IN THE
SUPREME COURT OF THE UNITED STATES

State of LINCOLN,

Petitioner

v.

CHASE PHARMA, INC. et al.,

Respondents

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

BRIEF FOR PETITIONER

Date: September 19, 2019

Counsel for Petitioner

Oral Argument Requested
QUESTIONS PRESENTED

I. In Zivotofsky ex rel. Zivotofsky v. Clinton, the Supreme Court narrowed the requisite test to determine whether a nonjusticiable political question bars judicial review of a claim. Petitioner alleges that Respondents fraudulent marketing practices ultimately created the current “opioid crisis” in the State of Lincoln. Did the lower courts err in finding Petitioner’s claims raised a nonjusticiable political question when they mischaracterized Respondents’ alleged conduct and failed to adhere to the narrower test established in Zivotofsky?

II. Courts reviewing dismissal motions must construe the facts in a light most favorable to the non-moving party. Petitioner alleges that Respondents created a public nuisance in the State of Lincoln through aggressive marketing practices and misrepresentation of opioid drugs. Did Petitioner plead a plausible enough claim of public nuisance based on Defendants’ misconduct when considering all allegations to be true?
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CONSTITUTIONAL AND STATUTORY PROVISIONS
This is a public nuisance case. The State of Lincoln ("Petitioner") alleges that
the Respondent opioid manufacturers ("Respondents") created a public nuisance by
engaging in a knowingly fraudulent marketing campaign to encourage doctors to
prescribe opioids for long-term, chronic pain, despite knowledge that opioids were
both ineffective at treating long-term pain and dangerously addictive. As a result,
Respondents caused the current Lincoln “opioid crisis”, and thus, a public a
nuisance under Lincoln state law.

I. Statement of Facts

A. Elements of a Public Nuisance Claim in the State of Lincoln.

The Lincoln Supreme Court has adopted the Restatement (Second) of Torts
definition of public nuisance which provides that a public nuisance is an
“unreasonable interference with a right common to the general public.” Seward Cty.
v. Blaine, 233 Linc. 3d 1008 (1998) (adopting Restatement (Second) of Torts § 821B
(1979)). Lincoln defines “nuisance” by statute as “any conduct or activity that is
injurious to health; indecent; offensive to the senses…so as essentially to interfere
Therefore, to constitute a public a nuisance, the subject 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 cause the injury in question.

R. at 10; see Restatement (Second) of Torts § 821B (1979).

B. The Lincoln Opioid Crisis.

Respondents are manufacturers of opioid medications including, *inter alia*,
hydrocodone, fentanyl, oxycodone, codeine and others. R. at 2. Prior to the 1990’s,
the consensus of the medical community was that opioid medications were
ineffectual at treating long-term, chronic pain due, in large part, to their unsafe risk
for addition. R. at 2-3. Accordingly, during that time, prescription of opioid
medication was limited to the treatment of short-term acute pain, such as that
resulting from surgery, cancer treatment, or end-of-life care. *Id.* To overcome that
widely held medical consensus and garner additional sales of opioid medication,
Respondents engaged in an aggressive marketing campaign to promote the use of
opioid medication to treat long-term, chronic pain. R. at 2.

The results have been devastating. In 2016 alone over 2000 people in Lincoln
lost their lives as a result of opioid use. R. at 2. Public hospitals report treating
dozens of overdose victims weekly, including newborn babies who suffer from opioid
addiction at birth as a result of their mother’s use during pregnancy. *Id.* Together
with the human suffering, opioid addiction has imposed a debilitating financial
burden on the state. Lincoln spends billions of dollars annually to provide social
services to families affected by opioid addiction, as well as to provide the additional
law enforcement officers and instrumentalities required to combat increased
criminal activity resulting from illegal opioid sale and use. Representatively, the
Lincoln Bureau of Prisons estimates that over 3200 inmates are treated for opioid
addiction annually. *Id.* These considerations led Governor Edwin Stanton to declare
the Lincoln opioid crisis as a state of emergency on January 23, 2017. *Id.*

Petitioner brought this lawsuit as a response to that declaration. *Id.*

C. Petitioner’s Factual Allegations.

Petitioners filed this lawsuit in Lincoln state court on April 13, 2017, alleging
that Respondents created a public nuisance by engaging in a strategic marketing
campaign that caused doctors to prescribe opioids both in quantities and for
treatment purposes that were “dangerous and ineffective.” R. at 4. Specifically,
Petitioners allege that Respondents knowingly made the following false assertions
to the medical community concerning opioid medications:

(1) through branded advertising, direct sales and the funding of supposedly
    independent opinion leaders and front groups, Respondents promoted the
    false assertion that opioid medications are safe and effective for the
    treatment of long-term, chronic pain;¹

(2) signs of addiction resulting from opioid use are actually symptoms of
    “pseudoaddiction,” a condition that results from undertreated pain, requiring
    higher doses of opioid medication;

¹ Front groups are organizations that advance a hidden agenda, at the direction of a separate
organization, by deceitfully appearing to advance a different agenda.
(3) precautions, such as screening for risk of addiction, discussions with patients, and drug testing will effectively detect potential addiction before it became a problem, thereby allowing doctors to prescribe opioids to patients who were predisposed to addiction;

(4) physical dependence is different and less serious than actual addiction;

(5) abuse deterring features of opioid medications, such as time-release formulas, will prevent physical dependence;

(6) the actual risks of non-opioid pain relievers are more serious than what the Food and Drug Administration ("FDA") or Centers for Disease Control ("CDC") had identified.

R. at 3-4. Respondents advanced these claims specifically towards medical providers whose patients were more likely to suffer from chronic pain, such as veterans or elderly patients, despite Respondents’ actual knowledge that those patients were at a greater risk of addiction from long-term opioid use than the general population. R. at 4 These marketing efforts led to increased prescription and long-term administration of opioid medications that ultimately caused the current opioid crisis. Id.

