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Purpose, Prudence, and Path: Reevaluating the Primary Jurisdiction Doctrine in the Context of Opioid Litigation

ABBY CUNNINGHAM

The primary jurisdiction doctrine is a judicially created discretionary tool which allows a court to halt proceedings in an action where a regulatory agency’s interpretation of an issue within the matter is sine qua non to the full and final determination of the case. The doctrine first took shape in the early years of the 20th century and continues to be used today. The contours of the doctrine, however, have remained somewhat indistinct; its purposes of promoting uniformity, utilizing agency expertise, and promoting a proper working have not always been considered; and courts have failed to properly implement the doctrine. Establishing definite doctrinal boundaries and application principles is a paramount concern. The doctrine is applicable in almost any litigation context as long as an issue within the matter comes under the authority of a regulatory body. Civil plaintiffs, and commercial defendants, will be best served by establishing clear guidelines for the doctrine’s use. This Note discusses the origins of the doctrine; reaffirms its core purposes; illustrates its current amorphous and borderless shape by analyzing the doctrine against the backdrop of the current wave of opioid litigation; and suggests a method courts should use to properly apply the doctrine.

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INTRODUCTION

Judicial doctrines are valuable tools that trial courts can use to adjudicate disputes, provided the courts engage in proper analysis to determine whether the doctrine should apply. The primary jurisdiction doctrine is a judicially created discretionary doctrine designed to come into play when a case properly within the jurisdiction of a trial court involves issues implicating the regulatory authority of an administrative body. The doctrine allows a court to halt proceedings in an action where an agency’s interpretation of an issue within the matter is sin qua non to the full and final determination of the case. The doctrine is a U.S. Supreme Court creation which came into being during the nascent years of administrative law. The Court recognized the potential for problems in adjudicating issues where the authority of both court and administrative agency overlap. The primary jurisdiction doctrine was designed to address the problems arising from potentially inconsistent rulings between court and agency by allowing the agency to have the first say, thus promoting uniformity in the administration of law. Over time, and as the body of administrative law grew, the proper utilization of agency

4. See Jaffe, supra note 2.
6. Nader v. Allegheny Airlines, Inc., 426 U.S. 290, 303-04 (1976) (“Even when common-law rights and remedies survive and the agency in question lacks the power to confer immunity from common-law liability, it may be appropriate to refer specific issues to an agency for initial determination where that procedure would secure ‘[u]niformity and consistency in the regulation of business entrusted to a particular agency.’”) (quoting Far E. Conference v. U.S., 342 U.S. 574, 574-75 (1952)).
expertise became a goal of the doctrine, as did fostering a proper working relationship between courts and agencies.

Utilizing the doctrine to achieve its core purposes, however, has always been predicated on the wisdom of doing so—a court must not only ask whether referral will achieve a core purpose of the doctrine, but also ask whether the matter is important enough to the resolution of the case that the court should consult the agency at all. The question is one of prudence and soundness, and not necessarily one of jurisdiction. To answer this question, a court must look to the arguments in the pleadings and considerations outside the instant litigation, if any, which may favor referral. A court must choose an appropriate method to “refer” the pertinent issue to the agency after it decides primary jurisdiction applies, which may include staying the case or dismissing without prejudice to allow the parties to pursue the issue before the agency, certifying a question to the agency, or requesting that the agency submit an amicus brief. The case continues once the question is answered or the issue resolved, if the agency’s involvement did not bring finality to the matter.

The doctrine has met criticism despite its ostensible utility as a mechanism to aid both court and agency in carrying out their respective regulatory

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9. The doctrine is a prudential one, discussed more fully in Part I, infra.
10. Ricci v. Chi. Mercantile Exch., 409 U.S. 289, 304 (1973) (upholding the application of the primary jurisdiction doctrine absent a determination of actual jurisdiction of the Commodities Exchange Commission over an issue in a case, stating, “there is sufficient statutory support for administrative authority in this area that the agency should at least be requested to institute proceedings.”).
11. See, e.g., Splitrock Props., Inc. v. Qwest Commc’ns Corp., No. 08-412-KES, 2010 WL 2867126, at *2-3, *12 (D.S.D. July 20, 2010) (holding that, in addition to agency expertise, the fact that more than sixteen other active cases sought to address the same FCC issue, at least five of which were stayed pursuant to primary jurisdiction, weighed in favor of a stay).
12. Reiter v. Cooper, 507 U.S. 258, 268 (1993) (“[The primary jurisdiction doctrine] requires the court to enable a ‘referral’ to the agency, staying further proceedings so as to give the parties reasonable opportunity to seek an administrative ruling.”).
13. Int’l Ass’n of Heat & Frost Insulators & Asbestos Workers v. United Contractors Ass’n, 483 F.2d 384, 400 (3d Cir. 1973) (holding trial courts may certify questions to the National Labor Relations Board) (amended by 494 F.2d 1353 (3d Cir. 1974)).
14. Ryan v. Chemlawn Corp., 935 F.2d 129, 132 (7th Cir. 1991) (“If the district court believed that it needed specific information from the EPA to decide this case, it could have asked the EPA to file an amicus brief.”).
15. Ricci, 409 U.S. at 305 (holding that a decision of the Commodities Exchange Commission would not need to be litigated again by the court holding jurisdiction over the original case, saying, “if the adjudication of the Commission, if it is forthcoming, will be subject to judicial review and would obviate any necessity for the antitrust court to relitigate the issues actually disposed of by the agency decision.”).
duties. The lack of structure and discretionary nature of the doctrine has allowed confusion to blossom in the courts. Judge Posner aptly described how the primary jurisdiction doctrine has developed two distinct faces, with one face resembling “exclusive agency jurisdiction” requiring a court to surrender the claim to an agency, and another that appears to be a close cousin of the Burford abstention doctrine. This interpretive dichotomy has resulted in inconsistent application and differing standards of review from appellate courts. Amidst the confusion, judicial decisions have shifted away from considering all three of the doctrine’s original purposes towards placing heavy emphasis on the purpose of utilizing agency expertise. As such, courts have not been concerned with whether the court should involve an agency, but rather whether courts are equipped to address the kind of issue

