IN THE
SUPREME COURT OF THE UNITED STATES

State of LINCOLN,
Petitioner

v.

CHASE PHARMA, INC., et al.,
Respondent

On Petition for Writ of Certiorari to the
United States Court of Appeals for the Twelfth Circuit

BRIEF FOR RESPONDENT

Date: September 19, 2019

Team # 2817

Counsel for Respondent

Oral Argument Requested
QUESTION PRESENTED

I. In *Baker v. Carr*, the Supreme Court laid out six factors that are used to determine the presence of a nonjusticiable political question. Petitioner alleges that Respondent’s manufacturing and marketing of FDA and DEA approved opioid drugs is a public nuisance that has created the opioid crisis in the State of Lincoln. Does Petitioner’s claim raise a nonjusticiable political question under the Baker factors when there are no judicially discoverable or manageable standards for the Court to use when analyzing Petitioner’s claim and when such an issue is better left to the legislative and executive branches of government for an initial policy determination?

II. Courts do not find a valid claim for public nuisance when all elements of public nuisance have not been met. Petitioner alleges that Chase Pharma has unreasonably manufactured and marketed its products to create a public nuisance in the State of Lincoln. Did Petitioner successfully state a public nuisance claim when (1) Petitioner has asserted a private right rather than a public right; (2) Respondent has acted reasonably by complying with federal regulation; and (3) Respondent lacks the ability to control and abate Petitioner’s alleged harm?
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CONSTITUTIONAL AND STATUTORY PROVISIONS

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STATEMENT OF THE CASE

This case involves allegations that Chase Pharma, Inc.'s (Chase Pharma) manufacturing and marketing of prescription opioid drugs has created a public nuisance and caused the opioid crisis in the State of Lincoln (the State).

A. Statement of Facts

Opioid medications have been used and prescribed for pain management throughout history. R. at 2. Respondent Chase Pharma is one of many pharmaceutical companies that manufactures opioids used to relieve post-surgery, chronic, and terminal pain of individuals across the country. R. at 4-5. The Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA) regulate Chase Pharma’s products. R. at 4. The FDA closely monitors the promotion and marketing of prescription drugs to ensure that drug companies do not make fraudulent claims or promote off-marketing uses of their products. R. at 5. Not only does the FDA monitor the promotion and marketing of prescription drugs, but it also ensures the safety of those drugs. R. at 4. The DEA regulates the production, distribution, and sale of narcotic drugs such as opioids to ensure proper medical use. R. at 5. Chase Pharma’s products are approved by and comply with both FDA and DEA regulations. R. at 5. Chase Pharma also uses standard industry practice marketing activities that are FDA approved. R. at 5.

The State alleges that, despite its compliance with FDA and DEA regulation, Chase Pharma’s manufacturing and marketing have unreasonably interfered with
Lincoln citizens’ common rights and in turn created the current opioid crisis in the State of Lincoln.

B. Procedural History

Despite Chase Pharma’s compliance with the law, on April 13, 2017, the State filed this action against Chase Pharma in Lincoln state court alleging that Chase Pharma’s marketing campaign caused doctors to prescribe opioids in quantities or for treatment purposes that were dangerous, ineffective, and threatened public health and safety. R. at 4-5. The State further alleges that Chase Pharma’s marketing caused Lincoln to incur substantial costs for addiction treatment, law enforcement for criminal activity related to drugs, and social services. R. at 4-5. The State argues that Chase Pharma has caused the “opioid crisis” declared in Lincoln on January 23, 2017 and Chase Pharma’s actions amount to a public nuisance in the State of Lincoln. R. at 5.

Chase Pharma timely removed this case to federal court on April 21, 2017 asserting diversity jurisdiction under 28 U.S.C. § 1332 and removal jurisdiction under 28 U.S.C. § 1441. R. at 5. Chase Pharma then filed its Motion to Dismiss under Fed. R. Civ. P. 12(b)(6) on April 28, 2017, asserting: (1) the State’s claim raises a nonjusticiable political question and (2) the State has failed as a matter of law to state a claim of public nuisance. R. at 5. The U.S. District Court for the District of Lincoln found that the State’s public nuisance claim involves a nonjusticiable political question and the case should be dismissed on that ground alone. R. at 15. The District Court further found that even if the case presented a
legal question, the complaint failed to set forth the requirements of a successful public nuisance claim. R. at 15.

On July 3, 2018, the State filed a timely notice of appeal, contesting the District Court’s order dismissing the complaint and putting the case before the Court of Appeals for the Twelfth Circuit. R. at 16. The Twelfth Circuit affirmed the decision of the District Court in all respects. R. at 16.

The State has since filed a timely petition seeking a writ of certiorari from the Supreme Court of the United States. R. at 26. The Supreme Court granted certiorari on the questions of (1) whether the State of Lincoln’s public nuisance claim states a nonjusticiability political question; and (2) whether the State of Lincoln failed to state a claim for public nuisance for the reasons set forth by the lower courts. R. at 26.
SUMMARY OF THE ARGUMENT

The Supreme Court should affirm the holdings of the Federal District Court for the District of Lincoln and the United States Court of Appeals for the Twelfth Circuit regarding both the nonjusticiable political question and the failure to state a successful public nuisance claim issues.

I. Nonjusticiable Political Question

Article III of the Constitution limits federal courts to deciding cases and controversies that are capable of resolution through the judicial process. Since Marbury v. Madison, the Supreme Court has recognized that sometimes it may face questions that are better entrusted to other political branches or involve no judicially enforceable rights. Such “political questions” are nonjusticiable and should be dismissed.

To determine the existence of a political question, the Supreme Court laid out six factors in Baker v. Carr in 1962. The Supreme Court and federal courts continue to use these factors to determine whether a nonjusticiable political question is present. If any one Baker factor is prominent on the surface of a case, then that case involves a political question. Courts have most commonly used Baker factors one and two to dismiss cases for the presence of a nonjusticiable political question. Most recently, the Supreme Court in Rucho v. Common Cause used Baker factors one and two to dismiss partisan gerrymandering suits. Baker factor two asks if there are judicially discoverable and manageable standards for resolving the issue presented. The State brought its claims against Chase Pharma under the guise of public
nuisance to hold Chase Pharma responsible for the opioid crisis in the State of Lincoln. The State’s claim implicates Baker factors two and three and thus presents a nonjusticiable political question that should be dismissed.