II. Procedural History

claiming Petitioner’s claims (1) raised a nonjusticiable political question and (2) failed to state a public nuisance claim as a matter of law. *Id.* Specifically, Respondents alleged that Petitioner’s claims failed to allege:

(1) any interference with a right held in common by the public;

(2) an unreasonable interference with that public right; and

(3) that the defendants had control of the instrumentalities at the time of the alleged injury and would have been able to abate any claimed public nuisance.

R. at 10. The Circuit Court granted the motion to dismiss, finding Petitioner’s complaint raised a nonjusticiable political question and failed to plausibly allege the required elements of a public nuisance claim. R. at 15.

Petitioners timely appealed the District Court’s ruling to the Twelfth Circuit. R. at 16. There, the divided court affirmed the lower court’s finding on both grounds. In determining Petitioner had raised a nonjusticiable political question, the Twelfth Circuit applied the factors established by the United States Supreme Court’s decision in *Baker v. Carr*, 369 U.S. 186 (1962). Relying on the second and third *Baker* factors, the Twelfth Circuit explained that Petitioner’s claims lacked a “judicially discoverable and manageable standard” to resolve the issue and required “an initial policy determination” for which the judicial branch was ill-suited to decide. The Twelfth Circuit also explained that, despite the nonjusticiable political question issue, Petitioner’s complaint failed to state a plausible public nuisance claim because (1) the harm alleged was not a “public right”; (2) sale of a legal
product in accordance with FDA and Drug Enforcement Administration ("DEA") regulations could not constitute an “unreasonable interference” with a public right; and (3) the harm alleged resulted from Respondents’ products being misused by a third party. R. at 18-19.

Justice O’Connor dissented, finding Petitioner’s claims did not raise a nonjusticiable political question. R. at 19. Justice O’Connor explained that, currently, the Supreme Court relies only on the first two Baker factors to determine whether a nonjusticiable political question exists: (1) a textual, constitutional commitment of the issue to a coordinate political department, or (2) a lack of judicially discoverable and manageable standard for resolving it. Finding neither party disputed that the first element did not apply to the current case, Justice O’Connor then explained that a manageable standard exists because the court would not need to formulate a national opioid plan of action—only to determine whether Respondents’ alleged nuisance caused the State of Lincoln’s injuries. R. at 21. Further, Justice O’Connor explained that even if the remaining factors did apply, the only disputed factor, whether Petitioner’s claims involved an issue that required an initial policy determination, did not. R. at 21-22.

Justice O’Connor also dissented from the court’s holding that Petitioner’s had failed to state a plausible public nuisance claim, finding Petitioner’s had a common interest in public health, welfare and safety, and that Respondents had unreasonably interfered with that right by affirmative conduct that “assisted in the creation of a hazardous condition.” R.22-24. Further, physical control of the product
in question was merely a “relevant factor” to determine liability for a public nuisance—not a dispositive element. Thus, Petitioners had alleged a sufficiently plausible claim. R. at 24.

Petitioner timely filed a petition with the Supreme Court of the United States seeking a writ of certiorari. R. at 26. The Supreme Court granted certiorari and should now find (1) Petitioner’s public nuisance claims do not raise a nonjusticiable political question; and (2) Petitioner sufficiently pled a plausible claim of public nuisance for which relief can be granted.
SUMMARY OF ARGUMENT

The Supreme Court should reverse the holdings of the United States Court of Appeals for the Twelfth Circuit on both issues of justiciability and failure to state a plausible claim of public nuisance.

I. Nonjusticiable Political Question

The separation of powers principle ensures that no one governmental branch impedes upon the powers of another, in order to ensure justice is ultimately achieved. The nonjusticiable political question doctrine is a function of the separation of powers that restricts the judiciary from deciding certain questions invested entirely in one of the other branches of government. Here, a determination that the nonjusticiable political question doctrine bars judicial review of Petitioner’s claims would prevent the very virtue the doctrine seeks to protect—ensuring that justice is achieved. Accordingly, this Court should find this case does not raise a nonjusticiable political question.

In 1962, this Court in *Baker v. Carr* established six factors to consider when addressing whether a case raises a forbidden political question. However, in the 50 years following *Baker*, courts applied the factors in several conflicting ways, leading to confusion and inconsistent decision making. To eliminate these concerns, this Court in *Zivotofsky ex rel. Zivotofsky v. Clinton* narrowed the *Baker* test by abandoning the final four “prudential” factors, and instead focusing their analysis only on the first two “textual” factors. Despite this refinement of the *Baker* test, the
lower courts in the current case improperly relied on a “prudential” *Baker* factor in determining Petitioner’s claims raised a nonjusticiable political question.

Further, the lower courts improperly assessed the conduct Petitioner claims caused the current opioid crisis—Respondents’ fraudulent marketing conduct—and instead focused their analysis on the actual administration and use of opioid medication. With Respondents’ alleged conduct properly defined, it’s evident that there are clear manageable judicial standards on which the Court can base its determination. The Court will not have to balance the utility and harm of opioid use, but rather the utility and harm of fraudulent marketing practices. Further, the harm here results from a discrete number of producers and does not stem from a series of disconnected events that would absolve Respondents of responsibility. Indeed, the concept of liability for pharmaceutical manufacturers relating to their products has already been envisioned in this Court’s pharmaceutical failure to warn cases.

Finally, assuming the third *Baker* factor--a requirement that an initial policy determination unsuited for judicial inquiry be made--is still relevant, that factor is not dispositive to Petitioner’s claims when Respondents’ conduct is properly defined. The global warming cases cited by Respondents, that required the Court to balance available alternative energy sources against the harm caused by petroleum production, do not apply to this case. Instead, as shown above, the Court will be required to assess Respondents’ fraudulent marketing conduct—a determination
the judiciary is clearly qualified to make. Accordingly, this Court should find that Petitioner’s claims do not raise a nonjusticiable political question.

