

In Defense of the Hare: Primary Jurisdiction Doctrine and Scientific Uncertainty in State-Court Opioid Litigation

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When state and local governments sue prescription opioid manufacturers in state courts, the defendants often move for courts to stay or dismiss proceedings under the doctrine of primary jurisdiction. This common-law doctrine instructs courts to issue stays when waiting for a federal agency to address specific issues within the case would promote uniformity or allow the court to benefit from the agency's expertise. In the prescription opioid cases, defendant manufacturers have argued that courts should stay proceedings until the completion of a new set of studies ordered by the Food and Drug Administration (FDA). State courts have divided on whether to issue stays under the primary jurisdiction doctrine in these cases. A case in California was under such a stay for four years.

This Comment examines the application of the primary jurisdiction doctrine in misleading advertising suits against prescription opioid manufacturers. The core principles of uniformity and expertise do not support issuing stays in these cases. Further, the particular scenario faced by state courts in these cases—requests for stays for the purpose of the production, rather than simply review, of new evidence—is not adequately addressed by concerns for uniformity or expertise. This Comment reframes these requests for stays as requests for courts to defer to the FDA on questions of evidentiary sufficiency. Because the FDA applies a higher standard of sufficiency to scientific questions than the tort system requires of plaintiffs, granting such deference has the effect of raising plaintiffs' burden of proof. When deciding whether to grant stays under the primary jurisdiction doctrine for the purpose of waiting for the production of new scientific evidence, courts should consider only whether plaintiffs have otherwise met the burden of proof required of them at the given stage of the trial.

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INTRODUCTION

From 2000 to 2017, more than three hundred thousand people died of overdoses involving opioids in the United States.¹ A 2017 report found that more than half of people addicted to illicit opioids like heroin first became addicted to prescription opioid painkillers.² Another report based on 2017 data found that, for the first time in history, Americans were more likely to die from an opioid overdose than a car accident.³ This crisis has precipitated a wave of litigation against prescription opioid manufacturers, beginning in the early 2000s with numerous individual and class action personal injury claims.⁴ The last decade has seen litigation shift toward suits brought by city, state, and tribal governments. These government plaintiffs claim that the manufacturers engaged in false, misleading, or fraudulent advertising.

¹ Rebecca L. Haffajee and Michelle M. Mello, *Drug Companies' Liability for the Opioid Epidemic*, 377 *New Eng J Med* 2301, 2301 (2017).

² *Id.*

³ *Odds of Dying* (National Safety Council), archived at <http://perma.cc/4HU5-KXTM>.

⁴ Richard C. Ausness, *The Role of Litigation in the Fight against Prescription Drug Abuse*, 116 *W Va L Rev* 1117, 1122 (2013).

They also claim that those advertising campaigns created a public nuisance, forcing local governments to devote funds to unnecessary prescriptions for government-insured persons and to combat the effects of abuse, addiction, and overdose. These suits, based in state-law claims, are being heard in both state and federal courts, depending on the diversity of the parties in each case and whether plaintiffs have chosen to bring federal claims. The suits in federal courts have been moved into a multidistrict litigation (MDL) in the Northern District of Ohio.⁵

Although the MDL has drawn public and academic attention,⁶ this Comment focuses on the suits in state courts. In the shadow of the MDL, a number of state and local governments have fought to keep their cases out of federal court, emphasizing their desire to maintain local adjudication of their claims. In contrast, the defendant manufacturers have repeatedly sought to shift control to national decision-makers. Manufacturers' tactics have frequently included requesting stays of litigation under the doctrine of primary jurisdiction. Primary jurisdiction is a common-law doctrine allowing parties to move for a court to stay or dismiss a case in one of two scenarios: (a) at least one issue raised by the claim falls within the exclusive jurisdiction of an administrative agency, or (b) the litigation involves an issue over which the court has jurisdiction but wishes to seek the agency's expert advice.⁷ In the opioid cases, defendant manufacturers have repeatedly argued that litigation should be delayed until the federal Food and Drug Administration (FDA) has answered certain scientific questions underlying plaintiffs' claims, such as the actual risk of addiction associated with long-term use of prescription opioid painkillers. State courts in California, New York, and Oklahoma have addressed such requests for stays directly. While the California

⁵ Abbe R. Gluck, Ashley Hall, and Gregory Curfman, *Civil Litigation and the Opioid Epidemic: The Role of Courts in a National Health Crisis*, 46 J L Med & Ethics 351, 359 (2018).

⁶ See, for example, Jan Hoffman, *Can This Judge Solve the Opioid Crisis?* (NY Times, Mar 5, 2018), archived at <http://perma.cc/AQ55-SJZC>; Andrew M. Parker, Daniel Strunk, and David A. Fiellin, *State Responses to the Opioid Crisis*, 46 J L Med & Ethics 367, 375 (2018).

⁷ See *Arsberry v Illinois*, 244 F3d 558, 563–64 (7th Cir 2001) (discussing the primary jurisdiction doctrine, but disputing the characterization of deference to agency expertise as an exercise of primary jurisdiction). But see *National Communications Association v American Telephone and Telegraph Co*, 46 F3d 220, 222–23 (2d Cir 1995) (supporting the use of primary jurisdiction to describe state court deference to federal agency expertise).

court issued a stay,⁸ judges in New York⁹ and Oklahoma¹⁰ declined to do so.

This Comment addresses the question whether stays of litigation under the doctrine of primary jurisdiction are appropriate in the context of state-law false advertising claims against prescription opioid manufacturers in state courts. Part I places the current litigation in the context of state and federal regulation of prescription drugs and describes lessons learned from litigation over an analogous public health crisis: tobacco. Part II details the disagreement among state courts as to whether stays should be granted under the primary jurisdiction doctrine. Part III delineates the doctrinal arguments for and against stays under the primary jurisdiction doctrine in these cases, concluding that adherence to the doctrine's guiding principles does not require judges to grant such stays. Part IV reframes the requests for stays in these cases as arguments over which institution—state courts or the FDA—should get to determine evidentiary sufficiency on questions of fact in the face of scientific uncertainty. This novel approach shows that requests for stays to await the creation of new evidence constitute a unique category of primary jurisdiction requests, which, if granted, can have the effect of raising plaintiffs' burden of evidence.

The differences between the evidentiary standards that state courts apply and those that the FDA apply can be analogized to the story of the tortoise and the hare. While state courts are willing to move more quickly and may be more error prone, the high standard of evidence that the FDA applies may render the agency more accurate but slower to reach a decision. Forcing plaintiffs to wait for FDA evaluation detracts from the tort system's goals of deterrence and compensation, goals which agencies like the FDA are not designed to address. Ultimately, because state court tort systems are uniquely focused on the specific harms caused to plaintiffs, they are better able to motivate research addressing those questions, raising the likelihood that an accurate assessment of liability will be reached in the long term.

⁸ *People v Purdue Pharma LP*, 2015 WL 5123273, *1 (Cal Super).

⁹ *In re Opioid Litigation*, 2018 WL 4760685, *2 (NY Sup).

¹⁰ *State v Purdue Pharma LP*, 2017 WL 10152334, *1 (Okla Dist).

I. BACKGROUND: DRUG REGULATION AND PUBLIC HEALTH CRISES

Like all prescription drugs, opioid painkillers are subject to both state and federal regulations. As the opioid addiction crisis has exploded and gained public attention in recent years, government officials at the local, state, and federal levels have all engaged in efforts to combat it. This Part explores the recent history of opioid regulation in the United States leading up to the current litigation, including the lessons that might be drawn from litigation against the manufacturers involved in the tobacco national health crisis. Both the opioid litigation and tobacco cases have involved allegations that companies concealed or misstated information about the health risk of their products, causing extensive harms to localities across the country.

A. Federal and State Regulation of Marketing for Prescription Drugs

Although the FDA regulates marketing of prescription drugs under the Food, Drug, and Cosmetic Act¹¹ (FDCA), the effectiveness of FDA regulation has been questioned on two fronts. First, the FDA rarely sanctions manufacturers for violating FDCA marketing violations.¹² Second, the FDA only regulates marketing materials that name a branded product.¹³ Prescription drug manufacturers can therefore skirt FDA requirements by creating marketing materials describing a *class* of drugs—such as opioid pain relievers—without mentioning any particular brand name.

The inefficacy of FDA regulation has motivated state governments to pursue litigation in an attempt to stem misleading advertisements of prescription drugs, including opioids. For example, in 2004, three states separately sued Janssen Pharmaceuticals to curb certain advertising practices.¹⁴ The states alleged that a letter Janssen sent physicians to promote

¹¹ 52 Stat 1040 (1938), codified as amended at 21 USC § 301 et seq.

¹² Vicki W. Girard, *Punishing Pharmaceutical Companies for Unlawful Promotion of Approved Drugs: Why the False Claims Act is the Wrong Rx*, 12 J Health Care L & Pol 119, 125 (2009) (noting that, rather than pursuing punitive sanctions, the FDA “typically attempts to achieve compliance from companies through less formal means,” such as warning letters).

¹³ 21 USC § 352(n). See discussion in Part III.B.

¹⁴ See generally *Ortho-McNeil-Janssen Pharm, Inc v State*, 432 SW3d 563 (Ark 2014); *State v Ortho-McNeil-Janssen Pharm, Inc*, 777 SE2d 176 (SC 2015), cert denied 136 S Ct 824 (2016); *State v Johnson & Johnson*, 704 SE2d 677 (W Va 2010).

the schizophrenia drug Risperdal violated state consumer protection laws by failing to accurately describe the risk of patients developing hyperglycemia and diabetes.¹⁵ Plaintiffs' claims relied in part on a "warning letter" the FDA had sent to Janssen raising the same concerns.¹⁶ In two out of the three cases, the state courts ultimately concluded that the FDA warning letter was not permissible evidence of wrongdoing because it was not the result of a formal review of the evidence by the agency.¹⁷ The states' attempts to put force behind a relatively weak FDA intervention therefore failed.

Viewed in this context, the current litigation against prescription opioid manufacturers is only the latest salvo in a long-running battle over the proper role of state and local governments in regulating the marketing of FDA-approved prescription drugs. The scale of the opioid addiction crisis heightens the stakes of the current fight and has generated a large number of similar cases. But the questions raised in these cases over the proper balance of state and FDA control in questions of misleading marketing will have ramifications for the regulation of marketing all prescription drugs, not just prescription opioids.

B. Current Litigation against Prescription Opioid Manufacturers

Local government plaintiffs in California, New York, and Oklahoma have levied similar claims against a heavily overlapping set of defendants including Purdue Pharma ("Purdue"), Actavis, and Teva Pharmaceuticals. Although the causes of action differ according to the specific laws of each state, the general assertion is the same: defendant manufacturers engaged in false or misleading advertising practices, and plaintiffs incurred damages because those practices forced them to expend public funds to address the resulting public nuisance. This Part outlines the details of these cases in order to demonstrate that they are sufficiently similar to merit analysis as a group, despite being heard by different states' courts.