The State’s claim implicates Baker factor two because it examines whether there are judicially discoverable or manageable standards for resolving the issue presented to the Court. No such standards exist to resolve the issue presented by the State's claim. Because the State has brought its claim under public nuisance, the Court would have to balance the benefits and utility of the legitimate uses of prescription opioid drugs against the risks posed by their misuse. The State’s claim is distinguishable from other public nuisance claims brought in the environmental injury context and is instead most similar to the greenhouse gas emission public nuisance claim seen in *Kivalina*. Like greenhouse gases, there are innumerable sources of opioids (both legal and illegal), the opioid crisis is not limited to the State of Lincoln, and finally, Chase Pharma is one of many drug manufacturers who produce a much needed and relied upon product. Petitioner cannot trace any of its far-reaching allegations to Chase Pharma’s manufactured opioids specifically or point to any one doctor misled into prescribing opioids. These considerations show that there are no judicially manageable standards available to aid the Court in balancing the benefits and utility of legitimate uses of prescription drugs against the risks posed by potential misuse and the State does not point to any.

Baker factor three is also implicated by the State’s opioid public nuisance claim. Baker factor three asks if in deciding an issue, the court would be required to
make an initial policy determination of a kind clearly for nonjudicial discretion. Baker factor three analyzes whether there is a preliminary policy decision that must be made by another branch of government in order to decide the case. The State’s claim, like the plaintiffs' claims in *Kivalina*, asks this Court to allocate the cost of and fault for the opioid crisis to Chase Pharma, one opioid manufacturer out of that complies with FDA and DEA regulations. Furthermore, the State’s claim asks the Court to decide whether prescription opioid use is good for the citizens of Lincoln. Such initial policy determinations are best left to the legislative and executive branches.

**II. Public Nuisance**

The State of Lincoln's public nuisance law directly follows the Restatement of Torts. The Restatement establishes four necessary elements of public nuisance—the offending conduct or activity must 1) substantially interfere with a right held in common by the public; 2) be unreasonable; 3) be within the defendant's control and be capable of abatement by the defendant; and 4) proximately caused the injury in question. All four elements must be satisfied to state a claim of public nuisance successfully. The State has failed to meet three of the four required elements of public nuisance.

First, the State has failed to show that Chase Pharma substantially interfered with a right held in common by the public. The State asserts that the additional money spent on law enforcement and social services to treat addiction constitutes a public right. The State, however, is mistaken; the Restatement of Torts adopts a
narrow definition of public right, and the alleged harm does not fall within this definition because the effects of addiction harm an individual and not the community. Expanding the scope of public nuisance to hold a manufacturer liable for the illegal use of their product would warrant unlimited claims, significantly overlap with products liability suits, and contradict the gradual and predictable evolution of common law. Courts that have expanded the scope of public rights rely on lenient state law to do so, and not the Restatement of Torts.

Second, the actions of Chase Pharma are reasonable. In a public nuisance suit, the court does not look at the unreasonableness of the conduct alone. Instead, the court must weigh the utility and benefit of the product or conduct against the alleged harm. Chase Pharma manufactures a drug used to relieve post-surgery, chronic, and terminal pain of individuals across the country. R. at 4-5. The benefit and utility of Chase Pharma’s product greatly outweigh the potential for misuse. Furthermore, Chase Pharma has complied with the laws in a heavily regulated market. The FDA and DEA have ensured that the product and the business practices of Chase Pharma are safe to the public. The laws regulating the opioid market represent the express intent of the legislature. To apply a new set of standards that contradicts the Legislature's written intent would be unconstitutional.

Lastly, control is a necessary element of a public nuisance claim, and the State has failed to show that Chase Pharma maintained control of the nuisance at the time of injury and is capable of abatement. In tort law, the element of control is
vital, and a public nuisance claim is no exception. Without control, the defendant is incapable of abatement, and consequently, the harm is not fixable. Doctors and distributors oversupply the drug, and individuals use the product illegally. The State does not assert any harm that occurs when the product is in the control of Chase Pharma. Accordingly, the Court should affirm the opinion of district court and court of appeals.
ARGUMENT

I. The court of appeals correctly affirmed the district court’s dismissal of the State’s claim because of the presence of a nonjusticiable political question.

The State's claim raises a nonjusticiable political question that was properly dismissed. Article III of the Constitution limits federal courts to deciding cases and controversies. Rucho v. Common Cause, 139 S. Ct. 2484, 2492 (2019). These cases and controversies are limited to questions that are historically capable of resolution through the judicial process. Flast v. Cohen, 392 U.S. 83, 95 (1968). Since Marbury v. Madison, the Supreme Court has recognized that sometimes it may face questions that are better entrusted to other political branches or involve no judicially enforceable rights. Vieth v. Jubelirer, 541 U.S. 267, 277 (2004); Marbury v. Madison, 5 U.S. 137, 166 (1803). Courts consider such questions “political questions” and nonjusticiable. Baker v. Carr, 369 U.S. 186, 217 (1962). Political questions pertain to the nation as a whole and not individual rights. Madison, 5 U.S. at 166.

The Supreme Court in Baker v. Carr debuted six factors to determine the presence of a political question. The Baker factors are as follows:

(1) a textually demonstrable constitutional commitment of the issue to a coordinate political department; (2) lack of a judicially discoverable and manageable standards for resolving it; (3) the impossibility of deciding without an initial policy determination of a kind clearly for nonjudicial discretion; (4) the impossibility of a court’s undertaking independent resolution without expressing lack of the respect due coordinate branches of government; (5) an unusual need for unquestioning adherence to a political decision already made; or (6) the potentiality of embarrassment from multifarious pronouncements by various departments on one question.
The State seeks to impose liability on Chase Pharma for the opioid crisis declared in the State of Lincoln on January 23, 2017 by bringing its allegations under the framework of public nuisance. R. at 24. The State alleges that Chase Pharma’s manufacturing and marketing practices have unreasonably interfered with Lincoln citizens’ common rights to public health, welfare, and safety and created a reasonable apprehension of danger to person and property from the adverse effects addiction has on the community. R. at 24. In a case that raises a potential political question, the Court should look to the six factors laid out by the Supreme Court in *Baker v. Carr* for guidance. The Lincoln District Court and Twelfth Circuit Court of Appeals correctly found that the State’s claim implicated Baker factors two and three, and thus the State's claim raised a nonjusticiable political question that should be dismissed.