II. Public Nuisance

As part of their inherent police power, states may bring public nuisance claims against any entity whose conduct is detrimental to their population at large. This cause of action provides states with a legal mechanism to ensure the safety and well-being of their citizens. Respondents’ fraudulent marketing of opioid medication has caused widespread, devastating effects to the State of Lincoln and thus constitutes a public nuisance.

The State of Lincoln has adopted the Restatement (Second) of Torts definition of public nuisance, which requires that (1) an injury to a public right; (2) an unreasonable interference with that right; (3) control, either at the time of abatement or when the nuisance was created; and (4) proximate cause. The Twelfth Circuit improperly frames Petitioner’s claims as an injury to an aggregation of individual rights—not a public right—which is reliant upon illegal use of a legal product. That said, many courts, and even the Restatement itself, have conclusively determined that the right to public health is a recognized common public right. Further, the catalyst of the current opioid crisis was the legal prescription of opioid medications to long-term, chronic pain patients predisposed to addiction—a result directly attributable to Respondents’ fraudulent marketing efforts.

Similarly, Respondents reliance on FDA regulations as evidence of the reasonableness of their conduct likewise fails to account for both (1) the statutory
requirement that pharmaceutical manufacturers have a continuing obligation to update their products warnings, even after initial FDA approval, and (2) the wide latitude granted to states in exercising their inherent police power. Unreasonable conduct is not reliant upon a showing of additional tort liability, as implied by the lower courts, but rather stems from any affirmative conduct that helped create the hazardous condition.

Finally, it’s clear that Respondents were in control of the instrumentality that caused the opioid crisis, their fraudulent marketing claims, despite the Twelfth Circuit’s improper narrowing of the control element. For these reasons, this Court should find that Petitioner has pled a plausible cause of action sufficient to satisfy the elements of a public nuisance claim.
ARGUMENT

The Court is asked to determine whether Petitioner’s claims raise a nonjusticiable political question barring judicial review, and whether Petitioner sufficiently pled a plausible claim to satisfy the elements of a public nuisance cause of action. Both the political question issue and failure to state a claim issue are subject to de novo review. *Baker*, 369 U.S. at 217-18; *Epstein v. Washington Energy Co.*, 83 F.3d 1136, 1139 (9th Cir. 1996).

I. The Court should reverse the Twelfth Court of Appeals’ holding that Petitioner’s claims raise a nonjusticiable political question.

The nonjusticiable political is a separation of powers principle that provides certain questions are improper for judicial inquiry because they are vested entirely in the other branches of government. See Zachory Baron Schemtob, *The Political Question Doctrines: Zivotofsky v. Clinton and getting Beyond the Textual-Prudential Paradigm*, 104 Geo. L.J. 1001, 1004 (2016). Notably, the doctrine is not a jurisdictional question, such as standing, but rather a subject matter inquiry that requires the court to determine whether “the duty asserted can be judicially identified, its breach judicially determined, and protection for the right judicially molded.” *Baker v. Carr*, 369 U.S. 186, 198 (1962). It is, therefore, a doctrine of judicial restraint. Schemtob, *supra* at 1004.

This Court’s 1962 decision in *Baker v. Carr* laid out six factors to consider when determining whether an issue raises a nonjusticiable political question. The first two factors are known as the “textual factors”: (1) a textually demonstrable
constitutional commitment of the issue to a coordinate political department; or (2) a lack of judicially manageable standards for resolving the issue. The remaining factors were prudential aspects for the court to consider. Until recently, these six factors have been applied in a variety of conflicting analyses, leading to inconsistent determinations. However, recent decisions by this Court have refined the *Baker* test to include only the first two textual factors in order to ensure a consistent analysis of cases that concern the political question doctrine.

A. Scope of Appeal.

Respondents argument, and both the District Court and the Twelfth Circuit analyses, rely exclusively on the consideration of the second and third *Baker* factors. Both lower courts agree that the first *Baker* factor, “a textually demonstrable constitutional commitment of the issue to a coordinate political department” does not apply to the current case. Additionally, the Courts’ failure to consider the remaining three *Baker* factors not raised points to their irrelevance to this matter. Petitioner therefore has not briefed those factors. That said, the arguments raised by Petitioner included within this brief are sufficient to dispel any passing connection those factors may have to the current inquiry. Further, any remaining gaps concerning those factors can be simply addressed at oral argument.

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2 The remaining prudential factors established by *Baker* are (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. *Baker*, 369 U.S. at 217.
B. The District Court improperly applied the prudential Baker factors.

Since *Baker*, this court has decided thirty-eight cases which considered the political question doctrine. Schemtob, *supra*, at 1002. A survey of the analysis in those decisions resulted in at least four conceptions of how the prudential *Baker* factors should be applied, causing confusion and inconsistent application of the political question doctrine. *Id.* This Court finally abandoned this piecemeal approach in its recent decision in *Zivotofsky ex rel. Zivotofsky v. Clinton*.

In *Zivotofsky*, the Court considered a claim brought by the parents of a newborn against the Secretary of State for refusing to list Israel, instead of Jerusalem, as the official birthplace on the child’s passport. *Zivotofsky ex rel. Zivotofsky v. Clinton*, 566 U.S. 189 (2012). In assessing the justiciability of the claim, the majority declined to apply the prudential *Baker* factors, instead relying *exclusively* on the first two textual factors in its analysis. *Id.* After determining the two textualist factors were not implicated, the Court was satisfied that the political question doctrine did not apply to the parents’ claim. *Id.* at 201; see also *Dist. of Columbia v. Trump*, 291 F. Supp. 3d 725, 756 (D. Md. 2018) (considering only the first two *Baker* factors before determining a political question did not bar judicial review).

