing happiness. These rights are by Nature bestowed upon all men,

²⁷ Scott, *supra* note 22, at 329.

²⁸ DANIEL P. FRANKLIN & MICHAEL J. BAUN, *POLITICAL CULTURE AND CONSTITUTIONALISM: A COMPARATIVE APPROACH* 99 (2015).

²⁹ FELDMAN, *supra* note 11, at 27.

and therefore, cannot be taken away (Bowen 109).³⁰

Utilizing new, “Western-style” concepts to illustrate that “life and liberty” and “obtaining a livelihood and pursuing happiness” were rights “Nature bestowed upon all men,” the rhetoric of this manifesto closely echoes a well-known phrase from the United States Declaration of Independence which states that each individual deserves the right to “Life, Liberty and the pursuit of Happiness.” This direct causal link between Japanese exposure to and concurrent integration of the Western legal system demonstrates a style of legal transplants through social conflict that changed the landscape of Japanese values.

V. The Movement of the Law

Legal transplants refer to “the moving of a rule ... from one country to another, or from one people to another” (Watson 21).³¹ The nomadic character of law proves the idea of a close relationship between law and society in legal theory, but this interpretation is a fallacy in the context of the explicit rules that govern society (Watson 108).³² While the act of interpreting the law is subjective and dependent on the workings of the social, historical, or cultural substratum, rules themselves are only bare propositional statements. Thus, the meanings ascribed from rules are “a function of the interpreter’s epistemological assumptions which are themselves historically and culturally conditioned” (Nelken and Feest 58).³³ This subjective interpretation is constitutive of a community’s articulated values and allows distinct cultural identities to endure.

Accordingly, legal transplants cannot, in effect, simply happen. It is improbable to translate a rule and extend its similarity to the borrowing nation past the bare form of the words themselves because “no language has identical taboos with any other...; no language dreams precisely like any other” (Steiner 10).³⁴ Rather,

³⁰ ROGER W. BOWEN, REBELLION AND DEMOCRACY IN MEIJI JAPAN: A STUDY OF COMMONERS IN THE POPULAR RIGHTS MOVEMENT 109 (1984).

³¹ ALAN WATSON, LEGAL TRANSPLANTS: AN APPROACH TO COMPARATIVE LAW 21 (1993).

³² *Id.* at 108.

³³ NELKEN & FEEST, *supra* note 3, at 58.

³⁴ GEORGE STEINER, WHAT IS COMPARATIVE LITERATURE? 10 (1995).

each legal transplant must suggest a specific relationship between rules and their content matter. The Japanese rule of law alludes to a modality of legal experience that is an intrinsically Japanese incorporative cultural form. These rules are part of the cultural expression and synthesis which define a nation's legal culture. Rules exist in a larger cognitive framework and articulate cultural sensibilities through the language of the text.

This relationship between the inscribed words that constitute rules in their bare propositional forms and their connected ideas is arbitrary because of its cultural determination (Nelken and Feest 61).³⁵ The word "regt," which contextually places value on individual rights, means something different to the Dutch than the Japanese word "kenri," which emphasizes social harmony as a right that benefits the community. To recapitulate, we cannot reduce law to rules and rules to bare propositional statements. While a given rule displaced amongst nations with Western cultural backgrounds is potentially equally at home anywhere in the Western world, these same legal transplants cannot occur between Western and East Asian nations without a change in the host culture's inherent values and integrative capacity.

VI. The Paradigm of Modern Japanese Law

The founders of the Movement for Freedom and Popular Rights were the first in Japan to continue the development of rights in its political sphere. They promoted a system in which individuals could participate in the government but could not assert their rights against it. According to Donald Calman, "They still appeared to think that the government was in some way of a higher status than the people, and could not convince themselves that the tasks entrusted to the government were in no way superior to those performed by the people" (Blacker 114).³⁶ While influential political thinkers like Etō Shinpei believed that the popular assembly had little value without public appreciation of rights, appeals to a rule of law that affirmed the creation of Japanese civil rights were rejected

³⁵ NELKEN & FEEST, *supra* note 3, at 61.

³⁶ CARMEN BLACKER, *THE JAPANESE ENLIGHTENMENT* 114 (1964).

by government authorities (Calman).³⁷ The political and legal sensibility of rights was not anomalous in the society of nineteenth-century Japan. Many protestors regularly engaged in the ritual of rights in support of litigation which would “guarantee happiness and... regain rights for our members” (Bowen 20).³⁸ However, the Japanese body politic saw the pursuit of individual rights as a disruption of social harmony.

Pre-World War II Japan placed priority “on moral (*giri*) over legal obligations (*gimu*)” and “humaneness (*nin jyō*) over rights (*kenri*)” in order to appeal to national values and traditions at the expense of individualism and justice (Dale 106).³⁹ Instead, rights were present within Japan’s communitarian nature, which allowed individuals to cultivate their fields, protect their economic livelihood, and settle social conflicts without legal involvement. Even in the modern, postwar civil law system, potential Japanese litigants continue to encompass an aversion to the courthouse, in fear that public trial might inflict a sense of “shame” on those in defiance of a widely accepted societal norm (Haley, *Law and Culture in China and Japan* 897).⁴⁰ To have one’s rights emphasized in court meant telling another that they had erred, and the legal system detests such judgments in favor of the preservation of social order and harmony (Hahn 519).⁴¹

Nonetheless, the Western legal system’s postwar paradigmatic view that Japanese legal behavior is predominantly characterized by a lack of rights assertion and a reluctance to go to court is flawed. Oftentimes, the United States is used as the foil to Japan without significant reference to each nation’s unique socio-cultural differences, leading to the misrepresentation of the Japanese legal system. In scholastic thinking about Asian and Western legal systems, cultural and structural explanations of Japanese legal behavior ignore the social inhibitions to litigation in the United

³⁷ CALMAN, *supra* note 20.

³⁸ BOWEN, *supra* note 30, at 20.

³⁹ PETER N. DALE, THE MYTH OF JAPANESE UNIQUENESS 106 (1995).

⁴⁰ John O. Haley, *Law and Culture in China and Japan: A Framework for Analysis*, 27 MICH. J. INT’L L. 895, 897 (2006).

⁴¹ Hahn, *supra* note 6, at 519.

States, treating Western legal constructs like access to courts, lawyers, and legal judgments as normative constructs (Feldman 141–142).⁴² On the international scale, Western rule of law, which greatly emphasizes litigation, is accepted as the norm for legal behavior. As a result, countries that do not follow Western cultural and legal traditions are seen as errant, even though this may not be true at all. Normative assumptions such as the aforementioned oversimplify Japanese legal behavior and erroneously emphasize the features of other legal systems. Furthermore, they misrepresent the complexity and ambiguity of the term “rights.” Perpetuating such a view undermines the complex, human institution of legal behavior and the arbitrary nature of legal transplants. Additionally, this theory fails because it empirically addresses rights assertion in Japan by examining the frequency of court filings instead of understanding the underlying socio-legal elements at play. To overcome the empirical limitation of this postwar paradigm, scholars must understand for what purpose, with what impact, and with what methods rights are asserted in Japan, especially since the Japanese maintain them in complex and myriad ways.

Comparatists must view the law as a polysemic signifier, where each manifestation of legal theory must be regarded as a cultural disposition that connotes political, historical, sociological, and anthropological referents; a refusal or inability to understand this multi-layered nature of interaction would place the success of the Japanese legal system in peril. As new models of legal theory improve international jurisprudence, more explicit comparative studies, which — in pursuit of justice and morality — possess a renewed focus on the specialized language and history of the legal system, will be essential in Japanese socio-legal scholarship.

⁴² FELDMAN, *supra* note 11, at 141-142.