¹⁵ The states were West Virginia, Arkansas, and South Carolina. For more discussion of these actions, see generally Cary Silverman and Jonathan L. Wilson, *State Attorney General Enforcement of Unfair or Deceptive Acts and Practices Laws: Emerging Concerns and Solutions*, 65 U Kan L Rev 209 (2016).

¹⁶ *Id.* See, for example, *Johnson & Johnson*, 704 SE2d at 683.

¹⁷ Silverman and Wilson, 65 U Kan L Rev at 227–30 (cited in note 15).

Attorneys for the County of Santa Clara and Orange County brought suit against Purdue and several other prescription opioid manufacturers on behalf of the people of California in 2014.¹⁸ Specifically, the suit claims that defendant manufacturers violated the California False Advertising Law,¹⁹ the California Unfair Competition Law,²⁰ and the California Public Nuisance Law.²¹ The counties alleged:

[Beginning in] the late 1990s . . . and *continuing today*, each Defendant began a sophisticated marketing scheme premised on deception to persuade doctors and patients that opioids can and should be used to treat chronic pain. Each Defendant spent, and some continue to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids and overstate the benefits of opioids.²²

The California Advertising Law explicitly forbids any statement in advertising “which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading.”²³

In New York, county government plaintiffs allege seven distinct causes of action: deceptive acts and practices,²⁴ false advertising,²⁵ common-law public nuisance, false statements to obtain public funds,²⁶ fraud, unjust enrichment, and negligence.²⁷ New York state law defines “false advertising” as

advertising, including labeling, of a commodity . . . if such advertising is misleading in a material respect. In determining whether any advertising is misleading, there shall be taken into account (among other things) . . . the extent to which the advertising fails to reveal facts material in the light of such

¹⁸ See generally *People v Purdue Pharma LP*, 2015 WL 5123273.

¹⁹ Cal Bus & Prof Code §§ 17500–09.

²⁰ Cal Bus & Prof Code §§ 17200–10.

²¹ Cal Civ Code §§ 3479–80. See Fourth Amended Complaint for Violations of California False Advertising Law, California Unfair Competition Law, and Public Nuisance, Seeking Restitution, Civil Penalties, Abatement, and Injunctive Relief, *People v Purdue Pharma LP*, No 30-2014-00725287-CU-BT-CXC, *4 (Cal Super filed July 7, 2017) (California Complaint).

²² California Complaint at *1 (emphasis in original) (cited in note 21).

²³ Cal Bus & Prof Code § 17500.

²⁴ NY Gen Bus Law § 349.

²⁵ NY Gen Bus Law § 350.

²⁶ NY Soc Serv Law § 145-b.

²⁷ *In re Opioid Litigation*, 2018 WL 3115102, *3 (NY Sup).

representations with respect to the commodity or employment to which the advertising relates under the conditions prescribed in said advertisement, or under such conditions as are customary or usual.²⁸

Cases brought by nine different counties were transferred to the Commercial Litigation division of the New York Supreme Court in Suffolk County for coordinated disposition.²⁹

Oklahoma Attorney General Mike Hunter meanwhile also brought suit. The complaint alleges that defendants³⁰ are responsible for “massive and unprecedented marketing campaigns through which they misrepresented the risks of addiction from their opioids”³¹ and alleges public nuisance, fraud and deceit, unjust enrichment, violations of state Medicaid laws, and Oklahoma Consumer Protection Act³² claims.³³ The Oklahoma Consumer Protection Act defines a “deceptive trade practice” as “a misrepresentation, omission or other practice that has deceived or could reasonably be expected to deceive or mislead a person to the detriment of that person.”³⁴

In response to the plaintiffs’ claims, defendants in the California, Oklahoma, and New York cases asked the state courts to dismiss or stay the claims under the doctrine of primary jurisdiction. This common-law doctrine permits judges to delay litigation in order to allow a federal agency to address an underlying issue, either because the issue is within the agency’s jurisdiction or because the court could benefit from the agency’s advice.³⁵ In such cases, the court may refer the issue to the relevant agency.³⁶ The decision to refer has the effect of delaying the case until the

²⁸ NY Gen Bus Law § 350-a.

²⁹ *In re Opioid Litigation*, 2018 WL 3115102 at *2.

³⁰ In March 2019, Purdue reached a settlement with the state of Oklahoma for \$270 million. See generally Consent Judgment as to the Purdue Defendants, *State v Purdue Pharma LP*, No CJ-2017-816 (Okla Dist filed Mar 26, 2019). In June 2019, the state of Oklahoma also settled with Teva Pharmaceuticals for \$85 million. See generally Consent Judgment as to the Teva Defendants, *State v Purdue Pharma LP*, No CJ-2017-816 (Okla Dist filed June 24, 2019). The case against the remaining defendants went to trial in July 2019, and as this piece was going to print no verdict had been announced. For a review of the trial, see Jackie Fortier, *Pain Meds as Public Nuisance? Oklahoma Tests a Legal Strategy for Opioid Addiction* (NPR, July 16, 2019), archived at <http://perma.cc/E45U-XW27>.

³¹ Original Petition, *State v Purdue Pharma LP*, No CJ-2017-816, *1 (Okla Dist filed June 30, 2017) (Oklahoma Petition).

³² 15 Okla Stat Ann § 752(13).

³³ See also Oklahoma Petition at *20–30 (cited in note 31).

³⁴ 15 Okla Stat Ann § 752(13).

³⁵ See *United States v Western Pacific Railroad Co*, 352 US 59, 63–64 (1956).

³⁶ *Id.* For further discussion of the primary jurisdiction doctrine, see Part III.A.

agency has completed its review, a timeline which can be indefinite. In the opioid cases, defendants are asking courts to delay trial pending the completion of a new set of studies recently ordered by the FDA. As further discussed in Part III, a stay in these cases would likely delay litigation substantially.

C. Existing and Ongoing FDA Reviews of Risks and Benefits of Prescription Opioids

At the heart of the state-law misleading advertising claims is a dispute over the actual risks and benefits of prescribing opioids for chronic, noncancer pain. In requesting that suits be dismissed or stayed, prescription opioid manufacturers point to both the FDA's previous reviews of scientific evidence and a series of new studies currently being conducted at the FDA's request. As described below, those new studies were ordered in response to concerns about the addictive qualities of prescription opioids brought to the FDA's attention by a group of physicians.

In 2012, a group of doctors calling themselves Physicians for Responsible Opioid Prescribing submitted a citizens' petition to the FDA (the "PROP petition").³⁷ The petition noted that "a four-fold increase in prescribing of opioid analgesics has been associated with a four-fold increase in opioid related overdose deaths."³⁸ The petition spurred the FDA to review evidence on three specific questions.³⁹ The first question is whether the FDA should remove "moderate" noncancer pain from the approved uses listed on labeling for opioid pain relievers. The second is whether the FDA should set a maximum approved daily dose of opioid pain relievers prescribed for noncancer pain. Finally, the third question is whether the FDA should set a ninety-day limit on the duration of prescriptions for noncancer pain.⁴⁰

In 2013, after completing a review of existing scientific evidence, the FDA made a series of binding factual determinations

³⁷ Petition from Physicians for Responsible Opioid Prescribing to Dockets Management Branch, Food and Drug Administration (July 25, 2012), archived at <http://perma.cc/ET36-FWUY> (PROP Petition). Regulations governing the FDA's conduct under the FDCA include a provision for citizens to submit such petitions. 21 CFR § 10.20. Upon receiving a petition, the FDA is obligated to respond. 21 CFR § 10.30.

³⁸ PROP Petition at *2 (cited in note 37).

³⁹ Food and Drug Administration, Center for Drug Evaluation and Research, *Letter from Dr. Janet Woodcock to Dr. Andrew Kolodny, President of Physicians for Responsible Opioid Prescribing* *1 (Sept 10, 2013), archived at <http://perma.cc/25ZF-SFBW> (FDA Petition Response).

⁴⁰ *Id.*

regarding the use of a subset of opioid pain relievers known as “extended-release/long-acting” (ER/LA).⁴¹ The FDA determined that some labeling changes were appropriate, including removal of the indication for “moderate” pain, but that existing evidence was not sufficient to justify the implementation of maximum daily doses or maximum durations for prescriptions.⁴² Regarding the maximum daily dose question, the FDA stated that while available research “appear[s] to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality . . . the point at which the risk of overdose-related death increases enough to change the benefit-risk assessment of the studied opioids cannot be determined from these studies.”⁴³ Regarding the maximum duration question, the response to the petition stated that “[t]he cited literature does not identify a duration threshold beyond which the risk of addiction outweighs the benefits of opioid treatment.”⁴⁴

Importantly, the FDA also announced that, for the first time,⁴⁵ it would require manufacturers of ER/LA prescription opioids to conduct new studies “to assess the known serious risks of misuse, abuse, hyperalgesia,⁴⁶ addiction, overdose and death” associated with long-term use.⁴⁷ The timelines laid out for these studies ranged from expected completion dates of August 2015 to 2018.⁴⁸ The defendant manufacturers argue that completion of these studies is crucial before determining their potential liability, and thus the state court litigation should be stayed.

D. Lessons from Tobacco Litigation

Many observers have pointed out the analogies between the litigation against prescription opioid manufacturers and that

⁴¹ Id. ER/LA opioid pain relievers are distinguished from “immediate-release” opioid pain relievers. Id at *4.

⁴² FDA Petition Response at *9, 11–17 (cited in note 39).

⁴³ Id at *14.

⁴⁴ Id at *16.

⁴⁵ For a thorough review of FDA action regarding prescription opioids, see FDA, *Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuses and Abuse* (Aug 6, 2018), archived at <http://perma.cc/J3NU-34EJ>.

⁴⁶ Hyperalgesia is a condition where “the patient becomes more sensitive to certain painful stimuli over time.” FDA Petition Response at *10 n 41 (cited in note 39).

⁴⁷ Id at *11.

⁴⁸ Id.

against big tobacco companies.⁴⁹ One aspect of the tobacco litigation worth highlighting here is the resolution in the 1990s of a large number of suits in the form of a master settlement agreement (MSA). This MSA provides a cautionary note against centralized resolution of national crises that manifest in local harms because such resolutions may not address the specific harms felt in each locality.