A. **The Supreme Court continues to use the Baker factors to determine the presence of a nonjusticiable political question.**

The Supreme Court continues to use the Baker factors in determining the presence of a political question. Most recently in *Rucho v. Common Cause*, the Supreme Court considered the justiciability of partisan gerrymandering claims. 139 S. Ct. 2484, 2492 (2019). In *Rucho*, the Court found that there was no “clear, manageable, and politically neutral” test for fairness in political districting. 139 S. Ct. at 2500. In other words, there is no case law indicating that racial and political gerrymanders are subject to the same constitutional scrutiny under the Fourteenth
Amendment. Id. at 2502. Because there are no legal standards discernible in the Constitution (or relevant case law), a judicial decision on what would be “fair” in the partisan districting context would be considered an “unmoored determination” that is characteristic of a political question beyond the competence of the federal courts. Zivotofsky v. Clinton, 566 U.S. 189, 196 (2012). Such a determination, or question, implicates Baker factor two because it does not have judicially discoverable and manageable standards. Rucho, 139 S.Ct. at 2489. The Supreme Court further concluded that the Constitution gave Congress the power to do something about partisan gerrymandering in the Elections Clause, implicating Baker factor one. Id. at 2507. The decision in Rucho reveals that the Baker factors are alive and well in determining the presence of a nonjusticiable political question. 139 S. Ct. 2484 (2019).

Furthermore, the Supreme Court in Baker qualified the announcement of the six-factor test in two ways: (1) that at least one of the factors must be prominent on the surface of any case held to involve a political question; and (2) that unless one of the factors is inextricable from the case at bar, there should be no dismissal for non-justiciability on the ground of a political question’s presence. Baker, 369 U.S. at 217. These qualifiers indicate that any one Baker factor may be dispositive. R. at 17; Zachary Baron Shemtob, The Political Question Doctrines: Zivotofsky v. Clinton and Getting Beyond the Textual-Prudential Paradigm, 104 Geo L.J. 1001, 1011 (2016). After the decision in Baker, courts determining the presence of a political question have referred to at least one of these six factors in reaching their decision,
most commonly factors one and two. *E.g.* *Nixon v. U.S.*, 506 U.S. 224, 228-229 (1993); *Gilligan v. Morgan*, 413 U.S. 1, 10 (1973); *Powell v. McCormack*, 395 U.S. 486, 548-49 (1969); *El-Shifa Pharm. Indus. Co. v. U.S.*, 607 F.3d 836, 845 (D.C. Cir. 2010); 767 Third Ave, Assocs. *v. Consulate Gen. of the Socialist Fed. Republic of Yugo.*, 218 F.3d 152,160 (2d Cir. 2000). However, because the Baker analysis lists the six factors in the disjunctive, not the conjunctive, a court need only conclude that one factor is present to find a political question. *Al-Tamimi v. Adelson*, 916 F.3d 1, 12 (D.C. Cir. 2019); *Schneider v. Kissinger*, 412 F.3d 190, 194 (2005). The State’s public nuisance claim implicates two Baker factors, one of which is Baker factor two. Thus, the State’s claim raises a nonjusticiable political question that should be dismissed.

**B. Baker Factor Two: The State’s public nuisance claim does not have judicially discoverable and manageable standards that allow the Court to weigh the alleged harm against the utility and benefit provided by Chase Pharma’s product.**

Baker factor two examines whether there are “judicially discoverable and manageable standards” for resolving the issue presented to the court. *Baker*, 369 U.S. at 217. This factor is not completely distinct from the first Baker factor: “a textually demonstrable constitutional commitment of the issue to a coordinate political department.” *Id.* Rather, the lack of judicially manageable standards may strengthen the conclusion that there is a textually demonstrable commitment to a coordinate branch. *Nixon*, 506 U.S. at 228-29. Baker factor two is most commonly regarded as requiring courts to discover the criteria for deciding the issue in question to determine whether “the judicial tests through which constitutional
(statutory or common law) norms are enforce” are manageable. Richard H. Fallon, Jr., Judicially Manageable Standards and Constitutional Meaning, 119 Harv. L. Rev. 1274, 1281 (2006). In other words, a court must ask whether it has the legal tools to reach a ruling that is principled, rational, and based upon reasoned distinctions. Native Vill. of Kivalina v. Exxon Mobil Corp., 663 F. Supp. 2d 863, 874.

The State has brought its claim against Chase Pharma under the guise of common law public nuisance. R. at 1. The Restatement and the State of Lincoln define a public nuisance as “an unreasonable interference with a right common to the general public.” Restatement (Second) of Torts §821B. The focus of a public nuisance claim is not on “unreasonableness” alone. Kivalina, 663 F. Supp. 2d at 874. Rather, whether the interference is unreasonable turns on weighing the gravity of the harm against the utility of the product or conduct. Id. The unreasonableness of an interference represents a judgment, comparing the social utility of an activity against the gravity of the harm it inflicts. Id.

Public nuisance claims have often been brought in the context of environmental injuries. Kivalina, 663 F. Supp. 2d at 874; Connecticut v. Am. Elec. Power Co., Inc., 582 F.2d 309 (2d Cir. 2009). The plaintiffs in Kivalina followed this trend and sued Exxon Mobil under public nuisance alleging that Exxon Mobil had substantially contributed to greenhouse emissions that caused global warming and threatened the plaintiffs’ way of life. 663 F. Supp. 2d at 869-70. The court in Kivalina distinguished the global warming and greenhouse gas public nuisance claim from those air and water pollution cases cited by plaintiffs. Id. at 875. The
court found that the commonality in air and water pollution cases was a discrete number of “polluters” identified as causing a specific injury to a specific area or waterway. *Id.* These claims were vastly different from those of the plaintiffs in *Kivalina* because greenhouse gas emissions come from innumerable sources around the world, these emissions affect the entire planet and atmosphere, and the global warming process involves a series of events too disconnected from the emission of the greenhouse gas itself. *Id.* at 876. Thus, the court concluded that there were no judicially discoverable and manageable standards to aid them in weighing alternative sources of energy, reliability, safety considerations, and impact on consumers and businesses against the benefits of the defendants’ conduct and product increasing greenhouse gases and heightening the risk of flooding in the plaintiffs’ village. *Id.* at 874-75.