16. See, e.g., Paula K. Knippa, Note, Primary Jurisdiction Doctrine and the Circumstantial Litigant, 85 Tex. L. Rev. 1289, 1292 (2007) (discussing how courts often misunderstand and misapply the doctrine’s purposes and functions, arguing that, “[n]ot only does such incoherence result in arbitrary or even improper application of the doctrine, it deprives parties of proper notice as to what they can reasonably expect from the judicial machinery they seek to engage in pursuit of their claims.”).

17. Id.

18. Arsberry v. Illinois, 244 F.3d 558, 563 (7th Cir. 2001) (“[The primary jurisdiction doctrine] applies only when, in a suit involving a regulated firm but not brought under the regulatory statute itself, an issue arises that is within the exclusive original jurisdiction of the regulatory agency to resolve, although the agency’s resolution of it will usually be subject to judicial review.”).

19. Id. (“Cases in which a court refers an issue to an agency because of the agency’s superior expertise . . . rather than because of the agency’s jurisdiction, are not felicitously described as cases of primary jurisdiction. They are akin to those Burford abstention cases that like the granddaddy of the line, Burford v. Sun Oil Co. . . . ”); See also Burford v. Sun Oil Co., 319 U.S. 315, 332-34 (1943).

20. See Nicholas A. Lucchetti, One Hundred Years of the Doctrine of Primary Jurisdiction: But What Standard of Review is Appropriate?, 59 Admin. L. Rev. 849, 867 (2007) (“[C]ourts are currently split on whether the doctrine is discretionary or a matter of law. No doubt this split stems from the unusual nature of the doctrine, blending prudential elements as well as elements generally accepted as matters of law.”); Bryson Santaguida, The Primary Jurisdiction Two-Step, 74 U. Chi. L. Rev. 1517, 1518 (2007) (discussing how “[c]ircuits currently disagree on how to review primary jurisdiction rulings. Some circuits review de novo, while others review for abuse of discretion. Both standards lack sufficient precision,” and discussing how a two-step review akin to that employed for abstention doctrines is appropriate).

21. See, e.g., Tassy v. Brunswick Hosp. Ctr., Inc., 296 F.3d 65, 68 (2d Cir. 2002) (“As the origin and evolution of the primary jurisdiction doctrine demonstrate, the reasons for its existence and the purposes it serves are twofold: the desire for uniformity and the reliance on administrative expertise.”); Ryan v. Chemlawn, 935 F.2d 129, 131 (7th Cir. 1991) ( “[T]he decision whether to apply it depends upon a case by case determination of whether, in view of the purposes of the statute involved and the relevance of administrative expertise to the issue at hand, the court ought to defer initially to the administrative agency.”).
Even where courts have made referrals, the decisions to refer are often devoid of discussion on why one referral mechanism was chosen over another. Not all referral methods are equal; some can result in litigants experiencing seemingly interminable delays.

Despite flaws in its application, the doctrine’s original values can still prove beneficial to courts, agencies, and litigants. This Note aims to minimize the gulf between how the doctrine is applied and how it should be applied by suggesting courts return to a simpler method of analysis: for proper application of the doctrine, a court should determine that (1) referral will achieve uniformity, properly utilize expertise, or promote comity between court and agency; (2) prudence dictates the matter should be referred; and (3) the chosen referral method avoids causing undue hardship to the parties, to the extent possible. To demonstrate how these principles should be applied, this Note will examine the primary jurisdiction doctrine against the backdrop of parens patriae suits against opioid manufacturers.

22. See, e.g., Lockwood v. Conagra Foods, Inc., 597 F. Supp. 2d 1028, 1035 (N.D. Cal. 2009) (holding application of the primary jurisdiction doctrine is not appropriate in an action alleging false or misleading advertising because, “this is not a technical area in which the FDA has greater technical expertise than the courts—every day courts decide whether conduct is misleading.”); accord Chacanaca v. Quaker Oats Co., 752 F. Supp. 2d 1111, 1124 (N.D. Cal. 2011); Ricos v. Proctor & Gamble Co., 782 F. Supp. 2d 522, 530 (S.D. Ohio 2011); see also In Re J.H. Ware Trucking, Inc., 159 B.R. 527, 532 (Bankr. E.D. Mo. 1993) (declining to apply the primary jurisdiction doctrine because a determination of what constitutes common carriage is well within the province of courts, stating, “[c]ourts are well equipped to apply a totality of circumstances test to determine the nature of transportation and absent a compelling need for the expertise of an administrative agency, the doctrine of primary jurisdiction does not compel referral.”).