The history of the MSA raises concerns about the ability of such centralized agreements to effectively compensate harms at the local level. In 1998, forty-six states, five US territories, and the District of Columbia entered into settlement agreements with the four largest tobacco companies.⁵⁰ In exchange for releasing those companies from liability for future claims, the states were promised a total of \$206 billion over the next twenty-five years, followed by up to \$9 billion per year in perpetuity.⁵¹ However, the agreement did not provide guidance on how that money would be spent. As of 2006, states were only spending about 5 percent of that money on tobacco control, and about 32 percent on health initiatives, with the remaining 60 percent or so going to a wide range of initiatives unrelated to the harms of tobacco use.⁵² Because state governments were parties to the settlement, it is unclear how much, if any, of that money made it to city and county governments, many of which are bringing suits against opioid manufacturers today.⁵³

The recent experience of the MSA may well be informing city and county governments' strategies in choosing to bring their own suits in state court.⁵⁴ Professors Abbe Gluck, Ashley Hall, and Gregory Curfman argue that local government plaintiffs have

⁴⁹ See, for example, Derek Carr, Corey S. Davis, and Lainie Rutkow, *Reducing Harm through Litigation against Opioid Manufacturers? Lessons from the Tobacco Wars*, 133 *Pub Health Reports* 207, 207–08 (2018); Gluck, Hall, and Curfman, 46 *J L Med & Ethics* at 351 (cited in note 5). At least one tobacco manufacturer also invoked the primary jurisdiction doctrine in an attempt to have an unfavorable verdict vacated. The federal district court declined to grant the stay, noting that the court, not the FDA, had the responsibility and expertise necessary to remedy violations of RICO, the statute under which the Government had sued. *United States v Philip Morris USA, Inc*, 787 F Supp 2d 68, 77–80 (DDC 2011).

⁵⁰ Carr, Davis, and Rutkow, 133 *Pub Health Reports* at 208 (cited in note 49).

⁵¹ Frank Sloan and Lindsey Chepke, *Litigation, Settlement, and the Public Welfare: Lessons from the Master Settlement Agreement*, 17 *Widener L Rev* 159, 161, 198–99 (2011).

⁵² *Id.* at 215.

⁵³ See Gluck, Hall, and Curfman, 46 *J L Med & Ethics* at 355 (cited in note 5).

⁵⁴ See *id.* (noting that local governments “have been motivated to sue by a concern that financial settlements to states may not necessarily result in money being transferred directly to local communities”).

been clear about wanting to maintain control of their litigation, even when they have struggled to articulate the precise form of relief they hope for.⁵⁵ As if to emphasize this point, Oklahoma City recently filed its own suit in state court, despite the state of Oklahoma's ongoing litigation.⁵⁶

The desire to maintain local control has manifested in multiple ways. Not only are city and local governments filing suit, but in many cases they are specifically choosing to do so in state court and resisting attempts by defendants to have those cases removed to federal court. For example, the motion for a stay under the primary jurisdiction doctrine in the California suit was only brought after that case had been removed to federal court and then remanded to state court.⁵⁷ The suit brought by the state of Oklahoma was only recently remanded to state court.⁵⁸ The defendant manufacturers had removed the case in June 2018, six months after the state court denied their request for stay under the primary jurisdiction doctrine.

The existence of the MDL appears to be heightening plaintiffs' desire to remain in state courts.⁵⁹ For example, an attorney for the state of Oklahoma stated at a press conference that "the effort to return [the] lawsuit to state court was to keep it from potentially being folded into more than 800 similar lawsuit[s] pending in Ohio."⁶⁰ In announcing the new suit by Oklahoma City, a city attorney similarly noted that the city "will resist any attempts by the 38 defendants to transfer the litigation to federal court and combine it with [the MDL] in Ohio."⁶¹ Such a desire may be counterintuitive to those who see the MDL as an opportunity to quickly and efficiently extract a large settlement from the major defendants. But the tobacco MSA may have taught some local governments that the transaction costs saved in a centralized settlement do not make up for losing the ability to control the flow of

⁵⁵ *Id.*

⁵⁶ William Crum, *Oklahoma City Files Its Own Opioid Lawsuit* (The Oklahoman, Nov 8, 2018), archived at <http://perma.cc/XN6W-LX6B>.

⁵⁷ *People v Purdue Pharma LP*, 2014 WL 6065907, *4 (CD Cal 2014) (order to remand due to lack of diversity jurisdiction).

⁵⁸ Ken Miller, *Judge Sends Oklahoma's Lawsuit against Opioid Makers Back to State Court* (Insurance Journal, Aug 7, 2018), archived at <http://perma.cc/PX9U-S6BN>.

⁵⁹ See Gluck, Hall, and Curfman, 46 *J L Med & Ethics* at 359 (cited in note 5).

⁶⁰ Miller, *Judge Sends Oklahoma's Lawsuit against Opioid Makers Back to State Court* (cited in note 58).

⁶¹ Crum, *Oklahoma City Files Its Own Opioid Lawsuit* (cited in note 56).

funds. At least one set of plaintiffs has gone so far as to withdraw its case in order to escape the MDL.⁶²

This desire to avoid a consolidated or centralized resolution of this dispute casts a new light on the application of the primary jurisdiction doctrine in these cases. Stepping back from the details of the doctrine to look at its effects as a whole, it is clear that invoking primary jurisdiction is a tool that manufacturer defendants can employ to centralize dispute resolution. Rather than let dozens of state courts resolve various factual issues for themselves, defendants' actions suggest they would prefer that such factual conclusions be drawn by a single federal agency, and are forcing plaintiffs to fight to continue proceedings under local control.

II. THE PRIMARY JURISDICTION DISAGREEMENT AMONG STATE COURTS

Three state courts have issued decisions responding to defendant opioid manufacturers' requests for stays under the primary jurisdiction doctrine. Although the legal questions, facts, and defendants are similar in all three cases, one court chose to grant the stay of litigation while two declined to do so. This Part summarizes defendants' arguments for staying litigation and the reasoning behind the three state courts' decisions. The following Parts will evaluate that reasoning in light of the scientific uncertainties surrounding the opioid litigation and explore the relevance of the FDA's planned course of action to the cases before state courts.

A. Defendants' Requests for Stays

Defendants' motions for stays under the primary jurisdiction doctrine emphasize the technical complexity of the scientific questions underlying plaintiffs' claims. For example, the California plaintiffs alleged that the prescription opioid manufacturers

⁶² A lawyer representing eleven municipal governments from Missouri told reporters that his clients decided to withdraw their suit because "[i]t got removed to federal court where we did not want to be. . . . At some point soon, we're going to refile back in state court." Jordan Larimore, *Attorney Withdraws Opioid Lawsuit, Plans to Refile* (The Joplin Globe, Nov 13, 2018), archived at <http://perma.cc/3BQM-ELYE>.

made seven different categories of misleading or misrepresentational statements.⁶³ In five of these seven counts, defendants have argued in near-identical language that “additional data from the ordered studies may assist in assessing this alleged risk.”⁶⁴ By contending that additional information would be useful to resolve the dispute, the defendants laid the basis for their subsequent assertion that granting a stay would meet the two goals of the primary jurisdiction doctrine: “allowing [the court] to take advantage of FDA’s expertise” and “ensur[ing] uniform application of the regulatory laws by avoiding a decision by this Court that may end up being contradicted by FDA’s subsequent assessment of the same issues based on the results of the ordered clinical studies.”⁶⁵

In Oklahoma, defendants’ motion for a stay of litigation also emphasized the FDA’s orders for new studies. The motion argues that plaintiff’s claims

will [] necessarily fail if the FDA-ordered post-market studies confirm that Defendants did not misrepresent the relative risks and benefits of using opioids for long-term treatment of chronic non-cancer pain. But even if FDA later determines that the science does not support some of the challenged representations, the State would still need to establish that Defendants knew the representations were false when made. Thus, it is inefficient and potentially problematic for the Court to wade into this issue before the science is fully developed.⁶⁶

⁶³ California Complaint at *1 (cited in note 21) (claiming that defendants (1) overstated the benefits of opioids in improving patient functioning and quality of life; (2) understated the risks of addiction from chronic use of prescription opioids; (3) misrepresented doctors’ ability to mitigate the risk of addiction; (4) falsely implied that “pseudoaddiction,” in which patients exhibit drug-seeking behaviors but are not actually addicted, is a scientifically recognized phenomenon; (5) misrepresented doctors’ ability to safely and easily manage withdrawal; (6) misrepresented the increased risks of addiction associated with increased doses; and (7) omitted or minimized other adverse effects of opioid use).

⁶⁴ See (1) Notice of Demurrer and Demurrer by Defendants on Primary Jurisdiction and Equitable Abstention Grounds; (2) Memorandum of Points and Authorities in Support, *People v Purdue Pharma LP*, No 30-2014-00725287-CU-BT-CXC, *14–17 (Cal Super filed May 24, 2015).

⁶⁵ *Id.* at *13.

⁶⁶ Defendants’ Joint Motion to Stay This Case under the Primary Jurisdiction Doctrine and the Court’s Inherent Authority to Stay Proceedings and Memorandum of Law in Support, *State v Purdue Pharma LP*, No CJ-2017-816, *1–2 (Okla Dist filed Sept 22, 2017) (Oklahoma Motion for Stay).

As in the California suit, defendants focused on the underlying scientific uncertainty and the possibility of conflict between the state court's findings and the FDA's future findings.

The New York state court judge's summary of defendants' arguments for a stay of litigation similarly highlights scientific uncertainty and the risk of inconsistent application of the law across jurisdictions.⁶⁷ “[D]efendants contend . . . that it would be premature to adjudicate claims that the defendants misrepresented those benefits and risks while FDA review remains ongoing.”⁶⁸ Furthermore, the “FDA is uniquely qualified to resolve such matters relating to public health, and [] imposition of a stay pending the outcome of its post-market studies will help ensure uniform and consistent application of the law in all the jurisdictions where similar litigation is taking place.”⁶⁹ Here, the defendants cited the fact that many cities, counties, and states across the country had filed suit against these defendants as a reason to issue a stay in favor of a centralized decision-maker. As described in Part I.D, this argument runs directly contrary to the desires of plaintiffs and the reason many of them have chosen to bring actions in state court to begin with.

B. State Courts' Responses to Requests for Stays

State courts have split on granting the manufacturer's requests for stays of litigation under the primary jurisdiction doctrine. While the California court granted a stay of litigation,⁷⁰ the courts in Oklahoma and New York declined to do so. As described below, although the different courts did not all provide elaborate analysis, the key disagreement appears to be over the extent to which the courts would benefit from the FDA's expertise in assessing the scientific questions at play in the opioid cases.

Notably, the California court did not explicitly state that it was granting the stay under the primary jurisdiction doctrine. Instead, the minute order states that the stay is granted “pursuant

⁶⁷ *In re Opioid Litigation*, 2018 WL 4760685 at *1.