Cooperative Federalism: Stigmatization and the Obstacles Surrounding Psychedelic Legalization

Jackson Stewart

This research paper analyzes the existing regulatory schemes for cannabis and compares them with the regulatory frameworks of psychedelics to determine whether cannabis schemes can provide a suitable legal structure for psychedelics or whether an entirely different regulatory scheme is warranted. Substantial research on the health benefits of psychedelics occurred during the 1950s and 1960s. Medical evidence collected from this period to present day indicates that psychedelics, under the care of health care professionals, can greatly benefit individuals in terms of treating refractory anxiety associated with cancer and other terminal illnesses, along with other ailments, such as depression and PTSD. However, the stigmatization behind psychedelics resulted in a string of regulatory restrictions that limited even medical access to psychedelic agents. In fact, it was a direct result of the stigmatization surrounding psychedelic usage that resulted in the Nixon Administration to declare a “war on drugs” in 1971. The Nixon administration created harsh regulatory schemes, such as the Controlled Substances Act (CSA), that have hindered the legalization of psychedelics at the federal level. However, through analyzing present medical marijuana policies, which has enabled over half of all US states to allow the medical use of cannabis products, it is apparent that a cooperative federalism model is the most effective way to legalize psychedelics in the near future. In this research paper, I suggest that Congress should pass an amendment to the federal CSA to enable states to opt out of psychedelic related provisions. This amendment would enable states to pass their own laws regulating the use of medicinal psychedelics. With the ability to opt out, the possession or distribution of psychedelics within state

boundaries pursuant to state laws would *also* be legal under federal law.

I. History Of Psychedelic Usage And Research

Dr. Stanislav Grof, a Czech psychiatrist with over sixty years of experience in the research of non-ordinary states of consciousness and one of the founders of transpersonal psychology, delineated in the book *Beyond The Brain* that “Western Science is approaching a paradigm shift of unprecedented proportions, one that will change our concepts of reality and of human nature, bridge the gap between ancient wisdom and modern science, and reconcile the differences between Eastern spirituality and Western pragmatism.”¹ This paradigm shift that Dr. Grof is referring to is a shift towards the utilization and legalization of psychedelics for medicinal purposes.

Psychedelics are powerful psychoactive substances that alter perception and mood and affect numerous cognitive processes. Also known as hallucinogens, these drugs have been used since ancient times in religion, medicine, magic, and prophecy. The history of psychedelic usage in humans dates back as far as 5,000 years ago. Blaise Pascal, a French mathematician, emphasizes how “Most of man's troubles come from their not being able to sit quietly in their chambers.”² The present degree of psychedelic usage today encapsulates the profound history of man’s attempt to wiggle, worm, and squirm his way out of himself – often at the cost of what are regarded as “basic drives.”³ Humanity’s age-old longing to lessen the pain of living and to find artificial euphoria is a story that begins in 2737 B.C. China where hashish⁴ was used extensively. Hallucinogenic mushrooms have been used by indigenous people for thousands of years, primarily in ceremonies that are religious or spiritual in nature. Their use can be traced back to rituals performed by native Saharan Africans between 8000 and 9000 years ago.⁵ There is evidence of ancient psilocybin use in other regions as well, including India,

¹ DR. STANISLAV GROF, *BEYOND THE BRAIN* (1985).

² BLAISE PASCAL, *PENSÉES* (1670).

³ *Id.*

⁴ Hashish, otherwise known as resin, is a drug made by compressing and processing parts of the cannabis plant, typically focusing on flowering buds containing the most trichomes.

⁵ Giorgia Samorini, *New Data from the Ethnomycology of Psychoactive Mushrooms*, 3 INT’L J. OF MEDICINAL MUSHROOMS 257, 257 (2001).

France, Greece, Spain, Siberia, and Mexico.⁶ Hallucinogens range from natural, plant-based drugs such as mushrooms (psilocybin), cacti (mescaline) and other plants (cannabis and salvia), to synthesized drugs such as LSD (d-lysergic acid diethylamide), MDMA (ecstasy, 3,4-methylenedioxymethamphetamine), and arylcyclohexylamines, such as PCP (phencyclidine) and ketamine.⁷

The story continues today with the recent dramatic advances in chemo psychiatry, altering the outlook for the treatment of mental illnesses. Throughout the 1950s and 1960s, the U.S. government invested significant resources into research involving psychedelics, primarily LSD. The utilization of psychedelic substances in the context of conventional (allopathic) medicine emerged in the newly created compound LSD, which was shipped to hundreds of psychiatrists in North America and given to an estimated 40,000 individuals as experimental treatment for a plethora of illnesses, including: alcoholism, mental health impairments such as schizophrenia, obsessive compulsive disorder, autism, somatic maladies such as cancer, and enhancing the wellbeing of healthy volunteers.⁸ Clinical psychedelic research came to an abrupt halt by the late 1960s due to the association with psychedelic substances to immoral behavior such as deviance, crime, and political rebellion. Among the 1960s counterculture, the “ego-death” experience became the ultimate initiation pathway for many psychedelic enthusiasts, encapsulating the gritty and basement realism of the existential “beat” movement with the elevated aura of grandeur emanating from those practicing mystics.⁹

By the 1970s, the flame of the psychedelic counterculture had burnt out, and psychedelia – in the form of language, music, art, and politically benign pharmacological¹⁰ experimentation – was engrossed into mainstream culture and became “integral to the sensory

⁶ Kathryn L. Tucker, *Psychedelic Medicine: Galvanizing Changes in Law and Policy to Allow Access for Patients Suffering Anxiety Associated with Terminal Illness*, 21 QUINNIPIAC HEALTH L. J. 239 (2018).

⁷ Do you know hallucinogens - hnhu.org, Do You Know... Hallucinogens, https://hnhu.org/wp-content/uploads/hallucinogens_dykl.pdf (last visited Jul 11, 2022).

⁸ A. Garcia-Romeu, et al., *Clinical applications of hallucinogens: A review*. 4 *Experimental and Clinical Psychopharmacology* 24, 229–268 (2016).

⁹ M.A. LEE & B. SHLAIN, *ACID DREAMS: THE COMPLETE SOCIAL HISTORY OF LSD - THE CIA, THE SIXTIES, AND BEYOND* (2001).

¹⁰ Pharmacology is a branch of medicine concerned with drug or medication action.

indulgences and leisured life of Americans.¹¹ Although research was conducted in universities during the decades that followed the 1960s, the research climate largely froze due to a wide “microphysics of power” related to the reputational risks for researchers, funding limitations, and ethical hurdles.¹² These risks arose in the wake of the moral hype associated with the 1960s counterculture.¹³ Not only did the microphysics of power play a huge role in the lack of research conducted on psychedelics, but so did many regulatory barriers. After the passage of the Controlled Substances Act of 1970, LSD and other psychedelics known at the time were placed into the most restrictive category of drugs, Schedule 1. This classification made it virtually impossible to study psychedelics clinically, effectively ending any significant research into the pharmacology and medical value of psychedelics, which did not begin to regain currency until the early 2000s. Since then, a series of research laboratories, clinics, and psychedelics organizations have emerged in North America and Europe, jettisoned by the return to human clinical trials of psychedelic-assisted therapy in the early 21st century. These clinical trials study the potential of psychedelic therapy and assess the possibility of integrating psychedelic therapy into modern health care services.

A prominent organization that has succeeded in accumulating much of the new and transformative data done has been through the Multidisciplinary Association for Psychedelic Studies (MAPS). Founded in 1986, MAPS is a non-profit that specializes in “research and education that develops medical, legal, and cultural shifts benefiting the careful uses of psychedelics and marijuana for mental and spiritual healing.”¹⁴

A holistic outlook of psychedelic usage emphasizes how the legalization of psychedelics in the 21st century is a prevalent topic due to the major psychological benefits. It is worthwhile to dive into the regulatory history of psychedelics to analyze why psychedelics have remained a Schedule 1 drug for so long and why legalization is

¹¹ G. St John, *Spiritual technologies and altering consciousness in contemporary counterculture*. In: E. CARDENA & M. WINKELMAN, *ALTERING CONSCIOUSNESS: MULTIDISCIPLINARY PERSPECTIVES, VOL. 1: HISTORY, CULTURE, AND THE HUMANITIES* (2011).