24. See Diana R. H. Winters, Inappropriate Referral: The Use of Primary Jurisdiction in Food-Labeling Litigation, Symposium, 41 AM. J. L. & MED. 240, 256 (2015) (“Referral to FDA under the primary jurisdiction doctrine does not mean that FDA is then required to take action in any specific timeframe. In fact, there is no mechanism for petitioners to challenge undue delay if no official petition has been filed. Even if the parties do choose to file a petition to expedite the process, FDA is statutorily permitted to extend the decision-making process indefinitely.”).

25. See Christine H. Monahan, Private Enforcement of the Affordable Care Act: Toward an “Implied Warranty of Legality” in Health Insurance, 126 YALE L. J. 1118, 1170 (2017) (“[S]o long as courts exercise care, the primary jurisdiction doctrine need not be a bar to litigation. . . . Instead, it may provide a useful mechanism for incorporating agency input while preserving a consumer’s right to judicial recourse.”).

26. This Note addresses only a procedural aspect within certain cases in the present wave of opioid litigation. Assigning fault, liability, blame, or determining whether opioids are safe for long-term use are outside the scope of this effort.
Use and abuse of opioids in the United States has reached a fever pitch. A recent report from the Centers for Disease Control (CDC) estimates that opioid abuse caused the deaths of over 300,000 people in the United States between 1999 and 2015. The CDC estimates that, out of the total number, over 215,000 deaths resulted from overdoses of prescription opioid analgesics. The current rate at which Americans die from opioid abuse stands at ninety-one people per day. Numerous lawsuits against opioid manufacturers have attempted to assign liability for the massive economic cost of addiction, many to no avail. One state revised its view on wrongful conduct as a collateral bar in light of the opioid epidemic, deciding to adopt the comparative fault rule to allow addicts—even those who admit to committing criminal acts to fraudulently obtain prescription drugs—to sue pharmacies and doctors for fueling their addiction.

Two recent suits against opioid manufacturers received different treatment under the primary jurisdiction doctrine. In 2014, two California counties and the City of Chicago, with the help of common outside counsel, brought parallel parens patriae suits against prescription opioid analgesic manufacturers, alleging that the companies aggressively promoted drugs they knew to be unsafe for long-term treatment of pain using deceptive marketing practices. The California case was stayed under rationale supporting the

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28. Underlying Cause of Death, supra note 27; Opioid Overdose: Understanding the Epidemic, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/drugoverdose/epidemic/index.html [hereinafter Understanding the Epidemic] [http://perma.cc/DJ9V-E2ZH] (“We now know that overdoses from prescription opioids are a driving factor in the 15-year increase in opioid overdose deaths. Since 1999, the amount of prescription opioids sold in the U.S. nearly quadrupled, yet there has not been an overall change in the amount of pain that Americans report. Deaths from prescription opioids—drugs like oxycodone, hydrocodone, and methadone—have more than quadrupled since 1999.”).


33. See generally Second Amended Complaint, California v. Purdue, supra note 32; Second Amended Complaint, Chicago v. Purdue, supra note 32.
purposes of the primary jurisdiction doctrine,\textsuperscript{34} but the court handling the Chicago matter summarily rejected applying the doctrine—twice.\textsuperscript{35} Analysis of the holdings in these substantially similar cases reveals the inconsistent treatment the primary jurisdiction doctrine receives in courts. Further examination shows that proper application of the primary jurisdiction doctrine could have yielded a different, more unified result.

Part I provides an evaluation of the primary jurisdiction doctrine and explores its most critical components. Part II presents the background of the opioid crisis and surrounding litigation by discussing the role of the FDA, a brief history of opioids, and the \textit{parens patriae} litigation. Part III attempts to reconcile the divergent holdings of the California and Chicago courts and proposes how the doctrine should have been analyzed and applied.

\textbf{PART I: EXAMINATION OF THE PRIMARY JURISDICTION DOCTRINE}

The primary jurisdiction doctrine is a judicially created mechanism designed to assist courts in addressing situations where the power of the court and one or more federal agencies overlap.\textsuperscript{36} The underlying reasoning behind the doctrine is sound. The doctrine grew out of the Supreme Court’s early twentieth century recognition that the growth of administrative regulatory schemes would require courts to coordinate their efforts with that of federal agencies to achieve uniform and cohesive application of general policy objectives.\textsuperscript{37} The goals the primary jurisdiction doctrine seeks to achieve include promotion of uniformity consistent with the policy goals of the regulatory agency under whose purview rests certain issues arising within a case, the rational exercise of judicial review at the trial level by utilizing an agency’s expertise, and fostering a “proper working relationship” between courts and federal agencies.\textsuperscript{38} To accomplish these ends, a court is permitted to refer those issues outside the scope of its conventional experience to the agency with requisite specialized knowledge or expertise.\textsuperscript{39}