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ The California court lifted the stay in a minute order issued on February 13, 2018, allowing discovery to proceed. The court did not provide reasoning for its decision. Minute Order, *People v Purdue Pharma LP*, No 30-2014-00725287-CU-BT-CXC, *1 (Cal Super filed Feb 13, 2018).

to the court's inherent authority to manage its own cases."⁷¹ However, the judge's reasoning sounds in the primary jurisdiction doctrine. Citing *Weinberger v Bentex Pharmaceuticals, Inc.*,⁷² the judge agreed with defendants' arguments regarding the need for the FDA's particular expertise in order to "protect the public's right to access this apparently important set of drugs, along with appropriately making certain that medical personnel are properly informed of the risks and benefits of the drugs and how to access them."⁷³ The judge also distinguished the FDA's technical expertise from the court's capacity to rule on questions of misleading advertising, noting that while

the FDA did not, and will not, rule on the propriety of the marketing which defendants employ, that . . . is not the issue on this motion. The issue on this motion is what determinations this court will need to make to rule on the propriety of the marketing. All of those determinations fall within the purview of the FDA.⁷⁴

In contrast to the California court's lengthier discussion, the Oklahoma court took only one sentence to deny defendants' request for a stay: "After review of the briefs and oral arguments from the parties, the Court finds and orders that the State's Petition sufficiently states its claims and those claims should not be dismissed . . . pursuant to the Primary Jurisdiction doctrine or the Court's inherent power."⁷⁵ The court did not explain its reasoning, nor did it address its divergence from the California court's stay, which defendants described in their motion.⁷⁶

The New York court also denied defendants' motion for a stay but, unlike the Oklahoma court, provided some reasoning. Specifically, the New York court disagreed with the California judge about the necessity of the FDA studies to the success of the government plaintiff's claims. Reaching the opposite conclusion from that of the California court, the judge acknowledged that

the FDA is generally responsible for ensuring that drugs marketed to the public are safe and effective . . . [and presumably has] expertise in evaluating pertinent scientific

⁷¹ *People v Purdue Pharma LP*, 2015 WL 5123273 at *1.

⁷² 412 US 645 (1973).

⁷³ *People v Purdue Pharma LP*, 2015 WL 5123273 at *2.

⁷⁴ *Id.*

⁷⁵ *State v Purdue Pharma LP*, 2017 WL 10152334 at *1.

⁷⁶ Oklahoma Motion for Stay at *2 (cited in note 66).

data. Here, however, the court will examine the state of scientific knowledge in the past and determine what data the defendants possessed to support their marketing claims when they were made—matters which the FDA will not address and which do not require its expertise but which, rather, routinely fall within the conventional experience of judges.⁷⁷

In other words, the New York court explicitly disagreed with the Oklahoma defendants' contention that plaintiffs' claims would necessarily live or die by the outcomes of the FDA's new studies.⁷⁸

Unlike the courts in California and Oklahoma, the New York judge went on to note the third major consideration of the primary jurisdiction doctrine: the harms of undue delay. Having dismissed the idea that the new studies ordered by the FDA would even be relevant, the order goes on to “express [the court's] concern that whatever value the studies might yield will be significantly outweighed, and justice defeated, by prejudice arising from the delays that inevitably accompany the agency process.”⁷⁹ Notably, unlike the California court, the New York court did not expressly address concerns of uniform application of laws.

These three opinions reveal a divide among state courts as to whether they should grant stays of litigation under the primary jurisdiction doctrine to prescription opioid manufacturers. While such different outcomes could have resulted from differences in the particular facts, statutes, and state-court precedents at play in each case, it is not at all evident that this is the case. The core defendants—Purdue, Teva, Johnson & Johnson, and Endo—do not vary across cases, nor do their briefs raise arguments particularized to each jurisdiction. As Part I.B describes, the statutes underlying the claims are also substantively similar.⁸⁰

Instead, the different rulings appear to result from the three courts' different understandings of how to apply the primary jurisdiction doctrine to the cases before them. In particular, the California and New York courts clearly disagree on the relevance

⁷⁷ *In re Opioid Litigation*, 2018 WL 4760685 at *2.

⁷⁸ Oklahoma Motion for Stay at *1–2 (cited in note 66).

⁷⁹ *In re Opioid Litigation*, 2018 WL 4760685 at *2.

⁸⁰ One possible argument is that the California statute's explicit call to whether the advertisements “should be known” to be misleading increases the relevance of newly created evidence to the suit in that state. See Cal Bus & Prof Code § 17500. However, the judge did not reference this possibility in his minute order, nor did defendants raise it in their motion. See *People v Purdue Pharma LP*, 2015 WL 5123273 at *1–2.

of newly created scientific evidence, the need for the FDA to review that evidence, and the costliness of delay. Although the exact cause of the disagreement is unclear, it may simply reflect different assessments of the comparative risks of continuing or staying litigation. The New York court seems fairly confident that it is capable of arriving at the right answer on the scientific question; the California court, less so. But it is also possible that the decisions are driven by different implicit judgments of which party should properly bear the risk of an incorrect or delayed decision. The possible answers to this question will be addressed in Part IV.

III. APPLYING THE PRIMARY JURISDICTION DOCTRINE

This Part will walk through the application of the primary jurisdiction doctrine to misleading advertising cases against prescription opioid manufacturers. Doing so requires considering whether a stay would support goals of uniformity and allow courts to benefit from the FDA's expertise, and weighing those benefits against the costs of delay. While on the surface these principles may appear to benefit from a stay in the opioid cases, strong arguments against granting stays emerge upon closer examination. The uniformity principle reflects a desire for a uniform application of law, not a uniform assessment of facts to which law will be applied. Uniformity can therefore be preserved without invoking primary jurisdiction by carefully crafting a state-court remedy that does not interfere with federal regulations. Similarly, the value of agency expertise is limited by the issues to which that expertise will be applied. Because the questions the FDA seeks to address are different than those underlying the cases in state courts, waiting for the new studies ordered by the FDA will not significantly assist the courts in understanding the issues before them. In the opioid cases, the marginal benefits to uniformity and expertise are dramatically outweighed by the plausible costs of delay, which may be measured in lives lost.

A. Principles of the Primary Jurisdiction Doctrine

Primary jurisdiction is a common-law doctrine. Supreme Court precedent instructs judges to consider two core factors in determining whether to grant a stay under the primary jurisdiction doctrine: uniformity and expertise. As described in *Far East*

Conference v United States,⁸¹ these two principles are distinct, yet often related:

[I]n cases raising issues of fact not within the conventional experience of judges or cases requiring the exercise of administrative discretion, agencies created by Congress for regulating the subject matter should not be passed over. . . . Uniformity and consistency in the regulation of business entrusted to a particular agency are secured, and the limited functions of review by the judiciary are more rationally exercised, by preliminary resort for ascertaining and interpreting the circumstances underlying legal issues to agencies that are better equipped than courts by specialization, by insight gained through experience, and by more flexible procedure.⁸²

As the Court’s language suggests, the application of the primary jurisdiction doctrine is not a matter of following a clear-cut formula. Judges must weigh the benefits of a stay against the risk of “unreasonable delay.”⁸³

Professor Diana Winters describes two “prongs” of the primary jurisdiction doctrine: “exclusive agency jurisdiction”⁸⁴ and “advice referral.”⁸⁵ Exclusive agency jurisdiction was first developed in the context of rate-setting cases for common carriers and public utilities, and separately in the context of labor relations.⁸⁶ It permits litigation to pause while an agency addresses an underlying issue that explicitly invokes a regulatory scheme within that agency’s jurisdiction.⁸⁷ The rationale in such cases is that permitting courts to rule on regulatory questions would violate the legislative purpose of establishing a uniform, national regulatory scheme.⁸⁸ But the doctrine has since expanded to include

⁸¹ 342 US 570 (1952).

⁸² *Id.* at 574–75.

⁸³ See *Ricci v Chicago Mercantile Exchange*, 409 US 289, 320 (1973) (Marshall dissenting).

⁸⁴ Judge Richard Posner coined this term in *Arsberry v Illinois*, 244 F3d 558, 563 (7th Cir 2001).

⁸⁵ Professor Winters coined this term herself. Diana R.H. Winters, *Restoring the Primary Jurisdiction Doctrine*, 78 Ohio St L J 541, 547–50 (2017).

⁸⁶ *Id.* at 542.

⁸⁷ This application of the primary jurisdiction doctrine is distinct from arguments regarding preemption. The primary jurisdiction doctrine is invoked when a plaintiff’s claim is cognizable in court and not preempted by a federal statute, but an issue of fact or law necessary to resolving the claim is within an agency’s jurisdiction. Defendants in these opioid cases have also raised preemption arguments, but those claims have been dismissed. See, for example, *State v Purdue Pharma LP*, 2017 WL 10152334 at *1.

⁸⁸ Winters, 78 Ohio St L J at 543 (cited in note 85).

“advice referral” situations in which the court wants to wait for an agency’s input even though no particular regulatory scheme would be at risk.⁸⁹

Defendants’ requests for stays in the opioid cases fall under this second prong. As Judge Richard Posner once put it, granting a stay or dismissing litigation under this flavor of the primary jurisdiction doctrine “allows a court to refer an issue to an agency that knows more about the issue, even if the agency hasn’t been given exclusive jurisdiction to resolve it.”⁹⁰ Unlike exclusive agency jurisdiction cases, advice referral is discretionary, with precedential cases providing only nonbinding guidance.⁹¹

The term “referral” is somewhat misleading, because in most cases there is no formal mechanism by which courts can ask the agency to answer a particular question.⁹² It could be the case, as with the opioid suits, that the federal agency in question has already commenced review of an issue. In this scenario, the stay merely allows time for such review to be completed. Alternatively, the stay could be issued in order to give defendants time to approach the agency on their own. For example, a railroad defendant in a classic rate-setting case might easily be able to ask the Interstate Commerce Commission to pass judgment on the reasonability of a rate.⁹³ Notably, neither situation involves direct communication between the court and the agency. Either the court is passively waiting for the agency to complete a previously planned action, or the defendants (but not the court) may be asking the agency to act.

The litigation over prescription opioids is far from the first invocation of the primary jurisdiction doctrine in the context of

⁸⁹ *Id.*

⁹⁰ *Arsberry*, 244 F3d at 563.

⁹¹ *Winters*, 78 Ohio St L J at 549 (cited in note 85). For examples of precedential cases providing discretionary guidance, see *Mashpee Tribe v New Seabury Corp.*, 592 F2d 575, 580–81 (1st Cir 1979) (describing the three factors used by the First Circuit to determine when advice referral is appropriate: “(1) whether the agency determination lay at the heart of the task assigned the agency by Congress; (2) whether agency expertise was required to unravel intricate, technical facts; and (3) whether, though perhaps not determinative, the agency determination would materially aid the court”); *National Communications Association v American Telephone and Telegraph Co.*, 46 F3d 220, 222 (2d Cir 1995) (describing the four factors used by the Second Circuit: (1) whether the issue is within the agency’s expertise; (2) whether the issue is within the agency’s discretion; (3) whether there is a significant risk of inconsistent rulings; and (4) whether a prior application has been made to the agency).

⁹² *Winters*, 78 Ohio St L J at 551 n 73 (cited in note 85).

⁹³ See, for example, *Texas and Pacific Railway Co v Abilene Cotton Oil Co.*, 204 US 426, 439–41 (1907).

prescription drugs regulated by the FDA.⁹⁴ In *Bentex Pharmaceuticals*, the FDA had withdrawn approval for a new drug application after a review process concluded that no available evidence showed that the drug was effective.⁹⁵ Manufacturers of “me-too drugs,” similar compounds which would have been covered by the same application, sued for declaratory judgment that their drugs were generally “safe and effective.”⁹⁶ The Court upheld the district court’s decision to refer the questions of whether a drug was a “new drug” for purposes of regulatory requirements and whether it was “safe and effective” to the FDA, because the two questions were, statutorily, tightly interrelated and required the evaluation of complex scientific evidence.⁹⁷ In doing so, the Court noted that “[t]hreshold questions within the peculiar expertise of an administrative agency are appropriately routed to the agency, while the court stays its hand.”⁹⁸ *Bentex Pharmaceuticals* illuminates the difficulty courts can face when disentangling the uniformity and expertise principles, as scientific (or other) expertise is frequently the motivation for giving an agency authority to set a uniform rule in the first place.