In the current case, the District Court determined that a nonjusticiable political question existed based on an analysis of the second and third *Baker* factors. However, *Zivotofsky* provides that the District Court’s reliance on the third *Baker* factor, “the impossibility of deciding without an initial policy determination,” was in
error—a mistake Justice O’Connor’s dissent on appeal recognizes. R. at 19-20. Accordingly, this Court should correct and clarify that the first two textual Baker factors are the exclusive considerations to determine whether a claim raises a political question.

Even if the textual factors are not the sole determining elements in deciding whether a claim implicates a political question, the Zivotofsky majority’s refusal to even consider prudential factors makes it clear that prudential factors standing alone cannot be dispositive to the inquiry. See Schemtob, supra at 1022 (citing Zivotofsky, 132 S. Ct. at 1434) (Sotomayor, J., concurring in part and concurring in judgment) (“To be sure it will be the rare case in which Baker’s final factors alone render a case nonjusticiable”). Further, the Twelfth Circuit states that “it only takes one Baker factor” to determine that a nonjusticiable political question bars judicial review. R. at 18. (citing Schemtob, Supra at 1011). Yet this contradicts the very source on which the Twelfth Circuit relies, which ultimately concludes that the Court has “refused to name one factor as dispositive.” Schemtob, Supra at 1013. Therefore, this court should find that any implication of a political question based exclusively on consideration of the prudential Baker factors, especially if only one prudential factor is relied upon, does not bar judicial review.

C. The Lower Courts Improperly Defined the Conduct at Issue.

To evaluate properly the political question doctrine, the court must “identify with precision the issue it is being asked to decide.” Zivotofsky, 132 S. Ct. at 1434 (Sotomayor, J. concurring). In Zivotofsky, the Secretary of State refused to list a
child born in Jerusalem’s birthplace as Israel, despite a federal statute expressly allowing for such a classification. *Id.* at 1425-26. In that case, the lower courts found the political question doctrine implicated because, to make a determination, the courts would need to decide the political status of Jerusalem. *Id.* at 1427. In overturning that decision, this Court explained that the issue had been improperly broadened and did not require a judicial examination of a President’s political decisions involving foreign relations. *Id.* Instead, the Court would simply need to determine whether the statute at issue was constitutional and whether the parents’ interpretation of that statute was correct—something the Court was clearly capable of. *Id*

Like *Zivotofsky*, the inquiry here has been inaccurately broadened. Petitioner’s claims allege injury from Respondents’ fraudulent marketing of their products—a proposition which both the District Court and the Twelfth Circuit Acknowledge. R. at 17. But in finding Petitioner’s claims barred, both the lower courts’ analyses relied on balancing the utility of opioid use itself. *Id.* This is not the conduct at issue. To evaluate this public nuisance claim, the Court will have to balance the utility of Respondents’ *knowingly* making fraudulent claims about their products against the opioid crisis harm that has resulted from that conduct. True, Petitioner’s claims will require them to establish that Respondents had actual knowledge of the ineffectiveness and danger of their products. Yet the Court can make that evaluation, applying the relevant *Baker* factors, without ever opining on how many opioids should be available to the public or the utility of opioids
themselves. With the issue properly narrowed, it’s clear the Baker factors on which the lower courts relied do not raise a nonjusticiable political question.

D. There Are Clear Judicially Manageable Standards to Decide this Issue.

The second Baker factor, whether there are clear judicially manageable standards to decide the issue, requires the court to determine whether they can reach a decision that is “principled, rational, and based upon reasoned distinctions.” Native Vill. of Kivalina v. ExxonMobil Corp., 663 F. Supp 2d 863,874 (N.D. Cal. 2009), aff’d on other grounds, 696 F.3d 849 (9th Cir. 2012). As discussed, for a public nuisance this requires the Court to balance the “gravity of the harm against the utility of the conduct,” and ensure that its reasoning meets that principled standard. Id. In determining there were no manageable standards in the current case, the District Court found Petitioner’s claims comparable to those addressed in the U.S. District Court of Northern California’s decision in Native Village of Kivalina v. ExxonMobil Corp.

In Native Village, twenty-four oil, energy and utility company defendants sought to dismiss a small Alaskan village’s suit alleging that the defendants’ production techniques ultimately caused global warming, arguing the town’s claims raised a nonjusticiable political question. Id. at 869. In finding the political question doctrine implicated, the court reasoned that assessing plaintiff’s claims would require balancing the utility and availability of energy producing alternatives against the harm caused by the continued production of defendants’ energy products. Id. at 874-75. This court determined that such a wide raging and influential determination
was not appropriate for the courts, but rather was entirely within the purview of the legislature. *Id.* at 875. The court also distinguished the town’s claims from previous public nuisance cases involving air and water pollution which were allowed to proceed, explaining that those cases involved a specific injury to a specific area, caused by a discrete number of polluters. Conversely, global warming resulted from “innumerable sources” and the injury alleged affected the entire planet. *Id.* Finally, the court determined that the series of disconnected events connecting the described conduct to the alleged harm prevented the court from assessing plaintiff’s claims in a reasoned manner. *Id.*

Here, relying on the reasoning in *Native Village*, the District Court explained that Petitioner’s claims would require the court to balance the utility of legitimate opioid use versus the risk of harm in their misuse. However, this improperly characterizes the required assessment. The conduct alleged is the knowingly fraudulent marketing of the Respondent opioid manufacturers. True, Petitioner’s causes of action will require them to show that Respondents had actual or constructive knowledge that their products were unsafe and ineffective for the treatment of long-term chronic pain; but, this element in no way requires the court to decide whether opioids are “good” for long-term pain or not. Rather, the court will have to determine whether Respondents did, in fact, have the knowledge that Petitioner alleges they did—an inquiry the Court is clearly suited for.