\begin{itemize}
  \item \textsuperscript{34} Order of Aug. 27, 2015, California v. Purdue, \textit{supra} note 32, at 2-3.
  \item \textsuperscript{35} Order of May 8, 2015, Chicago v. Purdue, \textit{supra} note 32 (first denial); Order of Sept. 29, 2016, Chicago v. Purdue, \textit{supra} note 32 (second denial).
  \item \textsuperscript{36} \textit{See} Jaffe, \textit{supra} note 2 at 1038-40.
  \item \textsuperscript{38} \textit{See} Pharm. Research & Mfrs. of Am. v. Walsh, 538 U.S. 644, 673 (2002) (Breyer, J. concurring).
  \item \textsuperscript{39} Far E. Conference v. United States, 342 U.S. 574, 574 (1952).
\end{itemize}
This part studies the foundational decisions shaping Supreme Court jurisprudence involving the primary jurisdiction doctrine. Here, the doctrine’s main goals are outlined through examination of the Supreme Court decisions in which the separate goals are first developed. The foundations of the doctrine trace back to a series of early twentieth century U.S. Supreme Court decisions invoking questions regarding the authority of the Interstate Commerce Commission over common law claims involving shippers and carriers. The Court’s manifest concern in these early decisions was uniformity and consistency between interpretations of the Commission and the judiciary in carrying out congressional intent. As such, the Court put forward uniformity in administration of laws the fundamental guiding purpose in its first decision establishing the doctrine. Decades later, two other decisions added contours to the doctrine’s rationale, adding to its intended purposes promoting the use of agency expertise when such expertise is implicated, and facilitating a proper working relationship between courts and agencies where agency interpretation will aid in bringing resolution to a complicated matter. The last, and arguably, most important decision discussed here unveils the true power of the doctrine, showing that proper application of the doctrine can result from the implication of agency authority, rather than jurisdiction.

A. The Purpose of Promoting Uniformity

The doctrine’s foundational origin is articulated in Texas and Pacific Railway Company v. Abilene Cotton Oil Company, where the court recognized the impropriety of subjecting a company to separate and possibly

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40. The primary jurisdiction doctrine has been addressed or discussed by the Supreme Court dozens of times since its foundational 1907 decision in Abilene Cotton v. Texas and Pacific Railway.

41. Great N. Ry. Co. v. Merchants’ Elevator Co., 259 U.S. 285, 291 (1922) (“Whenever a rate, rule, or practice of carriers is attacked as unreasonable or as unjustly discriminatory, there must be preliminary resort to the Interstate Commerce Commission, whether the function exercised is in its nature administrative, because directed to the determination of future practice, or judicial, because seeking to determine whether the shipper has been wronged, since in either case the inquiry is essentially one of fact and of discretion in technical matters, and uniformity can be secured only if its determination is left to the Commission.”); Loomis v. Lehigh Valley, 240 U.S. 43, 50-51 (1916) (needed ICC interpretation on regulations surrounding grain doors); Tex. & Pac. Ry. Co. v. Am. Tie & Timber Co., 234 U.S. 138 (1914) (needed ICC interpretation of tariffs for railroad ties); Tex. & Pac. Ry. Co. v. Abilene Cotton Oil Co., 204 U.S. 426, 441, 446 (1907).

42. See Jaffe, supra note 2 at 582.

43. Abilene, 204 U.S. at 441, 446.


disparate interpretations of the same issue of fact.\textsuperscript{46} In \textit{Abilene}, a cotton oil shipper sued the Texas and Pacific Railway Company in a state law cause of action alleging the shipper’s rates were unreasonably excessive.\textsuperscript{47} Texas and Pacific asserted that the trial court lacked the authority to decide the reasonableness of the rates in dispute, arguing that the authority to make such a determination was the exclusive province of the Interstate Commerce Commission (ICA).\textsuperscript{48} However, the ICA also provided that Abilene could elect either to “make a complaint to the Commission,” or “bring suit . . . for the recovery of damages . . . in any district or circuit court of the United States of competent jurisdiction,” and that Abilene’s common law remedies would remain untouched.\textsuperscript{49} Having found Abilene’s election of a common law remedy was preserved by the savings provisions within the ICA, the trial court rejected the argument of Texas and Pacific and subsequently found the disputed rates unreasonable.\textsuperscript{50}

The U.S. Supreme Court granted certiorari on later appeal, because the ultimate outcome of the matter depended heavily upon the statutory construction of the ICA.\textsuperscript{51} The Court conceded that any statute’s express preservation of a right to pursue an action at common law should not be disturbed by the statute’s implied grant of unilateral decision-making authority to a regulatory body,\textsuperscript{52} but when the preservation of rights frustrates the statute’s overall purpose and objective, the preservation should be withdrawn.\textsuperscript{53} Notably, the \textit{Abilene} Court never questioned the capability of courts or juries to determine the reasonableness of a shipping company’s rates.\textsuperscript{54} Rather, the Court concluded that determinations of reasonableness would vary from case to case, and the creation of varied standards of reasonableness is completely at odds