¹² N. LANGLITZ, *NEUROPSYCHEDELIA: THE REVIVAL OF HALLUCINOGENIC RESEARCH SINCE THE DECADE OF THE BRAIN* (2013).

¹³ James Pugh, *Matthew Oram, the trials of psychedelic therapy: LSD psychotherapy in America*, 32 *Social History of Medicine*, 648–649 (2019).

¹⁴ Support psychedelic science - multidisciplinary association for psychedelic studies MAPS, <https://maps.org/> (last visited Jul 13, 2022).

complex. Many users of psychedelics see their usages to be beneficial, while those who have never tried them certainly have reason to believe that they are not beneficial for medicinal use. This research paper seeks to explain not only what the legalization process should look like, but also the implications of legalizing such drugs and the feasibility of implementing a contemporary legalization methodology that can be accepted by the federal government.

Author Aldous Huxley – who collaborated with psychiatrist Humphrey Osmond in coining the term “psychedelic” – inspired the content in *The Psychedelic Experience*, a popular guide developed by the Harvard University psychologists Timothy Leary, Ralph Metzner, and Richard Alpert, which facilitated psychedelic experimentation beyond the clinic and became influential in the psychedelic counterculture from the late 1960s onwards.¹⁵ The guide directs users through an audio journey to “lose their ego” with mental techniques largely imported from Tibetan Buddhist texts.

The 1962 Good Friday Experiment was a notorious study conducted by Harvard Professors Timothy Leary and Richard Alpert, involving twenty Harvard Divinity School students who were given capsules of white powder half containing a placebo and the other half containing psilocybin.¹⁶ Upon ingesting the powder, the divinity students attended a Good Friday mass in Marsh Chapel at Boston University.¹⁷ Eight out of the ten in the group receiving psilocybin reported experiencing mysticism¹⁸ compared with only one in the placebo/control group. Dr. Charles Raison, the Director of Research on Spiritual Health at Emory University in Atlanta, describes mysticism as “a universal hunger to find purpose, to find meaning, to find ways to interconnect with the world around us that makes us feel that our lives are something worth living¹⁹.” This study emphasized how psilocybin can infuse mystical experiences in individuals who were religiously inclined (i.e. took it in a religious setting). Follow up-studies with the participants in the short-term demonstrated that all

¹⁵ TIMOTHY LEARY & RALPH METZNER, *PSYCHEDELIC EXPERIENCE: A MANUAL BASED ON THE TIBETAN BOOK OF THE DEAD* (1964).

¹⁶ DAVID F. MUSTO & PAMELA KORSMEYER, *THE QUEST FOR DRUG CONTROL: POLITICS AND FEDERAL POLICY IN A PERIOD OF INCREASING SUBSTANCE ABUSE* (2002).

¹⁷ Pollan, *supra* note 8.

¹⁸ Ron Cole-Turner, *Psychedelic epistemology: William James and the “noetic quality” of mystical experience*, 12 *RELIGIONS* 1058 (2021).

¹⁹ How Science Is Making Sense Of The Mystical Experience In Psychedelic Medicine (forbes.com)

those receiving the drug continued to feel that they had a mystical experience and that the experience helped shaped their lives and career paths, as well as their interpretations of both faith and the world in general. A 1991 follow-up study confirmed that the participants in the experimental group felt that the event had shaped their lives in profound ways, even decades later.²⁰ This field of research soon fell into disfavor in part because of a combination of the unorthodox methods employed by some researchers, as well as the sloppy implementation and controls in their experiments. Researchers Timothy Leary and Richard Alpert were dismissed from Harvard in 1963 following accusations of unconventional and inappropriate research methods.²¹ The Good Friday study was subsequently condemned for downplaying some of the participants' negative reactions to the drug: several experienced anxiety, and one had to be restrained and dosed with an antipsychotic.²² The importance of the 1962 Good Friday Experiment, duplicated later in a John Hopkins 2006 study using a similar model,²³ showed that psilocybin had a profound, mystical effect on the users for years and even decades later. The experiment became a political condemnation of the drug culture of the times instead of being perceived as a medicinal experiment – which was its intent. Because of this political condemnation, it was overlooked that 80% of the participants reported having a positive experience. Regardless of the aftermath of the 1962 Good Friday Experiment, the study affirmed that these kinds of experiences are real and not of the imagination, and that these participants were able to see the effects of some kind of connection to spiritual enlightenment and some form of mystical experience.

Data from the 2020 National Survey on Drug Use and Health (NSDUH) shows that 2.6 percent of people in the US aged 12 or over (or 7.1 million people) used hallucinogens (which include LSD, PCP, peyote, mescaline, psilocybin mushrooms), “Ecstasy” (MDMA or “Molly”), ketamine, DMT/AMT/“Foxy,” and Salvia Divinorum in the last year. A larger percentage of young adults aged 18 to 25 used

²⁰ Rick Doblin. *Pahnke's "Good Friday Experiment": a long-term follow-up and methodological critique.* 1 *The Journal of Transpersonal Psychology* 23 (1991).

²¹ Ronald R. Griffiths & Charles S. Grob, *Hallucinogens as Medicine*, 303 *Sci. AM.* 76, 78 (2010).

²² *Id.*

²³ R.R. Griffiths et al., *Psilocybin can occasion mystical-type experiences having substantial and sustained personal meaning and spiritual significance*, 187 *PSYCHOPHARMACOLOGY* 268-283 (2006).

hallucinogens than adolescents or adults aged 26 or older.²⁴ Furthermore, data on the estimated lifetime usage of psychedelics by age based on 2010 data of the National Survey on Drug Use and Health (NSDUH) shows that there were approximately 32 million lifetime psychedelic users in the US in 2010.²⁵ Analyzing psychedelic usage from a clinical studies review, the dominant user segments include: 1) spiritual and therapeutic use, 2) recreational and experimental use, and 3) problematic use.²⁶ The data from the 2010 NSDUH suggests that psychedelic usage today is prominent and diverse between the dominant user segments. Considering that young adults are the primary users of psychedelics and that a large number of Americans have tried psychedelics at least once, legalization efforts today would statistically receive less backlash from the populace than efforts over the last few decades.

II. Regulatory History

The Federal Food, Drug and Cosmetic Act (FDCA), as last amended in 1962, is the primary source for the restrictive policy against the use of psychedelics. The FDCA aims to prohibit the movement of food that is impure and/or misbranded in inter-state commerce. The Act distinguishes between food and drugs and defines drugs by categories. Articles are considered ‘drugs’ if listed as such in an official compendium or intended for specified purposes; they are considered “new drugs,” when they fall under certain criteria and qualifications.²⁷ The official term ‘drug’ means: “1) articles recognized in the official United States Pharmacopoeia... 2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and 3) articles (other than food) intended to affect the structure of function of the body of man or other animals.” Conversely, the FDCA definition of the ‘new drug’ is: “1) any drug, the composition of which is such that the drug is not generally recognized among experts qualified by scientific

²⁴ The percentage among young adults aged 18 to 25 (7.3 percent or 2.4 million people) was higher than the percentages among adolescents aged 12 to 17 (1.5 percent or 370,000 people) or adults aged 26 or older (2.0 percent or 4.3 million people).

²⁵ Teri S Krebs and Pål-Ørjan Johansen. *Over 30 million psychedelic users in the United States*. 2 F1000Research 98 (2013).

²⁶ Johnstad Petter Grahl. *Who is the Typical Psychedelics User? Methodological Challenges for Research in Psychedelics use and its Consequences*. 1 Nordic Studies on Alcohol and Drugs 38, 35-49 (2021).