B. Applying the Uniformity Principle

The first core principle of the primary jurisdiction doctrine is that a court should stay litigation and refer the issue to the federal agency if it is necessary to ensure the uniform application of federal law or regulation.⁹⁹ The risk posed to the uniform application of federal regulation is closely tied to the remedies a court might impose. For example, in *Bentex Pharmaceuticals*, the plaintiffs asked the Court to provide relief that was identical to the regulatory authority of the agency, which would have effectively superseded the agency’s ruling on a question of law.¹⁰⁰ But the government plaintiffs in the opioid cases are asking for remedies deriving from state rather than federal laws, requiring courts to

⁹⁴ For a thorough review, see generally Catherine T. Struve, *Greater and Lesser Powers of Tort Reform: The Primary Jurisdiction Doctrine and State-Law Claims Concerning FDA-Approved Products*, 93 Cornell L Rev 1039 (2008).

⁹⁵ *Bentex Pharmaceuticals*, 412 US at 647–48.

⁹⁶ *Id.*

⁹⁷ *Id.* at 652 (“[T]he ‘new drug’ definition under [21 USC § 321(p)] encompasses a drug ‘not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use.’”).

⁹⁸ *Id.* at 654.

⁹⁹ *Far East Conference*, 342 US at 574–75.

¹⁰⁰ See *Bentex Pharmaceuticals*, 412 US at 654.

conduct a more careful analysis of whether those remedies pose any threat to uniformity.

In the prescription opioid cases, plaintiffs have asked courts for a combination of money damages and equitable relief. For example, the Oklahoma suit seeks penalties permitted by the state laws allegedly violated; actual and punitive damages for fraud; disgorgement of ill-gotten gains; and equitable relief in the form of an injunction against further violations of the Oklahoma Consumer Protection Act and abatement of the public nuisance.¹⁰¹ Similarly, the California suit seeks civil penalties and damages, as well as an injunction against further violations of the Unfair Competition Law and abatement of the public nuisance.¹⁰²

Given these requests for relief, the next question is whether “the FDA could provide . . . the relief sought.”¹⁰³ In other words, if the FDA has regulatory authority to do what plaintiffs have asked the courts to do, the argument for staying the litigation in order to preserve the uniform application of that regulatory authority is stronger.¹⁰⁴ In the opioid cases, the FDA has no authority to grant civil penalties under state law or award damages, so the core of this question is the extent to which the agency’s regulatory powers overlap with state courts’ abilities to grant the requested forms of equitable relief.

The FDCA authorizes the FDA to regulate both the labeling of prescription drugs and certain forms of advertising.¹⁰⁵ “Labeling” includes any and all written, printed, or graphic matters attached to the container of or accompanying a drug.¹⁰⁶ The FDA has broad authority to require manufacturers to include specific information on any labeling for prescription drugs, including information regarding the risks and benefits of using the drug as prescribed.¹⁰⁷ But the agency’s authority to regulate nonlabeling

¹⁰¹ Oklahoma Petition at *31 (cited in note 31).

¹⁰² California Complaint at *48–49 (cited in note 21).

¹⁰³ Struve, 93 *Cornell L Rev* at 1045 (cited in note 94).

¹⁰⁴ *Id.*

¹⁰⁵ See *Wyeth v Levine*, 555 US 555, 566–68 (2009).

¹⁰⁶ 21 USC § 321(m).

¹⁰⁷ See 21 USC § 352.

advertising is more limited. The FDCA does not define “advertising,”¹⁰⁸ but does provide a series of requirements for advertisements of prescription drugs.¹⁰⁹ Specifically, advertising must include the “established name” of the drug (colloquially, its brand name) as well as the drug’s formula and any information regarding side effects and effectiveness that the FDA chooses to require.¹¹⁰

The FDCA therefore leaves a conspicuous gap in federal regulation of prescription drug advertisements: when a company distributes information about a *category* of drugs but does not include the brand name of any specific product, those materials are not subject to the FDCA’s requirements. The prescription opioid cases allege that in an effort to evade FDA regulation, the manufacturers did exactly that.¹¹¹ Because unbranded advertising does not meet one of the basic requirements of prescription drug advertising under the FDCA, the FDA has no authority to regulate its content, and manufacturers can escape its scrutiny.

Based on this assessment of the FDA’s authority to regulate prescription drug advertising and labeling, it appears that some of the forms of equitable relief requested by plaintiffs in these state court cases could, but do not necessarily, pose a threat to the uniform application of FDA regulations. Plaintiffs’ requests for injunctions against further violations of state consumer protection laws could implicate both branded and unbranded advertising, and possibly even labeling, presenting a possible conflict with FDA requirements. If every state reaches its own conclusion about exactly why and how the labeling of a particular opioid painkiller was misleading, a manufacturer might in theory be forced to produce fifty different labels for the same product. This could hardly be considered a uniform regulatory scheme.

And yet, it does not necessarily follow that this possibility of conflict requires state courts to halt proceedings pending FDA review. Instead, when it reached the point of granting relief, a court

¹⁰⁸ See Joseph G. Milner, *Sunlight and Other Disinfectants: Disclosure Obligations under the Federal Securities and Drug Regulatory Regimes*, 72 *Food & Drug L J* 141, 154 (2017).

¹⁰⁹ 21 USC § 352(n).

¹¹⁰ 21 USC § 352(n).

¹¹¹ Carr, Davis, and Rutkow, 133 *Pub Health Reports* at 209 (cited in note 49). One particularly conspicuous example comes from comparing statements made in unbranded advertising issued by defendant Endo Pharmaceuticals with statements made in branded advertising for Endo’s flagship opioid, Opana ER. The former states, “People who take opioids as prescribed usually do not become addicted.” The latter states that “use of opioid analgesic products carries the risk of addiction even under appropriate medical use.” California Complaint at *13 (cited in note 21).

could simply elect to grant only those forms of relief that would not threaten the uniformity of FDA regulation. These would include both monetary relief, in the form of damages and civil penalties, and certain forms of equitable relief. Specifically, the court could issue injunctions against the unbranded advertising outside of FDA purview.

The possibility of nonconflicting forms of relief distinguishes the opioid cases from the situation in *Bentex Pharmaceuticals*. That case asked a court to explicitly declare that plaintiffs' drugs were not "new drugs," a term defined by the FDCA, particularly for the purpose of determining whether the FDCA's requirements for new drugs applied to the drugs in question.¹¹² By contrast, state courts are not being asked to determine whether the labeling or advertising of prescription opioids is "misleading" for the purpose of determining whether they violate the FDCA, but rather for the purpose of determining whether they violate state laws.

So long as state courts limit the remedies they grant to avoid creating conflicts with federal regulatory requirements, the only remaining argument for defendants is that there is something problematic in a nonuniform determination of fact. That is, if a state court found as fact that the risk of addiction from long-term use of opioids was a percentage chance equal to X, but the FDA, after reviewing new evidence, found that the risk of addiction was equal to Y, and X did not equal Y, the defendant would argue that this conflicting determination of fact would itself threaten uniformity. But the uniformity principle does not require different fact-finding bodies to agree; it merely requires that the application of federal laws be the same across jurisdictions. Different findings of fact by state courts have no bearing on the decisions made by the FDA. If the FDA has determined that the underlying facts do not require a product to be labeled a certain way, the FDA simply won't impose that requirement. While the possibility of conflicting findings of fact raises interesting philosophical questions about the nature of truth, it is not in itself a point in favor of granting a stay under the doctrine of primary jurisdiction.

C. Applying the Expertise Principle

The second major principle of the primary jurisdiction doctrine is that courts may refer an issue to a federal agency when it

¹¹² *Bentex Pharmaceuticals*, 412 US at 652.

is “within the peculiar expertise” of that agency.¹¹³ In the context of claims regarding prescription drugs, the relevant “expertise” is frequently understood to be the ability to assess complex scientific evidence. For example, in *Bentex Pharmaceuticals*, the Court noted that evaluating whether a drug was “safe and effective” under the FDCA “necessarily implicates complex chemical and pharmacological considerations.”¹¹⁴ Courts might be particularly inclined to refer issues to an expert agency in cases in which the relevant scientific evidence is not only complex, but also highly uncertain.¹¹⁵

The helpfulness of an agency’s apparent expertise in a particular area of science must be balanced against the reality that courts make determinations of fact based on scientific evidence every day. Such evaluations, the judge in the New York case points out, “routinely fall within the conventional experience of judges.”¹¹⁶ This reality suggests that scientific complexity is not a sufficient condition to compel judges to refer questions of fact to expert agencies. Rather, there needs to be some compelling reason why this particular question of fact merits a stay.¹¹⁷

One possible reason blends the principles of expertise and uniformity. This line of argument reasons that the court *could* determine this fact, but because the agency *will also* determine this fact at some point, and in the event that the two determinations differ, the agency is more likely to be correct due to its expertise. Therefore, to avoid conflicting determinations of the same fact which might lead to conflicting regulation, the court should let the agency determine the fact first. There are echoes of such an argument in the California judge’s reasoning that the court should stay litigation because “the FDA . . . has taken action to further explore” the relevant questions of fact.¹¹⁸

But in order for such arguments to be applicable, it must be true that whatever future efforts the FDA might undertake could

¹¹³ *Id.* at 654.

¹¹⁴ *Id.*

¹¹⁵ See Winters, 78 Ohio St L J at 575 (cited in note 85) (describing courts’ willingness to refer questions about the scientific evidence supporting the health benefits claimed by certain foods to the FDA).

¹¹⁶ *In re Opioid Litigation*, 2018 WL 4760685 at *2.

¹¹⁷ Of course, evaluating questions of scientific uncertainty involves a different kind of complexity than the assessment of questions that are just technically complex. See Part IV.

¹¹⁸ *People v Purdue Pharma LP*, 2015 WL 5123273 at *2.

be reasonably expected to provide an answer to the specific question(s) of fact material to the case. In the opioid cases, there are two major concerns with regard to materiality. The first is an issue of time, and the second is a question of precision.

First, is scientific evidence that did not exist at the time defendants were making the allegedly misleading statements material to determining whether those statements were, in fact, misleading? Defendants may be liable under states' false advertising laws if they knew or reasonably should have known that their statements were false. As the judge in the New York case put it, "the court will examine the state of scientific knowledge *in the past* and determine what data the defendants possessed to support their marketing claims *when they were made*."¹¹⁹ Under this approach, new evidence to be examined by the FDA is totally immaterial to the case, because it could not have informed defendants' knowledge at the time they were making statements.