\begin{footnotes}
\item 47. Id. at 426.
\item 48. Id. at 430, 437-38; see also Act of Feb. 4, 1887, ch. 104, 24 Stat. 379-81 (1887). In fact, a federal statute, the Interstate Commerce Act (ICA), did command that rates charged by common carriers be “reasonable and just,” and required carriers to submit their rate schedules in advance to the Interstate Commerce Commission (ICC). Texas and Pacific’s argument that the ICC was responsible for determining reasonableness centered around the requirement for rate schedule submission, annual reporting, investigation by the commission, and the statutory penalties for various violations, including failure to file a rate schedule. §§ 6, 10, 13, 15, 20, 24 Stat. at 380-87.
\item 50. Abilene, 204 U.S. at 432.
\item 51. Id. at 433-34. The issue the Court was most concerned with addressing was the interaction between the explicit “savings” clauses and the determination of reasonableness by the ICC. Id. at 433-34.
\item 52. Abilene, 204 U.S. at 436-37. The Court finds the ICC’s duty to determine reasonableness is implied and encompassed within its duty to uniformly administer the ICA. Id.
\item 53. Id. at 437.
\end{footnotes}
with the purpose of the ICA. The Court thus repealed the common law savings provisions of the ICA not because the Interstate Commerce Commission had superior ability to determine reasonableness of shipping rates, but because Congress allocated that duty to the ICC, and because allowing courts and juries to make inevitable discordant determinations of reasonableness would frustrate congressional intent by destroying the act’s fundamental purpose.

B. The Purpose of Proper Utilization of Agency Expertise

The doctrinal purpose of promoting the beneficial use of agency expertise is articulated in Far East Conference v. United States. In Far East, a voluntary “conference” of maritime carriers who transported freight destined for the Far East constructed a dual-rate system where shippers who exclusively engaged the services conference members received a lower rate than shippers who did not. The United States brought an antitrust action against the Conference because of its unfiled dual-rate system. The Conference moved for dismissal, arguing that the kind of issues presented in the dual-rate schedule were issues better suited for preliminary consideration by the Federal Maritime Board than the district court. The Supreme Court agreed, finding the issues presented within the case were factual questions involving the shipping trade requiring “a high degree of expert and technical knowledge” outside the general scope of judicial experience, but fully within the general scope of the experience and expertise of the Board. Thus, in recognizing the value and authority of agency interpretations, the Far East Court stated, “[i]n cases raising issues of fact not within the conventional experience of judges or cases requiring the exercise of administrative

55. Id.
56. See id. at 446. Speaking of the savings clause found in §22 of the ICA, the Court stated, “[t]his clause, however, cannot in reason be construed as continuing in shippers a common-law right, the continued existence of which would be absolutely inconsistent with the provisions of the act. In other words, the act cannot be held to destroy itself.” Id. See also Nader v. Allegheny Airlines, Inc., 426 U.S. 290, 299 (1976) (in summarizing the effect of the savings clauses in Abilene, the Court said referral to the ICC was necessary due to “an irreconcilable conflict between the statutory scheme and the persistence of common-law remedies.”). But see Great N. Ry. Co. v. Merchs. Elevator Co., 259 U.S. 285, 290 (1922) (distinguishing Abilene, holding that uniformity in an agency’s administration of a law is not threatened where the issue before the court is purely a question of law).
58. Id. at 571-72.
59. Id. at 572.
60. Id. at 572-73.
61. Id. at 573 (quoting U.S. Navigation Co. v. Cunard, 284 U.S. 474, 485 (1932)).
discretion, agencies created by Congress for regulating the subject matter should not be passed over.\textsuperscript{62}

The \textit{Far East} Court added an additional contour to the purpose of the primary jurisdiction doctrine, where the goal of achieving rational exercise of judicial resources is realized when a court refers a matter within its purview, but outside its expertise, to an agency with requisite specialized experience.\textsuperscript{63} Further, the decision was the first step towards reshaping the character of primary jurisdiction doctrine from a tool to identify exclusive jurisdiction into a tool meant to facilitate appropriate use of agency expertise.\textsuperscript{64} In this way, the \textit{Far East} decision made a substantive departure from \textit{Abilene}.\textsuperscript{65} \textit{Far East} reiterates the assertion that the purpose of achieving uniformity is served when the court allows the relevant agency the opportunity to address some matter in the claim falling within its sphere of expertise, but adds that the matter subject to agency review is not cognizable by the agency alone but also by the court.\textsuperscript{66}

\textbf{C. The Purpose of Promoting a Proper Working Relationship Between Court and Agency}

Fostering a cohesive working relationship between agencies and courts was another doctrinal purpose first put forward by the \textit{Far East} Court and then further developed four years later in \textit{United States v. Western Pacific Railroad Co.}\textsuperscript{67} The decision is widely held to articulate the modern framework of the primary jurisdiction doctrine.\textsuperscript{68} The underlying dispute in \textit{Western Pacific} turned on the definitions of an incendiary bomb and reasonable rates.\textsuperscript{69} In \textit{Western Pacific}, three railroads transported a total of 211 shipments of steel bomb casings filled with napalm gel on behalf of the United