²⁷ R. C. Bates, *Psychedelics and the Law*. The Psychedelic Review Archives 1963-1971, <https://maps.org/research-archive/psychedelicreview/> (last visited Jul 13, 2022).

training and experience to evaluate the safety and effectiveness of the drugs... or 2) any drug the composition of which is such that the drug, as a result of investigations to determine its safety and effectiveness for use under such conditions...been used to a material extent or for a material time under such conditions.”²⁸

The official compendia of the FDCA fails to list LSD, mescaline, psilocybin, or any other psychedelics under the category of ‘drugs.’ The lack of a label for psychedelics as ‘drugs’ in the FDCA creates a loophole, where *zero* psychedelics are considered drugs *per se* under Clause 3 under the official ‘drug’ definition in the FDCA. If psychedelics were considered ‘drugs’ as analyzed through the lenses of the ‘drug’ definition in Clause 3, psychedelics must alter mental processes such as evaluating, thinking, imagining, and perceiving, and “affect a function in the body of man,” and are “intended” to do so. Although scientific research justifies that psychedelics could be labeled as a ‘drug’ in the official compendia, the loophole in the FDCA accentuates how plain and seemingly clear words can be misinterpreted and how they must yield to the impact of provisions in print. In the context of legalizing psychedelics in the future, the language of psychedelic provisions must be interpreted in light of 1) the statute as a whole, 2) the legislative policy expressed in it, 3) the related laws, and 4) the precedents.

The Single Drug Convention of 1961,²⁹ as amended by the 1972 Protocol, is one of the bedrocks of the United Nations global drug regimes. One of the primary goals of the Single Drug Convention of 1961 is to consolidate prior drug regulations to reduce their global impact and control their spread.³⁰ An equally important goal of the Single Drug Convention of 1961 is to establish regulatory control which will eliminate all abuses of the drugs while guaranteeing an adequate supply of those drugs for scientific and medical purposes. Following the Single Convention, the Convention on Psychotropic Substances of 1971³¹ focuses on the limitation of the use of psychotropic substances for solely medical and scientific purposes.

²⁸ 21 U.S. Code § 321 - definitions; generally, LEGAL INFORMATION INSTITUTE, <https://www.law.cornell.edu/uscode/text/21/321> (last visited June 22, 2022).

²⁹ David Bewley Taylor and Martin Jelsma, “Regime Change: Re-visiting the 1961 Convention on Narcotic Drugs,” *Internal Journal of Drug Policy*, 73.

³⁰ *Id.*

³¹ *Convention on Psychotropic Substances of 1971*, 2 February 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175 (entered into force 16 August 1976) [INCB].

Psilocybin first became subject to federal regulation pursuant to the Drug Abuse Control Amendments of 1965, modifying the Federal Food, Drug, and Cosmetics Act. This law banned "any drug which contains any quantity of a substance which the Secretary [of Health, Education, and Welfare] . . . has found to have a . . . hallucinogenic effect . . ."³² Further amendment of the Food, Drug, and Cosmetic Act in 1968 explicitly banned the possession of LSD and similar drugs (unless prescribed by a licensed practitioner) and added criminal penalties.

Following a tumultuous decade of violent citizen upheaval, from the civil rights crusade to the counterculture movement, the Nixon administration enacted the CSA to garner favor from a growing conservative population and the "silent majority," as a part of his infamous "Southern Strategy" for the midterm elections.³³ The CSA was successful in addressing rebellious behavior as it targeted the choice drugs of minorities and "hippies," who were regarded by the Nixon administration as cultivators of criminal activity and threats to the American way of life. Likewise, the mind-altering effects produced by LSD were the true embodiment of the counterculture movement, "provid[ing] a way to step outside of the restrictive bounds of one's culture, revealing alternatives, breaking down boundaries."³⁴ Nixon's Southern Strategy was designed to antagonize the racial grievances of conservative white Southern Democrats and encourage their migration into the Republican Party. Going further, the Southern Strategy became a kind of base for the Nixon administration to legalize psychedelic drugs for hippies and minorities.

In June of 1971, President Nixon declared a national "war on drugs."³⁵ Congress passed the Comprehensive Drug Abuse Prevention and Control Act of 1970, which was signed into law by Nixon. Title II of this law is the Controlled Substances Act (CSA), under which the Attorney General has authority to add and remove drugs from five categories, referred to as "schedules." The CSA was part of comprehensive legislation designed to (1) ban "Schedule 1" drugs

³² 21 U.S.C. § 802 (2012).

³³ Matthew Robert Bonito, *SONS OF ABRAHAM: A HISTORY OF THE REPUBLICAN PARTY, RICHARD NIXON'S SOUTHERN STRATEGY, AND THE FORMATION OF TWENTY-FIRST CENTURY CONSERVATISM* (2018).

³⁴ Rothsetin, A mind-altering drug altered a culture as well *The New York Times* (2008) <https://www.nytimes.com/2008/05/05/05conn.html> (last visited Jul 2, 2022).

³⁵ A history of the Drug War, *DRUG POLICY ALLIANCE*, <https://drugpolicy.org/issues/brief-history-drug-war> (last visited Jul 1, 2022).

(including marijuana) that had, in Congress's judgment, a high potential for abuse and no accepted medical use, and (2) regulate trade in legitimate drugs to prevent their diversion into illicit channels.³⁶ Factors relevant to scheduling include the "actual or relative potential for abuse," "history and current pattern of abuse," risk to public health, pharmacological effect, and "physiological dependence liability." After the passage of the CSA, LSD and other psychedelics known at the time were placed into the most restrictive category of drugs – Schedule 1. This classification made them virtually impossible to study clinically and effectively ended any significant research into the pharmacology and medical value of psychedelics for more than three decades.

Rather than implementing the CSA as a way to address “an increase in heroin addiction and the rising use of marijuana and hallucinogens by students” as the president himself claimed, Nixon’s domestic-policy advisor, John Ehrlichman, clarified the true reason for the enactment of the Controlled Substances Act:

The Nixon campaign in 1968, and the Nixon White House after that, had two enemies: the antiwar left and black people. You understand what I’m saying? We knew we couldn’t make it illegal to be either against the war or black, but by getting the public to associate the hippies with marijuana and blacks with heroin, and then criminalizing both heavily, we could disrupt those communities. We could arrest their leaders, raid their homes, break up their meetings, and vilify them night after night on the evening news. Did we know we were lying about the drugs? Of course we did.³⁷

The blatant deceit from the Nixon party in the reasoning behind the true intentions of the CSA devastated the chances of removing psychedelics from Schedule 1, created a system that makes it easy to target communities using drugs through strict criminalization, and forced the hands of medical practitioners to only have psychedelics be

³⁶ The controlled substances act, DEA, <https://www.dea.gov/drug-information/csa> (last visited Jul 5, 2022).

³⁷ Tom LoBianco, REPORT: AIDE SAYS NIXON'S WAR ON DRUGS TARGETED BLACKS, HIPPIES | CNN POLITICS CNN (2016), <https://www.cnn.com/2016/03/23/politics/john-ehrllichman-richard-nixon-drug-war-blacks-hippie/index.html> (last visited Jul 13, 2022).

utilized for medicinal usage rather than recreational usage that some states have with marijuana. Considering that the CSA is presently enforced by the Drug Enforcement Agency (DEA), the barriers to legalization remain prominent.

The indigenous peoples of North America have used peyote³⁸ for thousands of years. In the early stages of laws surrounding Peyote use for Native Americans, U.S. Congress passed the "Indian Religious Crime Code of 1883" that imposed ninety-day imprisonment and the withholding of government rations upon Indians found possessing peyote. This statute also authorized the "Court of Indian Offenses" to punish Indians who participated in indigenous religious ceremonies. In 1890, the Federal government not only classified peyote as an intoxicant, but also ordered Indian agents to destroy any peyote confiscated.