The State's public nuisance claim based on opioid manufacturing and marketing is similar to the *Kivalina* plaintiffs’ global warming and greenhouse gas public nuisance claim. Like greenhouse gas emissions, there are innumerable sources of opioids, both legal and illegal. There are more than 1,500 registered drug manufacturers and distributors nationwide. DEA Announces Enhanced Tool for Registered Drug Manufacturers and Distributors to Combat Opioid Crisis (Feb. 26, 2019), [https://www.dea.gov/press-releases/2019/02/26/dea-announces-enhanced-tool-registered-drug-manufacturers-and](https://www.dea.gov/press-releases/2019/02/26/dea-announces-enhanced-tool-registered-drug-manufacturers-and). This number does not include the rising number of illegal sales of opioids sold over the internet. FDA Takes New Enforcement Actions as Part of the Agency’s Ongoing Effort to Combat the Illegal
Online Sales of Opioids (Apr. 2, 2019), https://www.fda.gov/news-events/press-announcements/fda-takes-new-enforcement-actions-part-agencys-ongoing-effort-combat-illegal-online-sales-opioids. Furthermore, like global warming, the opioid crisis is not limited to the State of Lincoln. In 2017, the President along with the DEA, FDA, and Health and Human Services (HHS) declared a public health emergency to address the national opioid crisis. Ending America’s Opioid Crisis, https://www.whitehouse.gov/opioids/. Finally, like global warming, manufacturing and marketing opioid drugs is too far removed from the State’s alleged harm. Chase Pharma is one of many drug manufacturers who produce a much needed and relied upon product. Chase Pharma is not responsible for the prescription of these drugs. Instead, individual doctors prescribe opioids to their patients for a variety of medical purposes. These doctors monitor their patients and follow FDA guidelines on prescriptions. After the doctor makes a prescription, the patient goes to the pharmacy and picks up the prescription. DEA, The Primary Regulator of Controlled Substances, https://www.rollcall.com/sponsored-content/how-we-can-stop-americas-opioid-crisis-now/HDADEA.jpg. What the patient does with those drugs is out of the control of Chase Pharma. Chase Pharma’s manufacturing and advertising is too far removed from the individual choices that can lead to addiction and ultimately, the State’s alleged harm.

The State alleges far-reaching impacts and injuries that it cannot trace to any one specific drug manufacturer’s conduct or opioid product. R. at 9. Nor has the State identified any particular doctor misled into prescribing any of Chase
Pharma's opioid drugs. R. at 5. The State can offer no guidance as to precisely what judicially discoverable and manageable standards exist and should be applied in balancing the benefits and utility of the legitimate uses of prescription drugs against the risks posed by their potential misuse. Therefore, the State's public nuisance claim fails under Baker factor two and should be dismissed.

C. **Baker Factor Three: The State asks this Court to make an initial policy determination of a legislative nature rather than through legal and factual analysis.**

Baker factor three analyzes whether there is a preliminary policy decision that must be made by another branch of government in order to decide the case. Ron Park, *Is the political question doctrine jurisdictional or prudential?*, 6 UC Irvine L. Rev. 255, 268 (2016); *Baker*, 369 U.S. at 217. A political question under this factor exists when, to resolve a dispute, the court must make a policy judgment of a legislative nature, rather than resolving the dispute through legal and factual analysis. *EEOC v. Peabody W. Coal Co.*, 400 F.3d 774, 784 (9th Cir. 2005). This factor is aimed at preventing a court from removing an important policy determination from the Legislature. *In re Methyl Tertiary Butyl Ether (MTBE) Prods. Liabl. Litig.*, 438 F. Supp. 2d 291, 297 (S.D. N.Y. 2006); *Kivalina*, 663 F. Supp. 2d at 876. Federal nuisance claims inherently require the fact finder to consider both the harm alleged by a plaintiff as well as the utility or value of a defendant’s actions. *Kivalina*, 663 F. Supp. 2d at 876. The State's public nuisance claim requires balancing the social utility of the legitimate use of Chase Pharma's opioid products with the potential harm of the products’ misuse. *Id.*
In *Kivalina*, the plaintiffs’ claim also failed because it raised a nonjusticiable political question under Baker factor three. The court in *Kivalina* found that balancing the social utility of the defendant’s conduct (supplying energy and fuel) with the harm it inflicts (the emission of greenhouse gases and global warming) required the fact finder to determine what would have been an acceptable limit on the level of greenhouse gases emitted by defendants. *Kivalina*, 663 F. Supp. 2d at 876; *California v. GMC*, No.C06-05755 MJJ, 2007 U.S. Dist. LEXIS 68547, at *8 (N.D. Cal. 2007). The court further found that such a public nuisance claim required the judiciary to make a policy decision about who should bear the cost of global warming. *Kivalina*, 663 F. Supp. 2d at 877. In *Kivalina*, the plaintiffs alleged that the defendants were responsible for a “substantial portion” of greenhouse gas emissions, but also acknowledged that virtually everyone on Earth contributed to such emissions. *Id.* The court found that the plaintiffs were further asking the court to make a political judgment that the two dozen defendants named in the suit should be the only ones to bear the cost of contributing to global warming. Such an allocation of cost and fault, the court determined, were better left to the executive and legislative branch. *Id.*

The State’s public nuisance claim based on opioid manufacturing and marketing similarly asks the Court to weigh the harm allegedly caused to the State of Lincoln with the utility or value of Chase Pharma’s product. Such a balancing act in effect asks the Court to determine whether opioid drug use is good for the citizens of Lincoln. R. at 9. Furthermore, like the plaintiffs in *Kivalina*, the State’s claim
would require the Court to make a policy decision about who should bear the cost of opioid addiction. There are thousands of drug manufacturers of opioids, both legal and illegal, and the State cannot trace its far-reaching claims to any one specific drug manufacturer’s conduct or to opioid drugs as opposed to any other cause. DEA Announces Enhanced Tool for Registered Drug Manufacturers and Distributors to Combat Opioid Crisis (Feb. 26, 2019), https://www.dea.gov/press-releases/2019/02/26/dea-announces-enhanced-tool-registered-drug-manufacturers-and; FDA Takes New Enforcement Actions as Part of the Agency’s Ongoing Effort to Combat the Illegal Online Sales of Opioids (Apr. 2, 2019), https://www.fda.gov/news-events/press-announcements/fda-takes-new-enforcement-actions-part-agencys-ongoing-effort-combat-illegal-online-sales-opioids; R. at 9. Furthermore, the State has not identified any particular doctor misled into prescribing any of Chase Pharma’s opioid drugs. R. at 9. Despite the State’s inability to trace its claims, the State asks this Court to decide whether opioids are good for the citizens of Lincoln and to place the burden of the opioid crisis in Lincoln on Chase Pharma alone. Such determinations, as the court in Kivalina stated, are initial policy determinations that should be left to the executive and legislative branches of government.