One caveat to this understanding is that some states, including California, impose liability if defendants reasonably should have known that a statement was false or misleading.¹²⁰ Such liability kicks in only if the statement is determined to be *actually* false or misleading. Plaintiffs could argue that the scientific uncertainty at the time defendants made their statements obligated defendants to pursue additional research before making such claims. In other words, defendants should have known what the risks were because they should have undertaken the necessary efforts to find out. This line of argument concludes that, because defendants should have found out what the actual risks were, they are liable for statements which later turn out to be false. Here, new evidence—and the FDA's review of that evidence—is material to the outcome of the case, because *actual* falsehood of the statements is relevant regardless of defendants' *knowledge* of falsehood.

Even if new evidence could be material, there is still the question of precision: that is, whether the evidence being produced by the new studies and the questions to be addressed in the FDA's review of that evidence will answer the precise questions needed

¹¹⁹ *In re Opioid Litigation*, 2018 WL 4760685 at *2 (emphasis added).

¹²⁰ Cal Bus & Prof Code § 17500 (forbidding any statement "which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading").

in order to adjudicate plaintiffs' claims.¹²¹ Such a precise fit between the FDA's questions and the courts' questions is threatened by differences in both the scope of the inquiries and the nature of the facts.

The new studies ordered by the FDA are designed to address particular questions raised in the FDA's response to the PROP petition. These questions are limited to ER/LA prescription opioids. Most broadly, the new studies will "assess the known serious risks of misuse, abuse, hyperalgesia, addiction, overdose, and death," and in particular "the effect of dose and duration of opioid use on these serious risks."¹²² On February 4, 2016, the FDA announced that it would require the manufacturers of each ER/LA prescription opioid to conduct eleven specific studies, including ten observational studies and one clinical trial.¹²³ According to a sample letter sent to each manufacturer, the objectives of the observational studies include estimating "the incidence of misuse, abuse, addiction, overdose, and death associated with long-term use of opioids"¹²⁴ and "the incidence of abuse/addiction, overdose, and death associated with long-term use of opioid analgesics for chronic pain."¹²⁵ The clinical trial is required to "estimate the serious risk for the development of hyperalgesia following the long-term use of high-dose ER/LA opioid analgesics for at least one year to treat chronic pain."¹²⁶ The trial must "[i]nclude an assessment of risk relative to efficacy."¹²⁷

By contrast, courts need to address the particular questions of fact underlying the allegations raised by plaintiffs. To begin with, these allegations are not limited to concerns about ER/LA opioids. The drugs cited in the Oklahoma complaint include "immediate-release" (IR) opioid pain relievers such as Actiq, a brand of fentanyl manufactured by defendant Cephalon.¹²⁸ The

¹²¹ As described in Part III.A, referral to an agency does not involve direct communication between the court and the agency. Either the court is waiting for the agency to complete an action the agency already planned to take, or the court is providing defendants with the time to ask the agency for input.

¹²² FDA Petition Response at *10–11 (cited in note 39).

¹²³ FDA, *Timeline of Selected Activities* (cited in note 45).

¹²⁴ Judith A. Racoosin, Center for Drug Evaluation and Research, *Release from Postmarketing Requirement; New Postmarketing Requirement* *1 (FDA, Feb 4, 2016), archived at <http://perma.cc/BU9F-VQC6> (PMR Letter).

¹²⁵ *Id.* at *4.

¹²⁶ *Id.* at *7.

¹²⁷ *Id.*

¹²⁸ Oklahoma Petition at *5 (cited in note 31); FDA, *Prescribing Information for Actiq* (Dec 2016), archived at <http://perma.cc/UN2T-P2NG>.

new studies being conducted will not shed light on the risks of addiction and overdose from use of Actiq or any other IR opioid pain reliever.

Further, the veracity of the particular statements alleged to be false or misleading may not be tested by the FDA's new studies. For example, Oklahoma alleges that training materials produced by Actavis for sales representatives claimed that "long-acting opioids were less likely to produce addiction than short-acting opioids."¹²⁹ Similarly, the California complaint alleges that detailers hired by defendants have "[d]escribe[d] their opioid products as . . . less likely to be abused or result in addiction."¹³⁰ Such comparative claims will not necessarily be tested by the new studies ordered by the FDA, because each manufacturer is required to conduct these studies on its own products. There is no guarantee that each study will be designed in such a way that the results could be compared.

In summary, it is not obvious that the new studies ordered by the FDA will necessarily answer the material scientific questions underlying the claims in these cases. They may shed light on some aspects of some questions—for example, whether the incidence of addiction among long-term users of ER/LA opioid pain relievers is higher than previously known—but they will not provide the court with all of the scientific facts needed to resolve these claims. Given this reality, and in combination with the low risk to uniformity discussed above, courts must consider whether such a small possible gain of information is worth the costs of delay.

D. Concerns of Undue Delay

In assessing the risks associated with a delay of litigation, two major questions must be addressed: How long will the delay last, and what is likely to happen during that time period that otherwise would not if litigation continued without delay? In the opioid cases, the length of the requested delay is tied to an ongoing process that the FDA has already undertaken: namely, the completion of the new studies announced in 2013.¹³¹ The timeline on those new studies has already shifted once. When the requirement for new studies was announced in 2013, the FDA set out a

¹²⁹ *Id.* at *14.

¹³⁰ California Complaint at *11 (cited in note 21).

¹³¹ See FDA, *Timeline of Selected Activities* (cited in note 45).

timeline in which they would all be completed no later than 2018.¹³² But in 2016, the FDA changed the studies required for each drug from the original set of five studies to a new set of eleven.¹³³ The timelines set for this new round of studies extend through March 2020.¹³⁴ That date represents the deadline for the manufacturers to submit a report to the FDA. Although the California court lifted the stay in 2018, had the court continued to rely on the FDA timeline, that case would have been delayed for a *minimum* of five years.¹³⁵ As is, discovery in the case was delayed for four years.

The implications of a four- or five-year delay are difficult to assess precisely or generalize across cases, but some relevant facts are clear. According to the Centers for Disease Control, 17,087 people in the United States died of an overdose involving prescription opioids in 2016 alone.¹³⁶ State-specific data are not available for California, but New York saw 1,100 such deaths and Oklahoma saw 322.¹³⁷ Of course, the forward progress of litigation may not have prevented any one of those deaths. But it is clear that for every year of delay, new people become addicted to prescription opioids, and state and local governments continue to expend resources to treat and care for addicted residents. The precise extent to which these outcomes can be attributed to the defendants in these cases is as yet unknown, but the allegations against them are, at minimum, credible. In the event that courts ultimately find defendants liable, any delay in the proceedings will have meant delay in injunctive relief forbidding further misleading statements, as well as delay of monetary relief, which local governments could use to fund efforts to prevent and treat addiction and overdose.

IV. SCIENTIFIC UNCERTAINTY AND EVIDENTIARY SUFFICIENCY: WHO SHOULD DECIDE?

The preceding Part explained that the core principles of the primary jurisdiction doctrine do not clearly require courts to grant stays of litigation. Moreover, the application of the primary

¹³² FDA Petition Response at *11 (cited in note 39).

¹³³ PMR Letter at *3 (cited in note 124).

¹³⁴ *Id.* at *4.

¹³⁵ See note 70 and accompanying text.

¹³⁶ Puja Seth, et al, *Overdose Deaths Involving Opioids, Cocaine, and Psychostimulants—United States, 2015–2016*, 67 *Morbidity & Mortality Weekly Report* 349, 352 (2018).

¹³⁷ *Id.* at 353.

jurisdiction doctrine is highly discretionary. Any particular judge might feel that a case would benefit from waiting for the completion of the studies ordered by the FDA. The following Part considers the consequences of such a decision by reframing the question presented by these requests for stays as an issue of evidentiary sufficiency. This reframing, in turn, leads to an exploration in Part IV.B of the role of state courts in motivating the development of scientific evidence in contexts of scientific uncertainty. Part IV.C postulates that allowing state courts to proceed in the face of scientific uncertainty is the most efficient means available for motivating the development of new research needed to resolve that uncertainty. Part IV.D argues that even if a judge feels that a stay for the purpose of developing new evidence could be helpful to plaintiffs in a situation of scientific uncertainty, defendants enjoy certain advantages which will likely cause them to benefit disproportionately from such a stay.

A. Defendants' Requests for Stays as Evidentiary Sufficiency Arguments

Defendants' requests for stays of litigation reflect two underlying assumptions. First, the requests are premised on an argument that the scientific evidence currently available is insufficient to accurately assess the merits of plaintiffs' claims. For example, the defendants in *Oklahoma* argued that "it is inefficient and potentially problematic for the Court to wade into this issue before the science is fully developed."¹³⁸ As discussed in Part I.C, that assertion reflects the FDA's evaluation of the evidence available in 2013 to address the concerns of the PROP petition.

Second, by linking the requested delay to the completion of the new FDA studies, defendants seem to expect that those studies will produce sufficient evidence for the case to proceed. Thus, these requests represent a variation of the "advice referral" prong of the primary jurisdiction doctrine.¹³⁹ Rather than simply ask the court to rely on the FDA's expert assessment of existing evidence to answer a question of fact, defendants also ask the courts to rely on FDA expertise to determine whether the scientific evidence available is sufficient to allow any fact to be found. Furthermore,

¹³⁸ *Oklahoma Motion for Stay* at *2 (cited in note 66).

¹³⁹ *Winters*, 78 Ohio St L J at 549 (cited in note 85).

in the event that the court deems the available evidence insufficient, defendants implicitly ask the court to then rely on the FDA's assessment of what additional evidence would be sufficient. In other words, by asking the court to stay litigation pending the completion of a predetermined set of studies, the defendants are implying that *those particular studies* will provide sufficient evidence for the court to rule on.

The key question, then, is how state courts should respond when a stay is requested *because* the FDA (or another federal agency) has determined an underlying question of fact to be scientifically uncertain—that is, when there is insufficient evidence to answer the question. The court has three options. First, it can deny the request for a stay and allow the trial to proceed, giving plaintiffs the opportunity to present the available evidence, and then decide whether the available evidence is sufficient to support a verdict. Second, it can defer to the FDA's finding of insufficiency and choose to dismiss the litigation without prejudice, such that plaintiffs can bring suit again if and when new evidence becomes available. Third, it can defer to the FDA's finding by staying the litigation *in order for* new evidence to be produced, as the California court did. This final option necessarily raises questions of how and by whom new evidence is created, and to what extent the court can control that process. Because the second option merely represents a return to the pretrial status quo, the remainder of this Part will explore the consequences of the first and third options: allowing trial to proceed in the face of scientific uncertainty or staying litigation while actively seeking the production of new scientific evidence.