Oklahoma (which was once an Indian Territory) also had a similar history of peyote prohibition. In 1899, the Oklahoma legislature promulgated laws prohibiting the use and possession of peyote within the Territory of Oklahoma.³⁹ The Oklahoma anti-peyote law subjected violators to "a two-hundred dollar fine and six-month imprisonment, and resulted in the incarceration of several Comanche and Kiowa Indians for the possession of peyote in 1907." According to anthropologist and ethnobotanist Weston La Barre, "[a]fter the famous Comanche Chief Quannah Parker testified before the legislature, the anti-peyote law of Oklahoma was repealed in 1908, and failed of re-enactment in 1909 and again in 1927."⁴⁰

In terms of the federal regulation of peyote today pursuant to the federal CSA, peyote is classified as a Schedule I controlled substance that imposes "a one-year jail sentence, a one-thousand-dollar fine, or both for possession."⁴¹ However, the American Indian Religious Freedom Act (AIFRA)⁴² provides a federal exemption for

³⁸ Peyote (*Lophophora williamsii* or *Lophophora diffusa*) is a small, spineless cactus that is found in the southwest United States, northern Mexico, and Peru. The plant has been used for about six thousand years by native tribes for religious and healing purposes.

³⁹ 4 STEWART, *supra* note 1, at 131; LA BARRE, *supra* note 1, at 223. In 1909, without legal backing the B.I.A. agents raided peyote meetings and confiscated peyote buttons. SMITH & SNAKE, *supra* note 3, at 127.

⁴⁰ WESTON LA BARRE, *THE PEYOTE CULT* 193 (5th ed., Univ. Okla. Press 1989); OMER C. STEWART, *THE PEYOTE RELIGION: A HISTORY* 7 (Univ. Okla. Press 1987).

⁴¹ Schedule of Controlled Substances, 21 U.S.C. §812(c)(12)(2018); Penalties for Simple Possession, 21 U.S.C. §844(a)(2010).

⁴² Congress.gov. H.R.4230 - American Indian Religious Freedom Act Amendments of 1994.

NAC⁴³ members to legally use peyote for religious purposes."⁴⁴ According to U.S. Code 1966a, Congress finds and declares that 28 states have enacted laws (which are similar to the Federal regulation) that protect the ceremonial use of peyote by Indian religious practitioners. However, as 22 states have not done so, this creates a lack of uniformity, making the federal peyote exemption an ongoing issue and causing hardship for Indian people. However, case law shows an important precedent where members of the Native American Church who are not of Native American Ancestry can still legally utilize peyote for religious purposes. *United States v. Boyll* (1992) involved an Anglo, non-Native American NAC member being arrested and prosecuted under federal law for mailing peyote from Mexico to his post office box in the United States. The federal district court paved the way for granting non-Indians bona fide NAC membership and access to peyote,⁴⁵ deciding that the federal peyote exemption "included protections for any NAC member regardless of race." The court emphasized that "[t]o exclude individuals of a particular race from being members of a recognized religious faith is offensive to the very heart of the First Amendment."⁴⁶ This decision was affirmed by the U.S. Tenth Circuit Court of Appeals, which concluded that "[b]y choosing only to challenge the lower court's ruling on the interpretation of 21 C.F.R. 1307.31 (1990), it leaves us with no choice but to dismiss this appeal, thereby leaving the lower court's dismissal of this indictment intact."⁴⁷ Ultimately, the *Boyll* decision has created the possibility for non-Indians to exploit the legal access to peyote for legal use under the federal peyote exemption by claiming NAC membership and the ability to establish their own NAC churches.⁴⁸

Other constitutional amendments emphasize individual freedom - the lever that may dislodge the administrative weight on

⁴³ NAC stands for the National Council of Native American Churches.

⁴⁴ Native American Church, 21 C.F.R. § 1307.31 (1973)("Federal Peyote Exemption"). See also PROTECTION AND PRESERVATION OF TRADITIONAL RELIGIONS OF NATIVE AMERICANS, 42 U.S.C. §1996 (1994). " See, e.g., 17 NAVAJO NATION CODE §394(C)(2005)("Aze is lawful on the Navajo Nation."); §30-3.

⁴⁵ *United States v. Boyll*, 774 F. Supp. 1333 (D.N.M. 1991) (the judge making no distinction between Indian and non-Indian NAC members), appeal dismissed, 968 F.2d 21 (10th Cir. 1992)). See also *United State v. Boyll*, No. 91-2235, 1992 U.S. App. LEXIS 14537 (10th Cir., June 16, 1992)(unpublished opinion - appeal dismissed).

⁴⁶ *Id.* at 1340 (referring to *Walz v. Tax Comm'n of New York*, 297 U.S. 664, 668-69 (1970)).

⁴⁷ *United States of America, Plaintiff-appellant, v. Robert Lawrence Boyll, Defendant-appellee*, 968 F.2d 21 (10th Cir. 1992) :: Justia

⁴⁸ Anyone can become a member of a NAC Church. 21 C.F.R. § 1307.31 (1990).

psychedelics. In a critical case on the religious right of indigenous tribes – the honorable Yale McFate pronounced his decision in the case of *State of Arizona v. Mary Attakai*.⁴⁹ The defendant, a member of the Navajo Indian Tribe, was charged with the illegal possession of peyote, which is a crime under an Arizona statute.⁵⁰ The defendant admitted to the possession, but pleaded not guilty on the ground that the prayers, rights, and ceremonies of the Native American church centered on the use of peyote, such that the statute deprived her of the freedom of religious worship guaranteed by the 14th Amendment of the Federal Constitution and the Arizona Constitution. The court found that under the circumstances, the Arizona statute was unconstitutional, dismissed the complaint, and released the defendant. In the opinion of the court, the peyote plant, believed to be of *divine origin*, bore a similar relation to Indians as did the Holy Bible did to the white men. The judge thought it significant that many states which formerly outlawed the use of peyote have abolished or amended their laws to permit its use for religious purposes. This emphasizes the crucial role of *purpose* in psychedelic law: why does one use psychedelics and how much do the differences in the use of psychedelics affect the law of psychedelics.

III. Obstacles To Legalize Psychedelics For Medicinal Use

The use, sale, and possession of psychedelics in the United States is illegal under federal law under the CSA.⁵¹ According to the CSA, Schedule I substances have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of safety for use under medical supervision.⁵² The consequences of a drug's listing on Schedule I means it is substantially harder to research or make available than drugs on lower CSA schedules, which can often be administered or prescribed by physicians. Approvals from the government to *study* Schedule I controlled substances require substantial financing and manpower.⁵³

⁴⁹ U.S. District Court for the District of Arizona - 746 F. Supp. 1395 (D. Ariz. 1990) February 28, 1990.

⁵⁰ Az. Criminal Code § 13-3402 (2022).

⁵¹ 21 U.S.C § 812 (1970).

⁵² *Id.*

⁵³ Vince Sliwoski, HOW TO STUDY SCHEDULE I CONTROLLED SUBSTANCES HARRIS BRICKEN SLIWOSKI LLP (2021), <https://harrisbricken.com/cannalawblog/how-to-study-schedule-i-controlled-substances/> (last visited Jul 13, 2022).

At the federal level, removing psychedelics from Schedule 1 is a complex and entangled process. Central to federally legalizing psychedelics, [actors] must convince the U.S. Department of Health and Human Services (HHS), which include the U.S. Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid (CMS) that psychedelic drugs have an accepted medical use.⁵⁴ In order to acquire drug approval, an individual must start getting drug approval from an institutional review board (IRB). The inception of the IRB protocol under the National Research Act came in 1974 after President Richard Nixon rolled out the Controlled Substances Act. An IRB is an appropriately constituted group that is designed “to review and monitor biomedical research involving human subjects” in order to protect the rights and welfare of such participants.⁵⁵ In order to have a research study approved, five board members (which must include one doctor, one ethicist, and one member not affiliated with the institution), must find that: 1) the risks to study participants will be minimized in relation to the study’s health benefit, 2) the study recruitment will select participants in an equitable fashion, and 3) informed consent will be sought in accordance with 21 CFR 50).⁵⁶ Acquiring approval from the IRB will show the public benefits of biomedical and behavioral research into psychedelics, which thereby proves that it has “accepted medical use” under the CSA.