II. The Court should affirm the district court’s and court of appeals’ holding because the State has failed to state a claim of public nuisance under Lincoln’s public nuisance law.

By the inability to satisfy several required elements of public nuisance, the State failed as a matter of law to plead a plausible claim sufficient to survive a motion to dismiss. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). Under Rule 8(a)(2) a
pleading that states a claim for relief must contain a short and plain statement of the claim that shows the pleader is entitled to relief. Fed. R. Civ P. 8. In other words, assuming the facts in the pleading are correct, the allegations must be plausible to develop a prima facie case for a cause of action. Id.

A public nuisance cause of action is grounded in state law. The State of Lincoln directly follows the common law principles outlined in the Restatement of Torts. R. at 10. The State of Lincoln and the Restatement define nuisance as “any conduct or activity that is injurious to health; indecent; offensive to the senses; or an obstruction to the free use of property, so as essentially to interfere with the comfortable enjoyment of life or property.” Linc. Stat. 54-133 (2018). The Restatement establishes four necessary elements of public nuisance – the offending conduct or activity must 1) substantially interfere with a right held in common by the public; 2) be unreasonable; 3) be within the defendant's control and be capable of abatement by the defendant; and 4) proximately caused the injury in question. All four elements must be satisfied to successfully state a claim of public nuisance. See Victor E. Schwartz, Phil Goldberg & Christopher E. Appel, Can Governments Impose a New Tort Duty to Prevent External Risks? The “No-Fault” Theories Behind Today’s High-Stakes Government Recoupment Suits, 44 Wake Forest L. Rev. 923, 940 (2009).

The State fails to satisfy three of the four required elements of public nuisance. First, there has been no substantial interference with a right held in common by the public. Second, the conduct of Chase Pharma has not been
unreasonable. Lastly, the products at the time of the alleged injury were not in the control of Chase Pharma and not capable of abatement. Therefore, the district court correctly dismissed the State's complaint because the State failed as a matter of law to state a claim of public nuisance.

A. The manufacturing and marketing of opioids by Chase Pharma does not substantially interfere with a public right under Lincoln’s public nuisance law.

Chase Pharma has not substantially interfered with a right held in common by the public because the State's pleading asserts a private right, not a public right. A public right is common to all members of the public and not merely one enjoyed by a large number of people. Restatement (Second) of Torts § 821 B, cmt. G. The number of individuals affected is irrelevant; the court only looks to whether the public at large will be adversely affected. Ganim v. Smith & Wesson Corp., 780 A.2d 98, 132 (Conn. 2001). In other words, the harm is collective in nature and not individual. Olive v. deJongh, 57 V.I. 24, 47 (Super. Ct. 2012). In order to adhere to the Restatement’s definition of a public right, the State of Lincoln should follow the narrow interpretation of a public right.

1. The State unsuccessfully asserts a public right because the alleged harm is a private right.

The absence of a public right in the State's pleading bars the State from successfully stating a claim of public nuisance. The State claims the additional money spent on law enforcement and social services to treat addiction constitutes a public right. R. at 4. The State has not brought suit based on the violation of a legitimate public right but instead bases its claims on public interest concerns.
Opioids are a privately consumed product and not a resource communal among the general public. Common examples of public rights include air, water, and public rights of way. City of Chi. v. Am. Cyanamid Co., 355 Ill. App. 3d 209, 215 (2005). An individual in their capacity purchases and uses the product. These products are not open to the general public and easy to attain. A prescription from a certified doctor is required to legally obtain opioids.

The harm that results from the abuse of opioids is not collective. The State asserts that increased expenditures on law enforcement and social services have amounted to an interference with a public right. R. at 4. However, courts have rejected classifying increased medical costs, decreased tax revenues from lost productivity, police expenditures, and property repairs as a public right. Ganim, 258 Conn. 313 at 327 (2001). Thus, the State’s allegation that Chase Pharma has interfered with the health, safety, peace, comfort, and convenience of the residents of Lincoln is not evidenced in the State’s complaint. State v. Lead Indus. Ass’n, 951 A.2d 428, 453 (R.I. 2008). The State has misconstrued public nuisance to encompass any conduct that affects public health and safety. Rather, it is the individual suffering from addiction whose health and safety is at risk, not the health and safety of the general public.

Moreover, courts that hold opioid manufacturers liable for public nuisance rely heavily on state law and not the Restatement of Torts. In the recent district court decision, State of Oklahoma v. Purdue Pharma, L.P., the court held that an opioid manufacturer's conduct substantially interfered with a public right. No. CJ-
Because Oklahoma state law grants more leeway than the Restatement of Torts, the court had leniency in classifying a public right. Unlike Oklahoma, the State of Lincoln relies solely on the Restatement of Torts for determining the elements of public nuisance, and as a result, the State's allegations do not fall within the scope of a public right. Moreover, the holding in Johnson is not binding on the State of Lincoln and is not final. Johnson & Johnson announced that it will appeal the judgment of the Oklahoma state court. Johnson & Johnson To Appeal Flawed Opioid Judgment in Oklahoma (Aug. 26, 2019), https://www.jnj.com/johnson-johnson-to-appeal-flawed-opioid-judgment-in-oklahoma.

States that closely follow the Restatement of Torts, like Lincoln, do not consider the actions of manufacturers to infringe a public right. In Chicago v. Beretta, the City of Chicago sued the manufacturers, distributors, and dealers of handguns in an effort to combat gun violence. City of Chi. v. Beretta U.S.A. Corp., 213 Ill. 2d 351, 355 (2004). The City argued that the gun manufacturer’s marketing led to high levels of crime, death, and injuries to citizens. Id at 374. In addition, the City asserted that fear and discomfort resulting from the manufacturer’s products inconvenienced the residents of Chicago. Id. The court did not have case law to reference in their analysis and relied heavily on the definition of a public right in the Restatement of Torts. Id. at 371. Consequently, the court held that the alleged harm did not fall within the scope of a public right and dismissed the City’s public nuisance claim. The court was “reluctant to state that there is a public right to be
free from the threat that some individuals may use an otherwise legal product (be it a gun, liquor, a car, a cell phone, or some other instrumentality) in a manner that may create a risk of harm to another.” Id. at 374. The State’s public nuisance claim based on opioid manufacturing and advertisement is similar to the City of Chicago’s gun manufacturing public nuisance claim. Like Chicago v. Beretta, the State attempts to hold Chase Pharma liable for public nuisance in an effort to combat the opioid crisis. In addition, the State wrongly asserts that the alleged harm infringes on a public right. It is not a public right to be free from the threat that members of the public may commit crimes against individuals or illegally use a product. Id. at 371. Like the plaintiff in Chicago v. Beretta, the State unfairly attempts to assert a public right based on the illegal use of a manufacturer’s legal product.