Similarly, unlike the defendants in *Native Village*, whose alleged harm resulted from conduct from innumerable sources, the fraudulent marketing conduct
Petitioner has alleged results *exclusively* from the discrete number of opioid manufacturers named in this lawsuit. To illustrate, if the defendants in *Native Village* conduct never occurred, it is unclear if, and perhaps likely that, the global warming harm felt by plaintiffs would have still resulted. Here, it is unmistakably evident that, absent the Respondent opioid manufacturer’s conduct, there would not be an “opioid crisis” in Lincoln because the addiction caused by long-term, legal, opioid use would not have occurred.

Finally, unlike the necessary series of disconnected events required for global warming in *Native Village*, here, there is one step separating Respondents and the egregious harm felt by their consumers—the doctors. True, Petitioner’s claims required primary care doctors to prescribe opioid medications for long-term chronic pain based on the recommendations of Respondents. But this is the only step required for addiction to have resulted, considering the use of opioids for long-term pain treatment was not illegal, and thus would not have triggered an investigation by the distributor, pharmacist, or any of the other parties the lower courts explained may hold responsibility. As a result, this sequence of events is not comparable to the required emission of carbon dioxide, that then combines with other gasses in the atmosphere, that then causes the warming of the planet, that then leads to the ice caps melting, that then creates the erosion felt by plaintiffs. *Native Vill. of Kivalina*, 663 F. Supp. 2d at 875. Instead, Petitioner’s claims require one intervening event: that doctors trust the representations of pharmaceutical
opioid representatives whose companies’ manufacture serious, and potentially dangerous, medications.

Indeed, this Court’s has already envisioned the potential for tort liability resulting from this exact relationship in Wyeth v. Levine—a decision more commensurate to the current matter at issue. Wyeth v. Levine, 555 U.S. 555 (2009).

In Wyeth, a defendant drug manufacturer was found liable by the Vermont Supreme Court for failing to provide a warning on the label of their drug that would have instructed doctors to use a specific, safer method of IV injection. The lack of warning led plaintiff’s arm to be unnecessarily amputated as a result of a faulty, riskier method of IV injection.

In affirming the decision of the Vermont Supreme Court, this Court made, inter alia, two relevant determinations concerning the liability of drug manufacturers for harm resulting from their drugs. First, the trial court found evidence that the injured plaintiff’s physician’s assistant administered a dose exceeding the drug labels prescription, that the drug was injected into an artery rather than a vein, and that the physician’s assistant continued to inject the drug despite complaints from plaintiff. Wyeth, 555 U.S. at 564. However, the trial court still determined the drug manufacturers failure to warn was a but-for and proximate cause of plaintiff’s injuries. Id. The Supreme Court recounted these facts in the majority opinion, yet still found the record was adequate to support the jury’s finding of liability for the drug manufacturer. Id. Wyeth thus shows that, even if in the face of potentially egregious intervening conduct by a medical professional, a drug manufacturer can
still be liable in tort for harm that results from its conduct related to its products. *Id.*

Second, the Court found that compliance with FDA labeling regulations did not automatically pre-empt state law claims against pharmaceutical manufacturers. *Id.* at 578-79. On the contrary, state law claims are an important layer of protection that complement FDA regulations in protecting consumers against dangerous products. *Id.* In arriving at this conclusion, the Court explained that a state law is pre-empted only upon on a “direct and positive conflict” with the Federal Food, Drug and Cosmetic Act of 1938 ("FDCA"). *Id.* at 567. Further, in 2007, Congress amended the FDCA to require drug manufacturers to update their warning labels if new safety information became available after the initial approval of the drug, clearly establishing that manufacturers have a continuing responsibility for the safety measures of their products, despite initial FDA approval. *Id.* at 567-68. The Court also explained that “new safety information” included new analyses of previously submitted data. *Id.* at 569. Therefore, FDA approval of a drug’s labeling requirements created a “floor”, not a “ceiling” for drug regulation and it is ultimately the responsibility of drug manufacturers to ensure the adequacy of their labeling requirements. *Id.* at 574.

Like the medical staff in *Wyeth*, the prescribing doctors in the current case do not represent an intervening sequence of events that separate the drug manufacturers from the harm their products cause. As stated above, there is only one event between the victims and pharmaceutical companies— doctors’
prescriptions based on the drug manufacturers promises. When compared to the potentially negligent conduct of the physician’s assistant in *Wyeth* that did not eliminate responsibility for the drug manufacturers, it’s clear that prescribing physicians conduct in the current case does not absolve the causal connection between opioid manufacturers and the harmful effects of their products. In light of this Court’s finding in *Wyeth*, that drug manufacturers bear the ultimate responsibility for their products’ labeling requirements, Respondents’ argument that compliance with FDA regulations exonerates them from liability is meritless.

For these reasons, this Court should find there are clear, manageable judicial standards on which to evaluate Petitioner’s public nuisance claim.

E. Petitioner’s claims do not require an initial policy determination of a kind clearly for nonjudicial discretion.

This Court’s recent decision in *Zivotofsky* establishes that the third *Baker* factor, “the impossibility of deciding without an initial policy determination of a kind clearly for nonjudicial discretion,” is no longer relevant to the nonjusticiable political question analysis. However, even if the factor applies to the political question inquiry, the current case does not present an issue that requires a policy determination.

Both the lower courts in the current case correctly acknowledged that Petitioners claims allege that Respondents’ knowingly fraudulent marketing campaign caused the current opioid epidemic in Lincoln. R. at 17. Even so, both courts mistakenly found this would require the court to determine how many opioid
drugs should be available and how they should be used. *Id.* Once again, the District Court compared the analysis of the third Baker factor in *Native Village* to the current case. R. at 8.