B. The Tortoise and the Hare: Evidentiary Sufficiency Standards in State Courts and the FDA

Because the FDA and state trial courts serve different purposes, they also apply different standards of evidentiary sufficiency in determining questions of fact. The goals of a state court are to accurately compensate plaintiffs for harms suffered as a result of defendants' lawbreaking behavior, and to deter defendants from repeating the same violations.¹⁴⁰ Plaintiffs must meet different sufficiency burdens at different points in the trial, and the particular standards applied also vary across states. For example, a California judge must grant a defendant's motion for

¹⁴⁰ See Guido Calabresi, *Optimal Deterrence and Accidents*, 84 Yale L J 656, 671 (1975).

summary judgment before a trial “if all the papers submitted show that there is no triable issue as to any material fact.”¹⁴¹ Ultimately, in order to reach a verdict, juries conduct a meta-analysis of available evidence in order to decide whether an alleged fact is more likely to be true than not. As the District of Columbia Court of Appeals once described it, juries are “entitled to combine the studies ‘to produce a whole that [is] greater than the sum of its parts.’”¹⁴² Juries may therefore draw connections and make inferences across studies which, by any scientific standard, are not comparable, generating conclusions that an expert would be unwilling to draw. The judge must only decide whether a reasonable jury could find a legally sufficient evidentiary basis to support the verdict.¹⁴³ This willingness to draw conclusions, perhaps prematurely, likely contributes to a perception that state-court findings of fact as to scientific questions are less reliably accurate than conclusions drawn by the FDA.¹⁴⁴

In contrast to the clear standards set out by courts, it is not always obvious what standard the FDA applies when it makes determinations of fact. The agency plays a regulatory role, meaning its goals are the regular operation of actors under its auspices to the benefit of society.¹⁴⁵ When the FDA brings an action against a manufacturer for misleading labeling under the FDCA, it must prove that its decision is supported by a preponderance of evidence.¹⁴⁶ But when the FDA decides to take *no* action, it is not necessarily required to state what standard the available evidence failed to meet. For example, in declining to set limits on maximum dosage and length of treatment for ER/LA opioid painkillers, the FDA simply stated that “more data are needed . . . before the Agency can determine whether additional action needs to be taken.”¹⁴⁷ One possible explanation is that the FDA felt it would not be able to meet a preponderance of evidence burden if it took action against manufacturers. Another is that the FDA, as

¹⁴¹ Cal Code Civ Pro § 437c(c).

¹⁴² Rebecca Haw, *Delay and Its Benefits for Judicial Rulemaking under Scientific Uncertainty*, 55 BC L Rev 331, 369 (2014), citing *Oxendine v Merrell Dow Pharmaceuticals, Inc.*, 506 A2d 1100, 1110 (DC App 1986).

¹⁴³ See Haw, 55 BC L Rev at 368 (cited in note 142).

¹⁴⁴ See, for example, *id.* at 362–65.

¹⁴⁵ See Cass R. Sunstein and Adrian Vermeule, *The Law of “Not Now”: When Agencies Defer Decisions*, 103 Georgetown L J 157, 158–60 (2014).

¹⁴⁶ See *United States v 60 28-Capsule Bottles, More or Less*, 325 F2d 513, 514 (3d Cir 1963).

¹⁴⁷ FDA Petition Response at *10 (cited in note 39).

a regulatory agency, is also sensitive to the risks of overregulation in a way that juries, presented with a plaintiff claiming serious harms, may not be. The potential harm to consumers of making a product less available is a particularly potent concern in the context of prescription drugs, which are designed to *relieve* suffering even as they may end up causing other types of harm.¹⁴⁸ And because the FDCA does not provide a private cause of action, nobody can sue the FDA for failing to require a change to labeling or advertising.¹⁴⁹ It is therefore unclear how the FDA would be held accountable if it *could* have met the preponderance of evidence burden in court, but nevertheless chose not to require the change.¹⁵⁰ In other words, the threshold of evidence at which the FDA is willing to take regulatory action appears to be higher than the threshold at which a jury would be allowed to find liability.¹⁵¹

The difference in the respective evidentiary standards applied by state courts and the FDA turns the primary jurisdiction question into a story like that of the tortoise and the hare. Because they allow juries to draw inferences and conclusions from scientific evidence which an expert would not, state courts come across as the nimbler institutions, anxious to leap ahead despite the risk of reaching premature conclusions which may later be proven incorrect. The FDA provides a lumbering but more careful counterpoint. Indeed, the whole theory of the primary jurisdiction doctrine is that the agency is an expert body; its processes and standards are based in scientific methods, not the assessments of lay citizens. Because the FDA cannot be held accountable by private citizens for choosing not to draw any conclusion, and because its powers include the ability to require manufacturers to conduct

¹⁴⁸ See Cass R. Sunstein, *Beyond the Precautionary Principle*, 151 U Pa L Rev 1003, 1023 (2003) (“[A] highly precautionary approach . . . might protect people against harms from inadequately tested drugs; but it will also prevent people from receiving potential benefits from those very drugs.”).

¹⁴⁹ *Heckler v Chaney*, 470 US 821, 837–38 (1985) (“The FDA’s decision not to take . . . enforcement actions . . . is [] not subject to judicial review under the [Administrative Procedure Act].”).

¹⁵⁰ The sheer volume of possible enforcement actions available to an agency at any given time mandate that the FDA will, at least sometimes, defer such actions or “decide not to decide.” Professors Cass Sunstein and Adrian Vermeule argue that such deferrals are broadly within the bounds of agency discretion, even when not strictly motivated by resource constraints, unless Congress has mandated otherwise. Sunstein and Vermeule, 103 *Georgetown L J* at 161–62 (cited in note 145).

¹⁵¹ For a discussion of the ongoing debate about the carcinogenic risk of some antidepressants, and the risks involved in either restricting or promoting the use of those drugs, see Sunstein, 151 U Pa L Rev at 1025 (cited in note 148).

new research, its incentives to reach quick but uncertain conclusions are limited. The upshot is that the FDA will be slower to act, but when it does, its assessments of the scientific questions involved are likely to be more accurate.¹⁵² Whether to allow state-court trials to move forward is therefore a decision about which party should bear the costs of scientific uncertainty.

C. Allowing State Court Trials in the Face of Scientific Uncertainty

If the risk of an inaccurate finding of scientific fact by the state court is in fact higher than the risk of an inaccurate FDA determination years down the line, then the question becomes whether the costs of such inaccuracies outweigh the benefits of a rapid decision. Recognizing that the costs of inaccuracy can be extremely high, Professor Rebecca Haw argues that in the context of toxic torts litigation, those costs are not only justified by the tort system's twin goals of deterrence and compensation,¹⁵³ but that the rules of evidence applied by courts make the tort system uniquely positioned to both motivate and adapt to new scientific evidence.¹⁵⁴

First, overcompensating plaintiffs due to scientific uncertainty can motivate defendants to conduct new research.¹⁵⁵ For example, a jury in a 1980 case against the manufacturers of Bendectin, an anti-nausea drug prescribed to pregnant women, awarded \$20,000 to a family whose child suffered birth defects based on weak scientific evidence suggesting a possible association.¹⁵⁶ The successful lawsuit motivated both more suits and a series of studies designed to test the causal connection between the drug and the birth defects. By the mid-1990s, these new studies had reached consensus: the drug did not in fact cause the birth defects.¹⁵⁷ That consensus came at a cost. By the time the new

¹⁵² Of course, the FDA is an executive branch agency subject to political change, so its willingness to take regulatory action will vary over time. In some administrations, the FDA has explicitly seen itself as "setting only a floor" on prescription drug regulation, viewing state tort systems as providing useful additional oversight. Struve, 93 *Cornell L Rev* at 1040 (cited in note 94). In other words, at least some administrations see the possibility of state courts reaching their own conclusions prior to an FDA decision as a feature, not a bug.

¹⁵³ Haw, 55 *BC L Rev* at 361–62 (cited in note 142).

¹⁵⁴ *Id.* at 365–68.

¹⁵⁵ See *id.* at 365.

¹⁵⁶ *Id.* at 363.

¹⁵⁷ Haw, 55 *BC L Rev* at 363–64 (cited in note 142).

studies were complete, Bendectin's manufacturer had built up liability of more than \$250 million in verdicts and settlements.¹⁵⁸ A similar story played out in mass litigation over silicone gel breast implants.¹⁵⁹ But in the end, it was the threat of massive liability that motivated the research required to settle the underlying scientific uncertainty. A similar pattern could play out in the opioid litigation. As the PROP petition reflects, doubts and questions about the risks of prescription opioids have lingered for years without clear answers. Massive liability for opioid manufacturers may force them to do the studies that will answer the questions raised in litigation, whether or not those answers ultimately support liability.

Second, the rules of evidence make the tort system responsive to newly available scientific evidence. Trial court judges decide first whether scientific evidence is admissible, and then whether the totality of admissible evidence is sufficient to support a verdict.¹⁶⁰ Although standards of admissibility vary among state courts, most apply standards from either *Frye v United States*¹⁶¹ or *Daubert v Merrell Dow Pharmaceuticals*,¹⁶² which superseded the *Frye* standard in federal courts. The *Frye* standard requires evidence to have "gained general acceptance in the particular field in which it belongs,"¹⁶³ while the *Daubert* standard tests "whether the reasoning or methodology underlying the testimony is scientifically valid."¹⁶⁴ Haw argues that both standards permit the admission of new scientific evidence because the core of both tests is whether the studies are designed and conducted in such a way as to comport with scientific standards, not whether their findings are considered to be conclusive.¹⁶⁵ As a result, the findings of new studies responding to the questions raised by these cases should be admissible almost as soon as they are available.¹⁶⁶

¹⁵⁸ Id at 363. However, the verdicts were all later set aside or overturned on appeal. Id at 363 n 241.

¹⁵⁹ See Heidi Li Feldman, *Science and Uncertainty in Mass Exposure Litigation*, 74 Tex L Rev 1, 18–25 (1995).

¹⁶⁰ Haw, 55 BC L Rev at 365 (cited in note 142).

¹⁶¹ 293 F 1013 (DC Cir 1923).

¹⁶² 509 US 579 (1993).

¹⁶³ *Frye*, 293 F at 1014.

¹⁶⁴ *Daubert*, 509 US at 592–93.

¹⁶⁵ Haw, 55 BC L Rev at 366–68 (cited in note 142).

¹⁶⁶ It is also in courts' interest to be receptive to new scientific research, in so far as courts' legitimacy depends on the public belief that they are accurately drawing conclusions from fact. See Mike Redmayne, *Expert Evidence and Scientific Disagreement*, 30 UC Davis L Rev 1027, 1036 (1997) ("[C]ourts will usually be receptive to scientific evidence

In the opioid cases, that means that if manufacturers did complete a new study proving that plaintiffs' claims were unfounded, they would be able to rapidly have that evidence admitted and use it to avoid liability.