2. The narrow interpretation of a public right best represents the Restatement of Torts and Lincoln’s public nuisance law.

States should be cautious in expanding the definition of a public right. “Evolution of the common law should occur gradually, predictably, and incrementally.” Lead Indus. Ass’n, 951 A.2d at 454. Under the present understanding of public nuisance, the manufacturing of products is not an actionable violation of a public right. Id. at 448. Various courts have rejected attempts at expanding the scope of a public right to place liability on the manufacturers of guns and lead paint. Lead Indus. Ass’n, 951 A.2d at 450.; Beretta U.S.A. Corp., 213 Ill. 2d at 379. These courts deemed it would be an inappropriate and unprecedented expansion of a public right to classify mere manufacturing as
such. The State asks this court to drastically alter the scope of a public right. *Lead Indus. Ass’n*, 951 A.2d at 450

Fortunately, this does not leave consumers without a cause of action. Courts have recognized that these claims best belong in a products liability suit. *Beretta U.S.A. Corp.*, 213 Ill. 2d at 379. The purpose of a products liability suit is to hold manufacturers liable for a harmful product they place into the stream of commerce. *Lead Indus. Ass’n*, 951 A.2d at 456. There is undoubtedly a significant overlap between a public nuisance cause of action attempting to hold a manufacturer liable and a products liability suit. Consequently, an expansion of the public nuisance cause of action will allow plaintiffs to circumvent a products liability suit. *Id*.

Furthermore, choosing to expand the concept of public nuisance opens the door to endless claims. *Camden Cty. Bd. of Chosen Freeholders v. Beretta*, 273 F.3d 536, 540 (3d Cir. 2001). This expansion has the potential to “become a monster that would devour in one gulp the entire law of tort.” *Id*. Manufacturers in all areas will be in fear of litigation. “All a creative mind would need to do is construct a scenario describing a known or perceived harm of a sort that can somehow be said to relate back to the way a company or an industry makes, markets and/or sells its non-defective, lawful product or service, and a public nuisance claim would be conceived, and a lawsuit born.” *Lead Indus. Ass’n*, 951 A.2d at 457. For example, cell phone manufacturers could be subject to suit if a consumer who uses their product on a highway causes a car accident. *Id* at 454. Like Chase Pharma, a cell phone manufacturer makes a product that reaches a consumer from a series of
distributors, retailers, and various personnel. Afterward, the consumer illegally uses the product and causes harm to the public. By choosing to expand the concept of public rights, claims of a similar nature will surface. These claims attempt to free the public from the risk of consumers using a manufacturer’s product illegally. The court in Chicago v. Beretta held that to extend the meaning of public right in such a way would be improper. Beretta U.S.A. Corp., 213 Ill. 2d at 375. Maintaining a narrow definition of a public right most accurately represents the Restatement of Torts and embodies the purpose of a public nuisance suit.

B. **Chase Pharma has conducted its business in a reasonable manner.**

Because Chase Pharma has not violated Congress's express and unequivocally manifested intent, the State cannot state a claim upon which relief can be granted. Chase Pharma has reasonably conducted its business by strictly complying with a heavily regulated market and acting in good faith. R. at 5. Chase Pharma reported all statements and assurances with integrity and to the best of their knowledge. R. at 5. For Chase Pharma's conduct to be held unreasonable despite lawfully conducting its business would be an anomaly and go against the virtues of fairness and justice. Beretta U.S.A. Corp., 213 Ill. 2d at 381.

Although the Restatement holds that a public nuisance claim can be made against a defendant placing a lawful product in the stream of commerce, most courts restrict public nuisance claims to those that affect real property or involve an illegal act. Richard C. Ausness, ARTICLE: THE CURRENT STATE OF OPIOID LITIGATION, 70 S.C. L. Rev. 565, 572 (2019). Courts have been reluctant to expand
the scope of a public nuisance beyond lawful behavior because creating a new
standard of conduct conflicts with the Legislature's written intent. Beretta U.S.A. Corp., 213 Ill. 2d at 387. Furthermore, the State of Lincoln's public nuisance statute is silent as to whether this interpretation holds in the context of drug manufacturing. Thus, the Court should affirm dismissal because the State fails to meet the unreasonable element required for a successful public nuisance claim.

1. Chase Pharma complies with the laws and regulations governing the opioid market to provide a safe product to the citizens of Lincoln.

The FDA and the DEA set rigorous standards for opioid manufacturers to follow in every stage of opioid production. This includes the development, testing, production, manufacturing, distribution, labeling, advertising, prescribing, sale, possession, use, misuse, abuse, theft, resale, and inter-state transportation of opioid drugs. The FDA closely monitors the promotion and marketing of prescription drugs to ensure that drug companies do not make fraudulent claims or promote off-market uses of their products. U.S. Department of Health and Human Services & Food and Drug Administration, et al. Guidance for Industry: Oversight of Clinical Investigations—A Risk-Based Approach to Monitoring 1, 5 (2013) available at https://www.fda.gov/media/116754/download. The FDA has recently required changes to the prescribing information for all opioid medicines used in the outpatient setting to avoid misuse and inform doctors and patients on drug tapering techniques. Douglas Throckorton, M.D., About the Center for Drug Evaluation and Research (Apr. 9, 2019), https://www.fda.gov/news-events/press-

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The State concedes that Chase Pharma and its opioid drugs and labeling follow all pertinent regulations and does not point to any one doctor misled into prescribing opioid medication. R. at 9. The State asks this Court to overlook Chase Pharma’s compliance with federal regulation, law, and guidelines and assign blame for a crisis without basis in principled, rational, and reasoned distinctions. Kivalina, 663 F. Supp. 2d at 874. Chase Pharma has conducted a lawful sale of a non-defective and certifiably safe product, and therefore, has acted reasonably.