In *Native Village*, the Alaskan village plaintiffs argued that their global warming suit did not seek injunctive relief, and thus did not require the Court to determine retroactively the amount of acceptable emissions limits. *Native Vill. of Kivalina*, 663 F. Supp. 2d at 876. The District Court disagreed, reasoning that, regardless of the relief sought, determining whether a public nuisance exists requires the court to balance the utility of the conduct versus the harm it imposes. *Id.* By default, the court would have to determine an acceptable amount of greenhouse gas emissions—a determination the court is not suited to make. *Id.*

Unlike the court in *Native Village*, this Court will not need to determine an acceptable amount of opioid use or availability. The conduct alleged by Petitioner’s is advancing *knowingly* fraudulent marketing claims—not the actual administration of opioids. Petitioner will bear the burden to show that Respondents had knowledge that their products were ineffective at treating long-term chronic pain and imposed an unreasonably dangerous risk of addiction. But just as the Court need not opine on whether a breach of contract is “good” or “bad,” only that it exists, the Court here will be required only to determine whether Respondents had knowledge about these qualities of their products. If Petitioners establish this knowledge, as far as this Court is concerned, the amount of opioids available to treat long-term, chronic pain should effectively be zero. Further, with the inquiry
properly framed to evaluate Petitioner’s public nuisance claims, the Court will need to balance the social utility versus the harm in making knowingly fraudulent statements. While it may be theoretically possible to imagine some obscure social benefit that derives from fraud, the financial and personal harm that results from Respondents’ claims in the current case surely outweighs that theoretical benefit.

For these reasons, this Court should find that the third Baker factor is no longer relevant to the political question inquiry, or, in the alternative, that the conduct alleged in the current case does not require and initial policy decision better suited for nonjudicial discretion.

II. The Court should reverse the Twelfth Circuit’s holding that Petitioner failed to state a plausible claim of public nuisance.

For a complaint to survive Respondent’s Federal Rule of Civil Procedure 12(b)(6) motion to dismiss for failure to state a claim, the Court should determine from the pleadings “beyond doubt [that] the plaintiff can prove no set of facts” which would entitle her to relief. City of Cincinnati v. Beretta U.S.A. Corp., 768 N.E.2d 1136, 1141 (Ohio 2002); see Fed. R. Civ. P. 12(b)(6); see also Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). When making these determinations, courts must draw all reasonable inferences and construe all factual allegations in plaintiff’s favor. Cincinnati, 768 N.E.2d at 1141. For the reasons below, Petitioner has sufficiently alleged a plausible claim of public nuisance.

A. Petitioner’s public nuisance claim is sufficiently plausible on its face.
The elements of a public nuisance claim in the State of Lincoln have been discussed above. For convenience, Petitioner relists them here. The State of Lincoln’s nuisance law follows the second Restatement of Torts. *Seward Cty.*, 233 Linc. 3d at 1008 (adopting Restatement (Second) of Torts § 821B (1979)). Lincoln statute defines 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). Therefore, to constitute a public nuisance the offending conduct must:

1. substantially interfere with a public right;
2. be unreasonable;
3. be within the defendant’s control and be capable of abatement; and
4. proximately cause the nuisance.

R. at 10. For the purposes of this appeal, Respondents raise no issues regarding the State’s ability to prove proximate cause, and further concede that Lincoln law does not limit nuisance claims to those involving real property. R. at 10 n. 8. Accordingly, Petitioner addresses the remaining three elements of public nuisance below.

i. *The right to public health and safety is a recognized right held in common by the public.*

A plausible public nuisance claim requires that the alleged nuisance must interfere with an existing right held in common by all members of the public. Restatement (Second) of Torts § 821B (1979). Such “public rights” are distinct in
that, rather than a simple aggregate of individual rights held by multiple persons, they are “collective in nature.” See Restatement (Second) of Torts § 821B, cmt. g. To be considered a “public nuisance,” however, it is unnecessary for the interfering conduct to affect simultaneously an entire community. Id. Indeed, even a nuisance which ultimately creates danger for only one individual may be enough to constitute violation of a public right. Id.

In finding Petitioner’s claims did not address a right held in common to the public, the District Court relied on numerous firearms-related public nuisance cases. R. at 11. (citing City of Chicago v. Beretta U.S.A. Corp., 821 N.E.2d 1099, 1114-15 (Ill. 2004)); see also Ganim v. Smith & Wesson Corp., 780 A.2d 98, 132 (Conn. 2001). In City of Chicago, the Supreme Court of Illinois dismissed a public nuisance claim against a gun manufacturer, reasoning that the nuisance of widespread gun violence infringed not on a public right but on an individual right to not be assaulted 821 N.E.2d at 1116. The court also explained that the public's interest in remaining free from the threat of illegal use of a legal product, such as firearms, also did not constitute a public right.3 Id. Finding Petitioner’s asserted public right comparable to the current case, the lower courts determined Petitioner had not identified a commonly held public right. R. at 18.

Unlike the individual right not be assaulted in City of Chicago, Petitioner's claims (1) relate to the public rights to health and safety held in common by all

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3 Petitioner acknowledges that City of Chicago and other cases cited in the record challenge public nuisance claims under the remoteness doctrine. See State v. Lead Indus. Ass'n, Inc., 951 A.2d 428, 451 (R.I. 2008). However, Respondents have waived these theories because they raise no issue about whether Petitioner can prove proximate causation. R. at 10 n. 8.
members of the public, and (2) allege harms that do not strictly rely on the illegal conduct of a third person not party to this suit. In a recent public nuisance claim against opioid manufacturers, the District Court for the Northern District of Ohio spoke directly to this issue, expressly stating that public health is a recognized public right:

“Defendants conveniently overlook large portions of the Restatement. For example, the Restatement states that, at common law, ‘public nuisances included interference with the public health.’...Thus, ‘public health’ has traditionally been considered a ‘public right.’”