\begin{itemize}
\item \textsuperscript{62} Far E. Conference v. United States, 342 U.S. 570, 574-75 (1952).
\item \textsuperscript{63} \textit{Id.} at 574-75 (quoting United States v. Morgan, 307 U.S. 183, 191 (1939)).
\item \textsuperscript{64} See Aaron J. Lockwood, The Primary Jurisdiction Doctrine: Competing Standards of Appellate Review, 64 WASH. & LEE L. REV. 707, 713 (2007).
\item \textsuperscript{65} \textit{Id.} Beginning with the \textit{Far East} decision, the Court began to move decidedly away from \textit{Abilene}'s somewhat rigid doctrinal construction. \textit{Id.} at 715.
\item \textsuperscript{66} \textit{Far East}, 342 U.S. at 576-77. This proposition serves to support the idea that the primary jurisdiction doctrine is distinct from “exhaustion of remedies,” where the claim is first cognizable by an agency, only arriving before a court after all avenues for redress with the agency have been exhausted. See also United States v. W. Pac. R.R., 352 U.S. 59, 63 (1956).
\item \textsuperscript{67} \textit{See Far East,} 342 U.S. at 575. The \textit{Far East} Court explained that in its holding it was applying the vision of Justice Stone in \textit{United States v. Morgan}, 307 U.S. 183, 191 (1939), which proposed that court and agency are not independent regulatory bodies competing for dominance but rather a collaborative and complementary system where both exist as a “means adopted to attain the prescribed end.”
\item \textsuperscript{68} See Lockwood, \textit{supra} note 64, at 714.
\item \textsuperscript{69} \textit{W. Pac. R.R.}, 352 U.S. at 62-63.
\end{itemize}
States Army. The Government refused to pay the rate charged by the railroads and instead paid the rate it considered appropriate. The railroads brought suit against the United States in the Court of Claims for the difference between the rate paid and the rate allegedly due. The Government argued that the action should be stayed to give the ICC an opportunity to review the reasonableness of the rates pursuant to the primary jurisdiction doctrine. The Court of Claims refused to refer any portion of the matter to the Commission and rejected all of the Government’s arguments and defenses, granting summary judgment to the railroads.

The Supreme Court reversed, holding that although the issue of tariff construction is generally a matter “cognizable in the courts,” the circumstances of the case warranted consulting the ICC because its expertise and skill would bring clarity to the matter. The Court succinctly summarized the primary jurisdiction doctrine:

"Primary jurisdiction . . . applies where a claim is originally cognizable in the courts, and comes into play whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competency of an administrative body; in such a case the judicial process is suspended pending referral of such issues to the administrative body for its views."

In addressing when the doctrine should be applied, the Court stated, “[n]o fixed formula exists for applying the doctrine of primary jurisdiction. In every case the question is whether the reasons for the existence of the doctrine are present and whether the purposes it serves will be aided by its

70. Id. at 60. Some of the napalm incendiaries that the Western Pacific Railroad Company shipped between 1948 and 1950 may have ultimately been supplied to Greece to combat a communist uprising and used during the Korean conflict, both of which were complex socio-political issues. For a detailed history of napalm gel and the use of incendiary bombs in warfare, see Robert M. Neer, Napalm: An American Biography 91-95 (Harv. Univ. Press 2013).

71. W. Pac. R.R., 352 U.S. at 61. The ICC established different rate classes for shipments depending on the type of shipment. Carriers who transported shipments containing incendiary bombs could charge a higher rate than other products. In Western Pacific, the Government refused to pay the costlier first-class rate for the shipments because it asserted the casings were not incendiary bombs. Id.

72. See W. Pac. R.R., 352 U.S. at 60-61.

73. See id. at 61-62. The Government argued that its shipments fell outside the definition of an incendiary bomb put forth by the ICC. The Government contended that the casings were not actually bombs because the white phosphorous “burster” caps and fuses required to ignite the napalm gel were not incorporated into the casings. Id.


75. Id. at 68-70.

76. Id. at 63-64.
application in the particular litigation.” Put another way, a court properly applies the doctrine in situations implicating the need for uniformity in administration and regulation or the need for an agency’s specialized expertise, and referral to an agency for determination serves as a means to achieve either or both of those ends.

The Court found the issue of tariff construction, as it pertained to whether the shipped products were dangerous incendiary bombs, was so intertwined with the question of reasonableness of the rate that “the same factors [would be] determinative on both issues.” The Court explained that the primary jurisdiction doctrine “allocat[es] the law-making power over certain aspects of commercial relations. It transfers from court to agency the power to determine some of the incidents of such relations.” Given the question of reasonableness of a tariff rate involved specialized knowledge of the shipping industry, which the Court held was the unique province of the ICC, and that the ICC had not formally reviewed the tariff or offered prior clarification on its specific factors, the Court held the court of claims had not properly allocated the issues within the case between itself and the agency. In so holding, the Court recognized the authority of courts, but also emphasized that for the primary jurisdiction to function properly, courts should behave in a way that promotes a proper working relationship between themselves and agencies by appropriately allocating responsibility.

D. Prudence, Soundness, and the Question of “Should”

The Western Pacific decision is likely the primary jurisdiction doctrine’s most cited opinion because its ultimate holding describes the doctrine in relatively simple terms. The doctrine may apply to a claim discernible by both a court and agency when, in the court’s discretion, referring the matter will achieve uniformity, properly utilize agency expertise, or achieve a proper balance between the powers of the agency and the court. The decision reinforces the proposition that the Court intended the primary

78. Id.
79. Id. at 69.
80. Id. at 65 (quoting Louis L. Jaffe, Primary Jurisdiction Reconsidered, 102 U. PA. L. REV. 577, 583-84 (1954)) (internal quotation marks omitted).
82. Id. at 69-70.
83. Id. at 69. The Court stated, “By no means do we imply that matters of tariff construction are never cognizable in the courts. We adhere to the distinctions laid down in Great Northern R. Co. v. Merchants Elevator Co. . . . which call for decision based on the particular facts of each case.” Id.
jurisdiction doctrine to be a flexible judicial tool. But while Western Pacific is acknowledged for achieving a degree of synthesis between both Abilene and Far East, its most important aspect is often overlooked. The most important aspect of the Court’s holding is not how the several purposes of the doctrine coalesce, but rather how the Court finds the applicability of primary jurisdiction depends on whether the agency ought to be involved.