Moreover, the focus of a public nuisance claim is not on “unreasonableness” alone. Courts must weigh the gravity of the alleged harm against the utility and benefit of the conduct or product. Id. In this case, the benefits of the drugs’ therapeutic effect outweigh the associated costs of preventing their manufacture. Opioids are used for pain recovery in life saving circumstances, surgeries, and other instances of severe pain. Additionally, Chase Pharma has gone beyond the minimum safety precautions and taken steps to prevent addiction by introducing an abuse-deterring time-release formula. R. at 4.

Furthermore, oversupplying the market does not amount to unreasonable conduct. The court in Chicago v. Beretta held that a gun manufacturer supplying a non-defective product in compliance with the law did not constitute an unreasonable act. City of Chi. v. Beretta U.S.A. Corp., 213 Ill. 2d 351, 360 (2004). In
Beretta, the plaintiffs asserted that the gun manufacturers oversupplied the Illinois gun market and targeted individuals likely to use their product illegally. The plaintiff asserted that the defendant being aware of high gun violence rates and designing their product with a fingerprint resistant design, ease of concealment, and the ability to fire many rounds from single ammunition constituted unreasonable marketing and distribution practices by the defendant. The court rejected this contention. The State makes similar assertions, claiming that Chase Pharma has targeted individuals prone to addiction and doctors who prescribe opioids. R. at 3. However, the State cannot trace these claims. R. at 5, 9.

Chase Pharma has acted legally in its manufacturing and marketing of opioid products. Its products provide life-saving relief to those in pain and Chase Pharma has taken additional measures to make its products safer. Similar to Beretta, the Court should not deem the lawful actions of Chase Pharma unreasonable.

2. The lawful conduct of Chase Pharma is sufficient in proving reasonableness because the judicial branch cannot defy the express intent of Congress represented in the laws and regulations governing the opioid market.

To determine the intent of Congress, courts look to the canons of construction. Ct. Nat. Bank v. Germain, 503 U.S. 249, 253 (1992). The canons of construction are no more than rules of thumb that help courts determine the meaning of the legislation. Id. Statutory interpretation begins with the language of the statute itself. Ross v. Blake, 136 S.Ct. 1850, 1856 (2016). The court must presume that the legislature says what it means by the words in a statute. Id. If the intent of
Congress is clear, then the court must give effect to the unambiguously expressed intent of Congress. *Sebelius v. Cloer*, 133 S.Ct. 1886, 1889 (2013).

A court can use judicial perception to determine that a statute's result is unreasonable when analyzing an ambiguous statutory provision. *Lewis v. City of Chicago*, 130 S.Ct. 2192, 2200 (2010). However, a court should not exercise its judicial perception when the intent of Congress is apparent in an unambiguous statutory provision. *Id.* Even if the judiciary believes that Congress may not have foreseen all consequences of a statutory enactment, the judiciary must give effect to a statute's plain meaning. *Union Bank v. Wolas*, 502 U.S. 151, 158 (1991). The statutory provisions governing the opioid market are unambiguous. 21 U.S.C. § 811. The legislature's intent is clear, and there are no words or phrases that present ambiguity. *Id.* To contradict or supplement the given statutory provisions would render part of the statute inoperative. *U.S. v. Nordic Village*, 503 U.S. 30, 36 (1992). The court's interpretation cannot adversely affect provisions within a statute, and every word in a statute must have an operative effect. *Id.* The State asserts that the laws governing the opioid market produce an unfavorable result. This contention is irrelevant because the court cannot take into consideration the unforeseen consequences of the law when the statute is unambiguous. *Wolas*, 502 U.S. at 151, 158. Therefore, to go beyond Congress's intent would be unconstitutional.

At first glance, solving these public interest concerns may be seen as favorable. However, the judicial branch is ill-suited to act with legislative authority. Luther J. Strange III, ARTICLE: A PRESCRIPTION FOR DISASTER: HOW
LOCAL GOVERNMENTS’ ABUSE OF PUBLIC NUISANCE CLAIMS WRONGLY 
ELEVATES COURTS AND LITIGANTS INTO A POLICY-MAKING ROLE AND 
SUBVERTS THE EQUITABLE ADMINISTRATION OF JUSTICE, 70 S.C. L. Rev. 
517, 537 (Aug. 30, 2019). The FDA and DEA have developed a stringent set of laws 
for manufacturers to abide by. Developing these laws took years of research, 
supervision, and mindful deliberation. *Id.* The judicial branch has not invested the 
same amount of consideration and effort in creating rules for a pharmaceutical 
company to follow. *Id.* The Rhode Island Supreme Court acknowledged that public 
nuisance claims involving public policy present “a polycentric problem that cannot 
easily be resolved through a traditional courtroom-bound adjudicative process,” 
essentially admitting the judiciary's inability to resolve complex questions of health 
Supp. 699, 766-67 (E.D.N.Y. 1974)). The history of the United States’ court system 
supports the contention that courts should not use litigation to achieve a legislative 
goal. *Beretta U.S.A. Corp.*, 213 Ill. 2d at 387. Because Chase Pharma has complied 
with the written intent of Congress, the Court should deem its actions reasonable.

C. **The State’s alleged harm is not within Chase Pharma’s control, 
and therefore Chase Pharma is incapable of abatement.** 

Control is an essential element of a public nuisance claim. *Beretta U.S.A. 
Corp.*, 213 Ill. 2d at 397. The requirement of control is consistent with tort law, and 
the absence of control is generally fatal to any public nuisance claim. *Id.* There are 
two aspects of the control requirement. First, the law requires that a defendant
must have minimally controlled the nuisance at the time of the damage. *Lead Indus. Ass’n*, 951 A.2d at 449. Second, there must be sufficient control over the instrument so that the defendant can abate the harm. *Id.*

Courts that regard the element of control as a merely relevant factor in a public nuisance claim have misconstrued the law. In *re Lead Paint Litigation*, the court held that it is immaterial whether the defendants continued to exercise control over the nuisance. *Lead Indus. Ass’n*, 951 A.2d at 450. The Chief Justice in *re Lead Paint Litigation* cites the District Court of Rhode Island, as authority when it refused to bar recovery to a plaintiff who was unable to demonstrate control. *Id.* Later on, the District Court of Rhode Island clarified that it did not abandon the element of control; rather, the paramount question was when a defendant needs to exhibit control, not if control itself is necessary. *Id.*

In fact, Courts have further emphasized the element of control in a public nuisance suit, identifying it as an indispensable requirement. “Plaintiffs acknowledge the general rule that when a defendant is blameless for the subsequent misuse of its product, it bears no legal responsibility for a nuisance subsequently created by those who have purchased the product.” *Beretta U.S.A. Corp.*, 213 Ill. 2d at 397. The State concedes that consumers abuse opioids after the point of Chase Pharma's sale. R. at 3. The State does not and cannot show that the Chase Pharma had any control over the actual use of the product once it left its hands. Furthermore, the State fails to take into account the intervention of third parties that prevent Chase Pharma from maintaining control over the nuisance at
the time of injury. These third parties include doctors, distributors, drug traffickers, pharmacies, and consumers who subsequently misuse the product and create the nuisance. R. at 15.