Similarly, the harm resulting from Respondents’ fraudulent marketing program on public health does not stem from “the illegal use of a legal product.” R. at 12. While illegal acquisition and abuse of prescription opioids are contributing factors to the opioid crisis, illegal use of opioids is not the exclusive, or even substantial
conduct that created the current public nuisance. Rather, Respondents’ fraudulent misinformation led to excessive, long-term prescription and use of opioids fully within the bounds of the law. These legal excesses of an inherently dangerous product created scores of opioid-addicted patients and created the opioid crisis. Petitioner’s asserted public right is distinct from the right to protection against the illegal use of a legal product argued by Respondent. Accordingly, the Court should find that the public right of public health and safety satisfies the first requisite element of public nuisance.

ii. Petitioner’s factual allegations constitute an unreasonable, affirmative interference with public health and safety.

The second element of a public nuisance claim requires the alleged conduct to be an unreasonable interference with a public right. Restatement (Second) of Torts § 821B (1979). The Restatement provides several examples of circumstances where conduct may be considered unreasonable, including both intentional and unintentional interferences. Id. § 821B(2). Circumstances which (1) have significantly interfered with the public health or safety, (2) involve conduct proscribed by statute, or (3) have “produced a permanent or long-lasting [and] significant effect upon the public right,” are all grounds for determining that conduct was unreasonable. Id. The Restatement further clarifies that these listed circumstances are not conclusive tests for unreasonableness, nor are they each

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4 A 2017 comprehensive review of opioid abuse found, inter alia, (1) that Americans consume roughly 80% of the global opioid supply, (2) that retail sales of oxycodone increased nearly 2,300% from 1996 to 2000, and (3) that retail sales of all prescription opioids increased more than fourfold from 1999 to 2010. Alan D. Kaye et al., Prescription Opioid Abuse in Chronic Pain: An Updated Review of Opioid Abuse Predictors and Strategies to Curb Opioid Abuse: Part 1, Pain Physician, Feb. 2017, at S93.
independently sufficient to establish such unreasonableness. Further the listed factors are neither an exclusive nor exhaustive list of possible circumstances warranting a finding of unreasonableness. *Id.* cmt. e.

In finding a lack of unreasonable interference, the Twelfth Circuit reasoned that Respondents’ marketing efforts did not constitute unreasonable conduct because they complied with FDA regulations. R. at 18. Yet this argument fails to recognize that pharmaceutical manufacturers have an ongoing responsibility to update their labeling, after initial approval by the FDA, if new safety information becomes available. *Wyeth*, 555 U.S. at 567-68. Indeed, manufacturers bear the ultimate responsibility for their warning requirements. *Id.* Therefore, because tort liability can still attach to a pharmaceutical manufacturer, despite initial approval from the FDA, compliance with FDA standards does not automatically establish that Respondents’ conduct was reasonable.

Further, the degree of federal regulation of an industry does not categorically immunize defending manufacturers from tortious liability. This Court in *Medtronic Inc. v. Lohr* recognized the long-standing tradition of granting “great latitude” to states exercising their police power “to protect the health and safety of their citizens,” even in heavily regulated fields such as pharmaceuticals and medical devices. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996). In *Medtronic*, this Court found that common-law causes of action are not necessarily pre-empted by the existence of federal regulations. *Id.*, at 485-86. While Respondents do not cite a pre-empting statute, their assertion, that merely claiming compliance with regulations
is a sufficient defense to suit, implicitly rests on the pre-emptive capacity of federal law over state causes of action. Respondents argument is meritless.

Additionally, the lower courts have improperly restricted the standard of what constitutes unreasonable conduct. Courts have held that public nuisance liability does not require the existence of a separate tort, such as a defective product or failure to warn. Instead, a defendant is liable for any “affirmative conduct that assisted in the creation of a hazardous condition.” People v. ConAgra Grocery Prod. Co., 227 Cal. Rptr. 3d 499, 529 (Ct. App. 2017); see White v. Smith & Wesson Corp., 97 F. Supp. 2d 816, 829 (N.D. Ohio 2000) (holding that negligently or carelessly allowing a dangerous condition to exist constitutes negligence on which a public nuisance claim might rely). In ConAgra Grocery, the Sixth District Court of Appeals for California held that a defendant lead paint company was liable for public nuisance claims when they affirmatively “produced, marketed, sold, and promoted lead paint for residential use, despite knowledge that interior residential use of lead paint was harmful to children.” ConAgra Grocery, 227 Cal. Rptr. 3d at 529.

Here, like the defendants in ConAgra Grocery, Petitioners have alleged that Respondents manufactured, marketed, sold, and promoted opioid medication for the treatment of long-term, chronic pain, despite knowing or having reason to know the foreseeable risks to the public health that their conduct created. R. at 3-4. Respondents’ conduct is even worse considering allegations that Respondents and their agents knowingly made false representations of their products and engaged in unbranded marketing in contravention of FDA and DEA regulations. Id. Further, as
established by City of Chicago, Petitioner need only allege “the ultimate facts to be proved...not the evidentiary facts tending to prove such ultimate facts.” City of Chicago, 821 N.E.2d at 1113. As recognized by both the District Court and Justice O’Connor’s dissent, Petitioner has alleged sufficient facts that, if true, would more than satisfy the unreasonable interference element. R. at 23.

Finally, the public nuisance cause of action against Respondents is also strengthened by the plain language of Lincoln’s nuisance statute. Again, the Lincoln statute’s first clause defines nuisance as, “Any conduct or activity that is injurious to health.” Linc. Stat. 54-133 (2018) (emphasis added). Given the broad definitions of unreasonable conduct in both the Lincoln statute and the Restatement (Second) of Torts and the implicit favorableness to the non-movant in reviewing dismissal motions, the Court should find Petitioner sufficiently pled a claim of public nuisance to allege an unreasonable interference by Respondents.

iii. Respondents exclusively control their own opioid marketing practices and are capable of its abatement.