Once an applicant receives an IRB approval letter, the next step is to acquire permission from the Drug Enforcement Agency (DEA). Acquiring permission from the DEA is another arduous and difficult process in itself. The first step is to obtain a Schedule I license, wherein you must complete “DEA Form 225” which includes 9 sections.⁵⁷ The next step is to fill out the Risk Evaluation and Mitigation Strategy (REMS) paperwork, which is a required risk management framework to ensure that the benefits of a drug outweigh

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A history of the Drug War, DRUG POLICY ALLIANCE, <https://drugpolicy.org/issues/brief-history-drug-war> (last visited Jul 12, 2022).

⁵⁵ Office of the Commissioner, IRB-FAQS U.S. FOOD AND DRUG ADMINISTRATION, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/institutional-review-boards-frequently-asked-questions> (last visited Jul 12, 2022).

⁵⁶ The Federal Register, Title 21 - Food and Drugs, FEDERAL REGISTER, REQUEST ACCESS, <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-50> (last visited Jul 12, 2022).

⁵⁷ DEA form 225 – new application for registration, https://ehs.oregonstate.edu/sites/ehs.oregonstate.edu/files/dea_form_225_instructions.pdf (last visited Aug 19, 2022).

the risks.⁵⁸ Section 505-1 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) establishes FDA's REMS authority. The FDA must analyze six statutory factors when making a decision about whether to require a REMS, which include: "The seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug; the expected benefit of the drug with respect to the disease or condition; the seriousness of the disease or condition that is to be treated with the drug; whether the drug is a new molecular entity; the expected or actual duration of treatment with the drug; and the estimated size of the population likely to use the drug."⁵⁹ Furthermore, the requirements in the REMS paperwork specify that applicants must also: (1) develop and provide REMS training; (2) develop and disseminate REMS communications; (3) support REMS operations; and (4) ensure participants' compliance with the REMS. After this arduous step, applicants must apply for grants and funding to National Institute on Drug Abuse (NIDA)⁶⁰ in order to acquire the actual psychedelics.⁶¹

The use of psychedelics for research also includes a separate application to the FDA for an Investigational New Drug (IND) number. The IND represents an exemption from the legal requirement under federal law which requires "that a drug be the subject of an approved marketing application before it is transported or distributed across state lines."⁶² The FDA's role in the development of a new drug begins when the drug's sponsor (usually the manufacturer or potential marketer), wants to test its diagnostic or therapeutic potential in humans.⁶³ At that point, the molecule changes in legal status under the Federal Food, Drug, and Cosmetic Act and becomes a new drug subject to specific requirements of the drug regulatory system. The

⁵⁸ Format and content of a REMS document guidance for industry, <https://www.fda.gov/files/drugs/published/Format-and-Content-of-a-REMS-Document-Guidance-for-Industry.pdf> (last visited Jul 12, 2022).

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⁶⁰ About Nida, NATIONAL INSTITUTES OF HEALTH (2021), <https://nida.nih.gov/about-nida> (last visited Jul 12, 2022).

⁶¹ NIDA is the lead federal agency supporting scientific research on drug use and its consequences. See *Id.*

⁶² Center for Drug Evaluation and Research, INVESTIGATIONAL NEW DRUG (IND) APPLICATION U.S. FOOD AND DRUG ADMINISTRATION, <https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application#Introduction> (last visited Jul 9, 2022)

⁶³ The drugs sponsor will have already screened the new molecule for pharmacological activity and acute toxicity potential in animals before human trials.

main IND type that an individual would utilize in order to legalize psychedelics is an Investigator IND, which is submitted by a physician who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. As hallucinogens are Schedule 1 Drugs under the Federal CSA, the physician would submit a research IND to propose studying an unapproved drug. The IND application must contain information from animal pharmacology and toxicology studies, manufacturing information, and clinical protocols and investigator information. Once the IND is submitted, the sponsor must wait 30 calendar days before initiating any clinical trials. Upon approval, the sponsor would work hand in hand with the FDA as an individual proceeds with each phase of the study of psychedelics. If an individual were to acquire all of these drug approvals, the DEA has the ability to amend the Controlled Substances Act schedules (with recommendations from the FDA and HHS) to have psychedelics be taken off the Schedule I listing.

The plethora of steps required in the deregulation of psychedelics out of a Schedule 1 classification from the CSA is lengthy and ineffective process. The benefits of descheduling psychedelics from Schedule 1 are that research would now be much easier and that states would have new options for structuring legal psychedelics with the intention of improving health. However, it is unclear if the federal policy for psychedelics will be hands-off or if the federal government will support state efforts. Removing psychedelics from Schedule 1 to obtain an exception to the illegality in order to conduct clinical studies is not feasible in the short-term. Descheduling psychedelics from Schedule 1 are bound by the clinical research that is being conducted, and considering that the process undergoes supervision from multiple national organizations, it is my opinion that the federal route is not the most effective way for eventual psychedelic legalization.

Much of the debate regarding the legalization of psychedelics stems around the stigmatization that dates back to the 1960s counterculture. The medical profession and the Food and Drug Administration classifies them as "hallucinogens," or producers of hallucinations., this name is also a misnomer, since the drugs do not normally produce hallucinations (visions unrelated to environment)

but rather "illusions" (distortions in normal perception).⁶⁴ They have been both hailed as the salvation of the race and condemned as "living death."⁶⁵ The attitude of the majority of the population and the reaction of state and local government has been negative ever since the Nixon administration's efforts to crack down on drug usage. Historically, the medical profession, which includes psychiatrists, has engendered public fear about the drug *more* than the evidence available to them warranted. Jerome Jaffe, clinical professor and the drug "Czar" under the Nixon Administration, emphasized in *Goodman and Gilman's The Pharmacological Basis of Therapeutics* how "...the feature that distinguishes the psychedelic agents from other classes of drug is their capacity reliably to induce states of altered perception, thought, and feeling that are not experienced otherwise except in dreams or at times of religious exaltation."⁶⁶

IV. Modern Clinical Research

Psychedelic research has reemerged in the 21st century. In the first methodologically sound foray back into this arena, researchers at Johns Hopkins University conducted a double-blind study and reported results in 2006 on "medically and psychiatrically healthy" subjects.⁶⁷ In this study, a combination of participants, staff, and community observers rated participant moods, attitudes, and behaviors throughout the study. High-doses of psilocybin (between 22-30 mg) produced large decreases in clinician observed and self-rated measures of depressed mood and anxiety, increases in quality of life, life meaning, and optimism, and decreases in death anxiety. At 6-month follow-up, these changes were sustained, with about 80% of participants continuing to show clinically significant decreases in depressed mood and anxiety. This study mimicked the clinical research that was done

⁶⁴ Paige Bierma, HALLUCINOGENS HEALTHDAY (2022), <https://consumer.healthday.com/encyclopedia/substance-abuse-38/drug-abuse-news-210/hallucinogens-648302.html> (last visited Aug 19, 2022).

⁶⁵ "LSD jeopardizes the lives of human beings-It borderlines on living death," Carswell, J., United States District Court for the Northern District of Florida, upon sentencing a 22 year old defendant to four maximum one year terms to run consecutively, on a guilty plea to four counts of illegal possession and sale of LSD. The Gainesville (Fla.) Sun, Apr. 2, 1967, at 1, cols. 1, 2. *Matter of Abreu-Semino*, 12 I&N Dec. 775 (B.I.A. 1968)

⁶⁶ Jaffe JH. (1990) Drug addiction and drug abuse, in *Goodman and Gilman's the Pharmacological Basis of Therapeutics* (Goodman AG, Rall TW, Nies AS, Taylor P. eds) 8th ed, pp 522–573, McGraw Hill, New York.