Besides the fact that Chase Pharma lacks control of the nuisance at the time of injury, the State's claim also fails because Chase Pharma is incapable of abating the nuisance. Without control, the defendant is incapable of abatement, and the court cannot appropriately assign blame or resolve the issue. The essence of public nuisance law is ending the alleged harmful conduct, and in the present case, the manufacturing and marketing practices of Chase Pharma are too remote from the alleged harm. Lead Indus. Ass'n, 951 A.2d at 450. Changing the lawful behavior of a manufacturer will not produce substantial effects; this assumption is speculative at best. Beretta U.S.A. Corp., 213 Ill. 2d at 393. In fact, the Legislature and several government agencies have made efforts to combat the opioid crisis across the country. These efforts target the downstream distribution and prescription of opioid drugs. Most recently risks posed by misuse of opioids have been curbed with the publishing of federal guidelines to help prevent and monitor misuse and addiction. CDC Guideline for Prescribing Opioids for Chronic Pain (Aug. 31, 2018), https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf. Since 2015, at least thirty-three states have passed legislation limiting opioid prescription. Prescribing Policies: States Confront Opioid Overdose Epidemic (Jun. 30, 2019), http://www.ncsl.org/research/health/prescribing-policies-states-confront-opioid-overdose-epidemic.aspx. And finally, on October 24, 2019, the President signed the
Substance Abuse Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act into law. 115 P.L. 271, 132 Stat. 3894, 2018. Holding Chase Pharma liable for the independent actions of others is unfair and offers a mere band-aid solution to the opioid crisis.

In *Chicago v. Beretta*, the Court recognized this dilemma and granted a gun manufacturer’s motion to dismiss. *Id.* at 433. The court found that the plaintiff relied on the false assumption that criminals will not be able to obtain guns from other companies or dealers outside the defendants named in the suit. *Id.* at 393. The court concluded that the actions of the manufacturer were practically irrelevant, and that the purchase of illegal guns would persist. *Id.* Similar to *Beretta*, the black-market virtually ensures widespread accessibility to opioids regardless of the manufacturer’s marketing practices. *Id.* If the individual is not able to purchase the product legally, they will obtain possession of the product regardless. *Id.* Without holding downstream parties accountable for their actions, both gun violence and the opioid crisis are likely to continue. Because the State failed to show that Chase Pharma’s actions demonstrate control and capability of abatement of the alleged harm, the State’s public nuisance claim fails to meet the third element of control.
CONCLUSION

For the foregoing reasons, the Supreme Court should affirm the court of appeals’ and district court's dismissal of the State's public nuisance claim because the State raises a nonjusticiable political question and fails to state a successful public nuisance claim.

Respectfully Submitted:

Team 2817
Counsel for Respondent
Date: September 19, 2019
Section 2. The judicial power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made, or which shall be made under their Authority;--to all Cases affecting Ambassadors, other public Ministers and Consuls;--to all Cases of admiralty and maritime Jurisdiction;--to Controversies which the United States shall be a Party;--to Controversies between two or more States;--between a State and Citizen of another State;--between Citizens of different States;--between Citizens of the same State claiming Lands under Grants of different States, and between a State, or the Citizens thereof, and foreign States, Citizens or Subjects.
(1) A public nuisance is an unreasonable interference with a right common to the general public.

(2) Circumstances that may sustain a holding that an interference with a public right is unreasonable include the following:

(a) Whether the conduct involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience, or

(b) whether the conduct is proscribed by a statute, ordinance or administrative regulation, or

(c) whether the conduct is of a continuing nature or has produced a permanent or long-lasting effect, and, as the actor knows or has reason to know, has a significant effect upon the public right.
APPENDIX C

Any conduct or activity that is injurious to health; indecent; offensive to the senses; or an obstruction to the free use of property, so as essentially to interfere with the comfortable enjoyment of life or property.
APPENDIX D
21 U.S.C. § 811

(b) Evaluation of drugs and other substances. The Attorney General shall, before initiating proceedings under subsection (a) to control a drug or other substance or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance. In making such evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection. The recommendations of the Secretary shall include recommendations with respect to the appropriate schedule, if any, under which such drug or other substance should be listed. The evaluation and the recommendations of the Secretary shall be made in writing and submitted to the Attorney General within a reasonable time. The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance. If the Attorney General determines that these facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that the drug or other substance should be removed entirely from the schedules, he shall initiate proceedings for control or removal, as the case may be, under subsection (a).

(c) Factors determinative of control or removal from schedules. In making any finding under subsection (a) of this section or under subsection (b) of section 202 [21 USCS § 812(b)], the Attorney General shall consider the following factors with respect to each drug or other substance proposed to be controlled or removed from the schedules:
(1) Its actual or relative potential for abuse.
(2) Scientific evidence of its pharmacological effect, if known.
(3) The state of current scientific knowledge regarding the drug or other substance.
(4) Its history and current pattern of abuse.
(5) The scope, duration, and significance of abuse.
(6) What, if any, risk there is to the public health.
(7) Its psychic or physiological dependence liability.
(8) Whether the substance is an immediate precursor of a substance already controlled under this title

(f) Abuse potential. If, at the time a new-drug application is submitted to the Secretary for any drug having a stimulant, depressant, or hallucinogenic effect on the central nervous system, it appears that such drug has an abuse potential, such information shall be forwarded by the Secretary to the Attorney General.
APPENDIX E
DEA, The Primary Regulator of Controlled Substances

DEA, the primary regulator of controlled substances, oversees every part of the supply chain.