Courts’ analyses have varied widely on the standard to establish the third element of control. As the Twelfth Circuit highlights, the Supreme Court of Rhode Island held that, to be held liable for nuisance, a defendant must be capable of abating the nuisance, and therefore must control the instrumentality of harm at the time when damages occur. State v. Lead Indus. Ass’n, Inc., 951 A.2d 428, 449 (R.I. 2008). Contrastingly, the Third Circuit has held that defendants are liable if they exercise control over the “source of the interference with the public right,” but failed to consider whether control at the time of injury is a necessary factor. Camden Cty.
Further still, many courts have held that nuisance liability does not strictly turn on whether a defendant controls the instrumentality of harm at all. See ConAgra Grocery, 227 Cal. Rptr. 3d at 549 (“[L]iability for nuisance does not hinge on whether the defendant owns, possesses or controls the property, nor on whether he is in a position to abate the nuisance; the critical question is whether the defendant created or assisted in the creation of the nuisance” (quoting Cty. Santa Clara v. Atl. Richfield Co., 40 Cal.Rptr.3d 313, 325) (internal quotation marks omitted) (emphasis added)). The court in ConAgra Grocery also held that, in cases of public nuisance, the involvement of several negligent actors does not automatically serve as a de facto shield against liability for individual defendants. Id. at 556-58.

Petitioner’s complaint alleges that Respondents had sufficient control of the instrumentality that caused the harm, at the time of injury. Here, the Twelfth Circuit reasoned that, because Respondents do not physically control the actual opioids at the time of their use, Respondents cannot abate the alleged nuisance. R. at 18. This reasoning fails both because it (1) inappropriately narrows the conduct alleged by Petitioner and (2) misrepresents the causal connection between Respondent’s marketing practices and the current opioid crisis.

As established, Petitioner’s complaint focuses on Respondents’ fraudulent marketing practices. It is indisputable that these marketing practices were within the Respondents control as the opioid crisis began and has continued to occur. R. at
24. Because these practices were, and still are, only within their control, they are more than able to discontinue them. Respondents are more than able to abate the harms caused by their products by clarifying their factual misstatements, which would lead to an immediate discontinuance of opioid prescription for long-term pain and thus a drastic reduction in access to opioids in Lincoln. In the alternative, even if this Court finds that Respondents lack either minimal control over their conduct or an ability to abate, the Court should rely on ConAgra Grocery and find Respondents nonetheless liable for their contribution to the hazardous conditions which created the alleged nuisance. Whether by showing control, capacity for abatement, or contribution to hazardous conditions, Petitioner has satisfied its burden to allege a plausible claim upon which the third element of control is plausibly satisfied.

B. Dismissal of Petitioner’s claim creates a dangerous precedent which shield pharmaceutical companies from private and state causes of action.

The context of the Petitioner’s public nuisance claim is harrowing. The opioid epidemic has claimed more 300,000 lives in the United States between 2000 and 2016, averaging 50 lost lives per day, and is likely to claim another half million in the next 10 years. See Rebecca L. Haffajee & Michelle M. Mello, Drug Companies’ Liability for the Opioid Epidemic, 377 New Eng. J. Med. 24:2301, 2301 (2017). While federal and state agencies and regulations are in a place to curb and monitor opioid use, these efforts have shown to have minimal impact on per-capita opioids dispensed. See Joanne E. Brady, et al., Prescription Drug Monitoring and Dispensing of Prescription Opioids, 129 Pub. Health Rep. 2:139, 139-47 (2014); see

Furthermore, it cannot be said that federal suits against opioid manufacturers are enough to protect the public rights of health and safety. The federal suit against Purdue Pharma for their role in creating the national opioid crisis is illustrative. Despite egregiously negligent conduct by Purdue’s agents in 1997, the year after its launch of OxyContin, ten years passed before reaching a federal settlement. David Armstrong, *Sackler Embraced Plan to Conceal OxyContin’s Strength from Doctors, Sealed Testimony Shows*, ProPublica (Feb. 21, 2019, 1:45 PM), https://www.propublica.org/article/richard-sackler-oxycontin-oxycodone-strength-conceal-from-doctors-sealed-testimony. Even more troubling, the admittance of negligent conduct in Purdue’s deposition remained hidden from the public for nearly another decade, and the settlement amount, though one of the largest in the history of its kind at $600 million, paled in comparison to the multi-billion-dollar value of the opioid industry. *Id.* Even if the entire Purdue settlement went directly to the families of those 300,000 lives lost to the opioid epidemic, $2,000 per wrongful death is paltry relief.

Ultimately, the question before this Court is whether the Petitioner’s public nuisance claim should proceed to discovery. Respondents have waived issues of causation and Petitioner has sufficiently pleaded factual allegations which satisfy
the remaining three requisite elements of a public nuisance claim. If this Court still affirms the dismissal of the Petitioner’s claims, it creates a precedent which effectively bars all private and state tort claims against opioid manufacturers. The effective bar stems from the creation of an insurmountable burden on plaintiffs to prove defendants’ negligent conduct prior to discovery. Such precedent would allow opioid manufacturers to continue deceptively shifting liability onto others while continuing forward unscathed, leaving American citizens to pay the price.

To conclude, Petitioner refers to the poignant final words in Justice O’Connor’s Twelfth Circuit dissent:

“There is no doubt that with the opioid epidemic, the country faces a crisis unlike anything it has faced before. . . Whether this case will survive intact as it proceeds further into discovery is not clear today. What is clear is that the State of Lincoln should be allowed to make its case and prove its damages.” R. at 25.
CONCLUSION

For all these reasons, the State of Lincoln respectfully asks this Court to reverse the judgments of the Court of Appeals for the Twelfth Circuit and the District Court for the District of Lincoln.

Respectfully submitted,

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Team 2810
Counsel for the Petitioner
Date: September 19, 2019
APPENDIX A
Restatement (Second) of Torts § 821B (Am. Law Inst. 1979)

(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.