The Supreme Court later established that seeking an agency’s involvement is a paramount concern, even when actual jurisdiction is left undetermined; the Court in Ricci v. Chicago Mercantile Exchange addressed whether the primary jurisdiction doctrine was properly invoked to stay proceedings in an antitrust action against a futures trading exchange whose rules and operation fell under the regulatory authority of the Commodities Exchange Commission. Ricci purchased a membership in the Exchange with money from the Siegel Trading Company. The dispute arose when, as Ricci alleged, the Exchange and the Trading Company conspired to restrain Ricci’s business in violation of the Sherman Act by transferring his membership in the Exchange to someone else outside the Exchange’s procedural due process rules. The Court held the stay was proper, finding the Commission’s determination of whether the Exchange violated its rules or the Commodities Exchange Act (CEA) would ultimately aid in determining the outcome of the case. The Commission’s decision would be dispositive of the antitrust issue if the Commission found the Exchange in violation, but if it found no violation, the decision would place the lower court in a better position to

84. See Lockwood, supra note 64, at 707. The primary jurisdiction doctrine is a catch-all doctrine by design, applicable to any regulatory body and employable by any court. Id.

85. See id. at 713.

86. W. Pac. R.R., 352 U.S. at 65. Speaking of the multiple issues presented, the Court stated,

[...]thus the first question presented is whether effectuation of the statutory purposes of the Interstate Commerce Act requires that the Interstate Commerce Commission should first pass on the construction of the tariff in dispute here; this, in turn, depends on whether the question raises issues of transportation policy which ought to be considered by the Commission in the interests of a uniform and expert administration of the regulatory scheme laid down by that Act.

Id. (emphasis supplied).


88. Id.

89. Id.

90. Id. at 301-02. The Court’s greatest concern was whether consulting the Commission would materially aid the lower court in the underlying antitrust action. Id. at 305.
definitively determine whether antitrust immunity applied. Thus, by consulting the Commission for its views, the lower court would achieve uniformity in regulation, utilize the expertise of the agency, and achieve proper balance between its powers and those of the Commission.

The significance in the *Ricci* holding, however, lies in that the need to consult the Commission for its views arose out of the wisdom of involving the Commission in the matter, not out of its jurisdiction over the dispute. In fact, the Court explicitly refused to rationalize upholding the stay based on the Commission’s jurisdictional authority. Instead, the Court found the facts of the case implicating the Commission’s authority were strong enough to justify a stay under the primary jurisdiction doctrine. The Court said:

> We make no claim that the Commission has authority to decide either the question of immunity as such or that any rule of the Exchange takes precedence over antitrust policies. Rather, we simply recognize that the Congress has established a specialized agency that would determine either that a membership rule of the Exchange has been violated or that it has been followed. Either judgment would require determination of facts and the interpretation and application of the Act and Exchange rules. And either determination will be of great help to the antitrust court in arriving at the essential accommodation between the antitrust and the regulatory regimes.

Thus, *Ricci* establishes that the propriety of a stay or dismissal under the primary jurisdiction doctrine turns closely on the prudence and soundness of deferring to an agency prior to fully litigating the matter. Questions of prudence turn on whether the agency’s involvement will help to achieve proper resolution of the underlying dispute. The soundness of the decision to

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91. *Ricci*, 409 U.S. at 306 (“The adjudication of the Commission, if it is forthcoming, will be subject to judicial review and would obviate any necessity for the antitrust court to relitigate the issues actually disposed of by the agency decision.”).

92. *Id.* at 304 (“We need not finally decide the jurisdictional issue for present purposes, but there is sufficient statutory support for administrative authority in this area that the agency should at least be requested to institute proceedings.”).

93. *See id.* at 302-04. The Court’s finding that the Commission’s “administrative authority” in the field was enough to support a stay under the primary jurisdiction doctrine was based upon the Court’s understanding of the agency’s position in the regulatory scheme surrounding commodities exchanges, the Commission’s oversight of the rulemaking process of the Exchange, the Commission’s familiarity with the kinds of issues presented, and that referral would carry out Congressional intent. *Id.*

94. *Id.* at 307.