On the whole, the tort system's twin goals of deterrence and compensation¹⁶⁷ are better served if defendants bear the costs of scientific uncertainty. Allowing juries to decide that the available evidence makes plaintiffs' claims more likely than not, even when a scientific expert would say that available data are insufficient to confidently draw any conclusion, places those costs on defendants who, like the Bendectin defendants, both face high liabilities for jury verdicts and must fund new studies in order to prevent future unfavorable verdicts.¹⁶⁸ If new studies retrospectively show the verdicts to be incorrect, this seems harsh. But if the trial is not allowed to go forward, plaintiffs are left uncompensated for credibly alleged harms, and defendants are not incentivized to conduct new research. Plaintiffs would therefore bear the cost of the harms suffered and, potentially, of trying to fund research to generate the necessary evidence.¹⁶⁹

Asking plaintiffs to bear the cost of research would create two fairness problems. First, conducting research would require plaintiffs to obtain large quantities of the drug in question. Put plainly, plaintiffs would have to purchase the drug from manufacturers, adding the insult of profits for defendants to the injury of a large expense for plaintiffs. Second, although plaintiffs in a suit bear the burden of proving their claims, that burden is met when they achieve the standard of evidence required of them by

. . . when it comes from traditional 'hard' scientific disciplines. This is because such evidence can be used to bolster the legitimacy of a court's verdict and enables it to impose effective closure on a dispute.").

¹⁶⁷ See note 153 and accompanying text.

¹⁶⁸ One theory is that juries choose to award verdicts to plaintiffs in cases of scientific uncertainty in part because they feel that defendants should have already conducted such research. See, for example, David E. Bernstein, *The Breast Implant Fiasco*, 87 Cal L Rev 457, 486 (1999):

[W]hen a jury is faced with a plausible claim that a defendant's product injured a plaintiff, and is convinced that the defendant did not adequately research the health effects of that product, it will frequently find for the plaintiff and be upheld on appeal unless the defendant can present solid scientific evidence refuting the plaintiff's claims.

¹⁶⁹ Of course, in the context of the opioid cases, defendant manufacturers *have* been asked to conduct research. The distinction is that that requirement was imposed by the FDA, not motivated by a suit, and so the studies required are not specifically responsive to the questions raised by the suit. For further discussion, see Part III.B.

the state-court's rules of procedure. Requiring plaintiffs to meet a higher standard—that is, to satisfy the standards applied by the FDA, another agency, or the scientific community at large—raises that burden, weakening the ability of the tort system to pursue its goals of compensation and deterrence. In this regard, questions of scientific uncertainty should not be treated as “special.” They are simply questions of fact, and should be subject to the same treatment as any other question of fact that arises in the context of a torts case.

Thus, instead of deferring to the FDA on the threshold question of evidentiary sufficiency, judges ruling on requests for stays under the primary jurisdiction doctrine for the purpose of waiting for new evidence to be produced should deny such stays when plaintiffs have met the standard of evidentiary sufficiency which would otherwise apply at that stage of the case. The principles that would guide judges' discretionary decisions regarding requests for stays for the purpose of waiting for an expert to evaluate evidence do not sufficiently guide decisions regarding requests for stays under primary jurisdiction for the purpose of waiting for new evidence. In this particular category of primary jurisdiction requests, judges need to consider the evidentiary burden before getting to questions of expertise and uniformity. For example, in the California case, in which a motion for a stay was entered after the pleadings but before a hearing, the judge should have considered whether the evidence in plaintiffs' pleadings was sufficient to indicate a triable question of material fact. If defendants had instead moved for a stay after a jury reached a verdict, the court should have then considered whether plaintiffs could survive a motion for judgment notwithstanding the verdict. To grant a stay when a plaintiff has met those sufficiency standards would be to replace a sufficiency standard designed to serve the goals of the tort system with a standard designed to serve the goals of a regulatory agency.

D. Rebutting the Arguments for Awaiting New Evidence

There are reasons a judge might see a temporary stay under primary jurisdiction as an appealing middle ground between going forward with a trial and terminating the case, but they prove unavailing. For example, if after reviewing the allegations in the complaint a judge believes plaintiffs have done enough to survive a motion to dismiss but are unlikely to survive summary judgment, then the judge might reasonably be tempted to grant the

stay in order to enable the new evidence to be produced. Granting stays only within this narrow window of evidentiary sufficiency may not appear to be unduly favorable to either plaintiffs or defendants. Defendants gain the possibility of being exonerated by new evidence; plaintiffs suffer from the delay, but gain the possibility of having their case boosted by new evidence when they were otherwise likely to lose at summary judgment. However, a careful consideration of the mechanisms available for developing new evidence reveals that the defendant manufacturers are systematically more likely to be able to take advantage of such a stay than are state and local government plaintiffs.

The first available mechanism is to simply wait for, and rely on, the new FDA studies. This is far from an ideal solution for either party, but it imposes a particular disadvantage on plaintiffs. First, as described in Part III.B, the studies required by the FDA are not directly responsive to the questions underlying the suits in state courts. To the extent that the tort system is designed to deter particular harms to specific plaintiffs, its ability to motivate research into the causes of those particular harms may be unique. Second, the studies required by the FDA will be conducted by the defendant manufacturers themselves as a result of the mechanism empowering the FDA to request studies. Because the FDCA grants the FDA authority to approve labeling, the burden is on the manufacturers to prove to the FDA that their labeling is accurate by providing requested information.¹⁷⁰ But making litigation reliant on evidence produced under the exclusive control of one party (here, defendants) is contrary to the ideals of the adversarial system.¹⁷¹ Not only would this raise concerns about accuracy, but it may also allow defendants to manipulate the timeline in which those studies are completed in order to extend the delay. Although flagrant delays might cause the court to take disciplinary action, a judge might have difficulty distinguishing between legitimate delays due to the logistical complexity of undertaking large scientific studies and intentional delay tactics. In an ideal world, plaintiffs, who bear the burden of proving facts at

¹⁷⁰ 21 USC § 352.

¹⁷¹ Of course, plaintiffs can always present experts who will interpret and challenge any evidence introduced by defendants. The difference here is that defendants have a monopoly on the *generation* of scientific evidence. Compare, for example, a suit against a defendant company for polluting a public water source. Both sides would have access to the water to measure the presence of the pollutant and study its effects. In the prescription opioid cases, only defendant manufacturers can conduct the analogous research.

trial, should have the opportunity to run their own studies or identify studies by a neutral third party.

A court frustrated by the limitations of the FDA studies may use its discretion to implement a second mechanism: creating a “race to sufficiency” by tying the length of the stay to the identification of new, admissible, and sufficient evidence from any source by either party.¹⁷² Such a solution would allow courts to seek new research on the specific questions raised by the case at hand without the imposition of potentially wasteful costs on defendants. A judge who truly wanted to utilize the FDA’s expertise in *interpreting* the new evidence could require litigants to petition the FDA to review the outside studies via the same mechanism used by the PROP petition.¹⁷³

In theory, such a rule could motivate both parties to seek out new evidence without the costliness of inaccurate verdicts. But in practice, plaintiffs still face dramatically higher hurdles to winning such a race than defendants. As discussed in Part IV.C, defendant manufacturers by definition hold a monopoly on the production of the prescription drugs in question. In order for plaintiffs or neutral third parties to conduct studies, they must first obtain large quantities of the drug from the manufacturer. Indeed, there is some reason to expect that if it were economically feasible for state and local government plaintiffs to conduct such research, they would have already done so. Many state universities are premier research institutions that have the facilities necessary to conduct the appropriate research.¹⁷⁴ But manufacturers are under no obligation to sell the necessary quantities of the drug to such institutions, let alone to do so at an affordable price. One could imagine procedural mechanisms that would allow a court to compel manufacturers to provide the drug at little or no cost, but

¹⁷² Indeed, in the context of a national health crisis, it is quite possible that an independent organization such as a university has already commenced studies that are just as well suited—or, hopefully, better suited—to addressing the particular factual questions relevant to the case. Of course, such a rule would introduce the risk that litigants hustle along seemingly comparable but shoddy research in order to have a favorable study be the first to completion. But any new study would be subject to the court’s usual admissibility standards, and the judge would have to be satisfied that the identified sufficiency gap had truly been filled in order to lift the stay.

¹⁷³ FDA Petition Response at *1 (cited in note 39).

¹⁷⁴ Indeed, Purdue’s settlement with Oklahoma includes a commitment to provide \$102.5 million “to establish a new foundation for addiction treatment and research at Oklahoma State University.” Bernstein and Zezima, *Purdue Pharma, State of Oklahoma Reach Settlement* (cited in note 30).

such a mechanism would seem to put the court in the uncomfortable position of managing a scientific study, a task that courts are not competent to take on. Thus, even this alternative mechanism for seeking new evidence turns out to unduly benefit defendant manufacturers. The structural constraints on plaintiffs' ability to meet the higher evidentiary burden implicit in the granting of a stay cannot be overcome by a more flexible consideration of other sources of evidence.

In summary, state court judges tempted to grant stays in the context of scientific uncertainty can do little to mitigate the burden that such stays impose on plaintiffs relative to defendants. Allowing state court trials to proceed when basic sufficiency standards are met therefore remains the best—albeit very costly—mechanism for motivating new research to fill evidentiary gaps in scientific questions underlying cases. So long as plaintiffs can meet the sufficiency burdens imposed by the court's rules of procedure, delaying trial in deference to a federal agency's finding of uncertainty is detrimental to the goals of the tort system and removes a key motivating factor for the pursuit of new research.

CONCLUSION

In state court cases involving allegations of false or misleading advertising by manufacturers of prescription opioid painkillers, a straightforward application of the principles of the primary jurisdiction doctrine does not necessarily direct judges to grant stays of litigation. Allowing the litigation to proceed does not inherently threaten the principles of uniformity or expertise espoused by the primary jurisdiction doctrine. If and when a verdict is reached in favor of plaintiffs, state courts can respect the uniformity principle simply by granting remedies that avoid conflicting with FDA regulations for the marketing of prescription drugs.

Instead, courts should recognize that these motions for stays are premised on arguments about evidentiary sufficiency and base their decision on whether plaintiffs are able to meet the sufficiency burden they would otherwise bear given the stage of the case. By applying a lower standard of evidentiary sufficiency than the one the FDA utilizes, state courts can play a unique and essential role in resolving questions of scientific uncertainty at play in mass torts cases like the suits brought against opioid manufacturers. Jury verdicts in favor of plaintiffs may motivate defendant

manufacturers to conduct the studies needed to determine the underlying facts more conclusively, while ensuring plaintiffs' harms are compensated. And in cases when plaintiffs have repeatedly fought to maintain local control over litigation—particularly because they fear that a centralized remedy would, for them, be no remedy at all—there is a heightened concern that allowing a slow-moving and relatively unaccountable federal agency to so heavily influence the pace and outcome of litigation would systematically benefit defendants at plaintiffs' expense.

This approach is potentially applicable in a broad variety of cases involving scientific uncertainty. The same types of arguments could arise when a catastrophe of national scale manifests in local harms, and particularly when the causal links in that catastrophe are a matter of scientific controversy. The result is a multitude of plaintiffs filing nearly identical suits against a core cadre of defendants. The opioid and tobacco litigations fit this pattern, but so too could litigation over such diverse issues as climate change, gun control, and the 2008 financial crisis. In all of these cases, the arguments laid out above suggest that the interests of all parties in reaching a rapid and accurate final conclusion would be best served by allowing litigation in state courts to proceed. In the opioid cases, the time delays of waiting could cost thousands of lives.