⁶⁷ Roland R. Griffiths et al., Psilocybin Produces Substantial and Sustained Decreases in Depression and Anxiety in Patients With Life-Threatening Cancer: A Randomized Double-Blind Trial, 30 J. OF PSYCHOPHARMACOLOGY 1181, 1195 (2006).

during the 1960s (including the Good Friday Experiment), though a more profound commitment to scientific rigor. Tucker emphasizes how “subjects found the experience personally and spiritually meaningful, catalyzing sustained positive changes in attitudes and behavior.”⁶⁸

Furthermore, much of the new and transformative data done has been through the Multidisciplinary Association for Psychedelic Studies (MAPS). MAPS sponsored the first study of the therapeutic use of LSD in humans in over 40 years, which concluded in September of 2012. This Switzerland-based study investigated the safety and effectiveness of LSD-assisted therapy in participants with life-threatening illnesses who were also experiencing associated anxiety. This double-blind, randomized, active placebo-controlled pilot study done on 12 participants included drug-free therapy sessions supplemented by two LSD-assisted therapy sessions scheduled 2 to 3 weeks apart. Two months after treatment, participants showed a reduction in anxiety, with no acute or chronic adverse events persisting beyond one day after treatment and no treatment-related serious adverse events.⁶⁹ This MAPS study indicates how when administered in a therapeutic setting, LSD-assisted therapy can be associated with lasting reductions in anxiety *without safety concerns*.

MAPS has completed clinical research in LSD, MDMA, marijuana, ibogaine⁷⁰, and ayahuasca. The company’s research, such as the aforementioned study, is governed by rigorous scientific evaluation of their risks and benefits. Although clinical psychedelic research has increased significantly, especially through MAPS, the United States National Institutes of Health (NIH) remains the largest public funder of biomedical research in the world. It is thus critical to understand the degree to which the organization is supporting clinical trials of psychedelic-assisted therapies. MAPS is especially important to psychedelic legalization because of their emphasis on the components that are intertwined with the Risk Evaluation and

⁶⁸ Kathryn L. Tucker, *Psychedelic Medicine: Galvanizing Changes in Law and Policy to Allow Access for Patients Suffering Anxiety Associated with Terminal Illness*, 21 QUINNIPIAC HEALTH L. J. 239 (2018).

⁶⁹ Lysergic acid diethylamide (LSD)-assisted psychotherapy in people with illness-related anxiety - full text view, FULL TEXT VIEW - CLINICALTRIALS.GOV, <https://clinicaltrials.gov/ct2/show/NCT00920387> (last visited Jul 13, 2022)

⁷⁰ Ibogaine is a psychoactive alkaloid naturally occurring in the West African shrub iboga. While ibogaine is a mild stimulant in small doses, in larger doses it induces a profound psychedelic state. Historically, it has been used in healing ceremonies and initiations by members of the Bwiti religion in various parts of West Africa.

Mitigation Strategy (REMS) protocol for federal legalization.⁷¹ Before conducting scientific experiments, MAPS embarks in rigorous scientific evaluation of risk and benefits, which can be characterized as a “psychedelic cost-benefit analysis.”⁷² Legalizing psychedelics for medical use will come down to the overwhelming research and evidence of the health benefits, and the more research MAPS conducts, the further they will go in the right direction.

V. Medical Marijuana as A Model

In order to determine the feasibility of legalizing psychedelics, a structured analysis of how marijuana has been legalized and the frameworks surrounding marijuana legalization must be considered as a possible model for psychedelic legalization. Marijuana is a Schedule I drug under the Federal CSA that has become available for medicinal use. As of 2022, six states still have a “fully illegal” status under state law, 26 states have a “mixed” legal status wherein marijuana has been either decriminalized or allowed medicinally (but not in tandem), and 18 states have marijuana being fully legal.⁷³ State laws vary depending on “whether patients are allowed to cultivate cannabis on their own versus procuring it from a state-licensed dispensary or both, as well as in the amount, form, and type of cannabis a patient is permitted to have at a given time.”⁷⁴ The drug has experienced exponential growth in its popularity since prohibition in 1970. In 1969, 4% of American adults had tried marijuana;⁷⁵ in 2017, 52% of American adults had tried marijuana.⁷⁶ Currently, marijuana is being used as treatment for conditions such as chronic pain, alcohol and drug addiction, depression, PTSD, social anxiety, epilepsy, Alzheimer’s prevention, and seizures.⁷⁷ Marijuana is currently subject to a national debate, and

⁷¹ Brian S. Barnett, Sloane E. Parker, Jeremy Weleff, United States National Institutes of Health grant funding for psychedelic-assisted therapy clinical trials from 2006–2020, *International Journal of Drug Policy*, Volume 99, 2022, 103473, ISSN 0955-3959, <https://doi.org/10.1016/j.drugpo.2021.103473>.

⁷² *Id.*

⁷³ Map of marijuana legality by State, DISA (2022), <https://disa.com/map-of-marijuana-legality-by-state> (last visited Jul 6, 2022).

⁷⁴ *Id.*

⁷⁵ Jennifer Robinson, DECADES OF DRUG USE: DATA FROM THE ‘60S AND 70’S GALLUP.COM (2021), <https://newsgallup.com/poll/6331/Decades-Drug-Use-Data-From-60s-70s.aspx> (last visited Jul 13, 2022)

⁷⁶ New poll finds majority of Americans have smoked marijuana, NBCNEWS.COM (2017), <https://www.nbcnews.com/news/us-news/new-poll-finds-majority-americans-have-smoked-pot-n747476> (last visited Jul 13, 2022).

⁷⁷ What are the health benefits and risks of cannabis?, MEDICAL NEWS TODAY, <https://www.medicalnewstoday.com/articles/320984> (last visited Jul 13, 2022).

increasing receptivity and changing perceptions of the drug by the US populace may lead to the rescheduling of marijuana in the future, paving the way for other current Schedule I drugs to be evaluated more extensively by the scientific community and possibly rescheduled, as well.

The federal government has the authority to enforce criminal laws, but has prosecutorial discretion to refrain from acting. The scope of federal preemption is unclear. Several state courts have ruled against local government officials who advanced arguments seeking to invalidate state medical marijuana laws on the grounds that they were *preempted* by federal law,⁷⁸ and the Supreme Court has declined to review these cases.⁷⁹ Under the Obama administration, the U.S. Department of Justice opted not to enforce federal marijuana laws in states with their own marijuana regulations, so long as the regulations were strong and effective and did not pose a threat to federal enforcement interests.⁸⁰

Congress has prohibited the Justice Department from expending federal resources to hamper state medical marijuana laws in some respects, as is set out in the Rohrabacher-Farr Amendment to the 2015 Appropriations Act. The Amendment states that the Department of Justice is barred from utilizing the Appropriations Act funding to prevent states that have legalized medical marijuana "from implementing their own State laws that authorize the use, distribution, possession, or cultivation of medical marijuana."⁸¹ The Rohrabacher-Farr Amendment was at the heart of an October 2015 decision handed down by the U.S. District Court for the Northern District of California. In *United States v. Marin Alliance for Medical Marijuana*, petitioners asked the District Court to dissolve a permanent injunction entered in 2002 that prevented a medical marijuana dispensary from dispensing

⁷⁸ Marijuana preemption conflicts between state and local governments, BALLOTPEDIA (2021), https://ballotpedia.org/Marijuana_preemption_conflicts_between_state_and_local_governments (last visited Aug 19, 2022).

⁷⁹ Kyle Jaeger, U.S. SUPREME COURT DENIES MEDICAL MARIJUANA WORKERS' COMPENSATION CASES MARIJUANA MOMENT (2022), <https://www.marijuanamoment.net/u-s-supreme-court-denies-medical-marijuana-workers-compensation-cases/> (last visited Aug 19, 2022).

⁸⁰ CONFLICTS BETWEEN STATE AND FEDERAL MARIJUANA LAWS, <https://www.govinfo.gov/content/pkg/CHRG-113shrg93426/html/CHRG-113shrg93426.htm> (last visited Jul 13, 2022).

⁸¹ Consolidated and Further Continuing Appropriations Act, 2015, Pub. L. No. 113-235, § 538, 128 Stat. 2130, 2217 (2015).

marijuana.⁸² The court held that, under the Rohrabacher-Farr Amendment, the Department of Justice could not enforce the permanent injunction because such enforcement would interfere with state laws governing medical marijuana.⁸³ Instead, the permanent injunction could only be enforced to the extent that the dispensary failed to comply with state law. Therefore, so long as the dispensary complied with state laws that permit and regulate medical marijuana, the Department of Justice is arguably left without a viable path by which to prosecute. *United States v. Marin Alliance for Medical Marijuana* remains the central case directly addressing how the Rohrabacher-Farr Amendment applies to Department of Justice action in states with legalized medical marijuana.⁸⁴

The Rohrabacher-Farr Amendment solely addresses medical marijuana- it does not impact psilocybin and related agents. However, both the Amendment and the *Marin* decision offer a useful view of how federal legislation and state laws, in time, might permit the use, distribution, possession, or cultivation of psilocybin and other psychedelic drugs.

VI. Recommendations

As studies establish that medical and therapeutic uses of psilocybin and related agents have clear benefits, "cooperative federalism," similar to that occurring with medical marijuana, may become possible. In a cooperative federalism model, federal and state laws would work together to address a shared issue such as the legalization of medicinal psychedelics. This could involve, for example, amendments to the federal Controlled Substances Act to allow states to opt out of psilocybin-related provisions. A state then could choose to opt out while passing laws permitting and regulating the use of medicinal psilocybin. In this scenario, possession or distribution of psilocybin within state boundaries pursuant to state laws would also be legal under federal law. There would be no need for a Rohrabacher-Farr type Amendment because state practice would not violate federal law.

The most feasible option for this cooperative federalism model is to enforce the Risk Evaluation and Mitigation Strategy (REMS)

⁸² *United States v. Cannabis Cultivator's Club*, No. C 98-00085 CRB, 2002 WL 1310460, at *4 (N.D. Cal. June 10, 2002).

⁸³ *See United States v. Marin All. for Med. Marijuana*, 139 F. Supp. 3d 1039, 1047 (N.D. Cal. 2015).

⁸⁴ *Id.*

drug safety program, which is synonymous with a cost-benefit analysis strategy. When deciding whether a REMS is required as aforementioned in Section 3.1, the FDA considers six factors as part of their decision making-process, including: the seriousness of any known adverse effects, the background incidence of adverse events in the population likely to use the drug, the expected benefit, whether the drug is a new molecular entity, the actual duration of treatment with the drug, and the estimated population size likely to use the drug.⁸⁵ Psychedelic drugs are difficult to approve by the FDA based upon their benefit-risk profile, given their classification as a Schedule 1 drug. Therefore, REMS may offer a practical solution for tipping the balance in favor of approvability by instituting additional safeguards to mitigate risk. The FDA bases their decision about the REMS and its constituent elements on an integrated benefit-risk framework and several key considerations related to the therapeutic area and the drug itself, as well as any potential negative impacts on patients and healthcare providers that the REMS may cause.

Furthermore, as medical research and findings are critically important to lawmakers in their decisions to enact or change drug policy,⁸⁶ a REMS approach can be adopted in cooperative federalism models to spur advocates on the state and federal level to encourage and support innovative lawmaking. Advocacy around clinical findings about the efficacy of psychedelics in treating debilitating conditions such as PTSD, as well as in mitigating and palliating anxiety related to end-stage terminal illness, will be necessary to galvanize changes in law and policy, and enable patient access to psychedelics. Outreach to inform the public, as well as elected representatives, of the potential use of these agents to improve the lives (and deaths) of millions of people will be important as well.

Access to psilocybin-along with other psychedelic medications could be achieved by reclassifying it from a Schedule I drug to a lower level classification. However, such a federal reclassification is difficult, as discussed in Section 3.1 of this paper. Efforts to reschedule cannabis provide a case in point, as multiple attempts to do so over the

⁸⁵ Format and content of a REMS document guidance for industry, <https://www.fda.gov/files/drugs/published/Format-and-Content-of-a-REMS-Document-Guidance-for-Industry.pdf> (last visited Jul 12, 2022)

⁸⁶ For example, North Carolina's "Enact Medical Cannabis Act," introduced in 2015, begins by proclaiming: "Modern medical research has discovered beneficial uses for cannabis in treating or alleviating pain, nausea, and other symptoms associated with certain debilitating medical conditions...." H.B. 78, General Assembly., 2015 Sess. (N.C. 2015).

past four decades have yet to succeed.⁸⁷ While rescheduling presents many difficulties, other avenues are available. The relatively wide and growing access to medical marijuana in the United States demonstrates that reclassification is not necessary for considerable access to be achieved.

Another recommendation would be for other states to continue the processes of legalizing psychedelics (through laws removing the penalties for the possession, personal use and social sharing of certain natural and synthetic psychoactive drugs to laws enabling states to study the medical use of psilocybin, MDMA, ketamine, etc).⁸⁸ As more and more clinical research comes out from scientific institutions and the general public grows increasingly aware of the medicinal potential of psychedelics, more states and jurisdictions will roll out legislative proposals to open access to psychedelics in a plethora of ways across the United States. The process in overturning prior date bills regarding psychedelics is a huge component of legalization in the next decade.

The first step towards acceptance and integration of these Schedule I drugs into society lies in dissuading popularly held beliefs and stigmas surrounding the substances. These destigmatizing campaigns can be achieved through proper scientific analysis. For many years, it was believed that MDMA--commonly referred to as ecstasy--caused permanent damage to both attention and memory. A study, funded by the National Institute on Drug Abuse in 2011, found that “regular ecstasy use was not associated with cognitive impairment” In fact, the Food and Drug Administration (FDA) is currently being evaluating MDMA is in Stage III trials by to determine its safety in the treatment of severe Post Traumatic Stress Disorder (PTSD). Phase III designation is the final step that must be taken in the process of getting a drug approved fit for human consumption. Following extremely promising Phase I and Phase II trials, the FDA granted the highly revered title of: “Breakthrough Therapy Designation” to this form of MDMA-assisted psychotherapy.

VII. Conclusion

Cooperative federalism is a promising legal framework which would enable state and federal governments to work together to

⁸⁷ See Marijuana Justice Act of 2017, S. 1689, 115th Cong. (2017).

⁸⁸ SB 519 would remove criminal penalties for possessing numerous psychedelics—including psilocybin mushrooms, DMT, ibogaine, LSD and MDMA—for adults 21 and older. Kyle Jaeger,

address the issue of psychedelic legalization. Through these modes, states would also maintain their independence through their own sets of powers and responsibilities.

Additionally, too much evidence of the medical health benefits of psychedelics exists for psychedelics to be classified as a Schedule 1 drug, as this classification diminishes the ability for scientists and physicians to study psychedelics clinically. Although the stigmatization of psychedelics that stemmed from the Nixon administration postponed true change for decades, the 21st century has seen a remarkable shift to profound research about the medicinal health benefits of these drugs. All of the parties involved in psychedelic legalization – scientists, physicians, drug manufacturers, Native Americans, religious and non-religious citizens, those individuals who compose state and federal governments, and all others are indispensable and inextricably linked. Cooperative federalism suggests compromise, and without it, we may never see the removal of psychedelics from a Schedule 1 classification. Ultimately, western science has, *in fact*, changed society's concepts of reality and of human nature, bridged the gap between ancient wisdom and modern science, and reconciled the differences between Eastern spirituality and Western pragmatism.

* * *