95. *See Ricci*, 409 U.S. at 305-06.
invoke the doctrine depends upon whether the issue referred resonates with a core function granted the agency by Congress. Neither consideration hinges on the agency’s jurisdiction over the matter its determination will affect. The timing of the *Ricci* decision coincided with a period of rapid growth of administrative programs. Today, the current administrative law scheme is so comprehensive that many cases involving a party or a cause of action related to a regulated industry could potentially trace back at least some issue within the matter to the authority of a regulatory body. As such, the primary jurisdiction doctrine is conceivably applicable wherever an agency’s power is implicated. However, courts are somewhat reluctant to relinquish control over such a broad swath of cases by engaging in wholesale application of the doctrine, and, in truth, application of the doctrine in every possible instance runs contrary to the doctrine’s overarching

96. See *Ricci*, 409 U.S. at 305-06.

97. See *id*. Speaking of the wisdom of consulting the Commission and how it would aid the litigation, the Court stated:

We also think it very likely that a prior agency adjudication of this dispute will be a material aid in ultimately deciding whether the Commodity Exchange Act forecloses this antitrust suit, a matter that seems to depend in the first instance on whether the transfer of Ricci’s membership was in violation of the Act for failure to follow Exchange rules. That issue in turn appears to pose issues of fact and questions about the scope, meaning, and significance of Exchange membership rules. These are matters that should be dealt with in the first instance by those especially familiar with the customs and practices of the industry and of the unique marketplace involved in this case. They are matters typically lying at the heart of an administrative agency's task and here they appear to be matters that Congress has placed within the jurisdiction of the Commodity Exchange Commission. We would recognize “that the courts, while retaining the final authority to expound the statute, should avail themselves of the aid implicit in the agency’s superiority in gathering the relevant facts and in marshaling them into a meaningful pattern.”


100. See Astiana v. Hain Celestial Grp., Inc., 783 F.3d 753, 760 (9th Cir. 2015).
purposes. Application of the doctrine is thus reserved for issues germane to the litigation and important enough to warrant involving a federal agency.

E. The Path: Testing Whether and How to Apply the Doctrine

There is a lack of uniformity amongst courts in the “tests” or factors used to decide whether the doctrine should apply. For example, the Ninth Circuit has a four-step test, stating that the doctrine should apply where there is, “(1) the need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity to a comprehensive regulatory authority that (4) requires expertise or uniformity in administration.” The Second and Third Circuits consider four factors:

1) whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency's particular field of expertise; 2) whether the question at issue is particularly within the agency's discretion; 3) whether there exists a substantial danger of inconsistent rulings; and 4) whether a prior application to the agency has been made.

Although these factors or tests may prove helpful in aiding a court’s analysis of whether the doctrine should apply, the Western Pacific decision cautions against such a formulaic approach. Courts should ask only whether the

101. See Clark v. Time Warner Cable, 523 F.3d 1110, 1114 (9th Cir. 2008) (“[T]he doctrine is not designed to ‘secure expert advice’ from agencies ‘every time a court is presented with an issue conceivably within the agency’s ambit.’”) (quoting Brown v. MCI WorldCom Network Servs., 277 F.3d 1166, 1172 (9th Cir. 2002)).

102. See Occidental Chem. Corp. v. La. Pub. Serv. Comm’n, 810 F.3d 299 (5th Cir. 2016) (discussing how invoking the doctrine is inappropriate “when the agency's position is sufficiently clear or nontechnical or when the issue is peripheral to the main litigation, courts should be very reluctant to refer [the matter].”) (quoting Miss. Power & Light Co. v. United Gas Pipeline Co., 532 F.2d 412, 419 (5th Cir. 1976)); see also MCI Worldcom, 277 F.3d at 1172 (“Primary jurisdiction is properly invoked when a claim is cognizable in federal court but requires resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to a regulatory agency.”) (emphasis supplied).

103. Syntek Semiconductor Co. v. Microchip Tech., Inc., 307 F.3d 775, 781 (9th Cir. 2002).


105. See United States v. W. Pac. R.R., 352 U.S. 59, 64 (1956) (“No fixed formula exists for applying the doctrine of primary jurisdiction. In every case the question is whether
arguments in the pleadings can support application of the doctrine to promote at least one of the doctrine’s three core purposes, and whether the referred issue is important or complex enough to make referral prudent and sound.

If an issue is ready for referral, the last step a court must take is to choose an appropriate referral method. The problem of referral, though, is that it lacks precise definition and shape, a fact which critics of the doctrine cite as a serious weakness.\(^\text{106}\) The Supreme Court said that referral is “loosely described as a process whereby a court refers an issue to an agency.”\(^\text{107}\) Some agencies have established procedures for primary jurisdiction referrals, such as the Surface Transportation Board\(^\text{108}\) and the Federal Communications Commission.\(^\text{109}\) However, most other agencies have not.\(^\text{110}\) Still, courts have successfully petitioned agencies in absence of clearly delineated referral procedures.\(^\text{111}\) But even when an agency is set up to receive referrals, or even

\(^{106}\) See Knippa, supra note 16, at 1305-06 (“Court decisions are, in fact, rife with references to ‘referral’ under primary jurisdiction doctrine, which seems to imply either that there is some mechanism through which a court can make such a referral or that each agency is equipped with a procedure that explicitly permits such a referral. Surprisingly . . . there is no such mechanism or procedure.”).


\(^{108}\) See 28 U.S.C. § 1336 (2012) (part (b) describes how courts will retain jurisdiction over the dispute in the event of referral, part (c) provides the timeline for a response, stating “[a]ny action brought under subsection (b) of this section shall be filed within 90 days from the date that the order of the Surface Transportation Board becomes final.”).

\(^{109}\) See Richard Welch, Demystifying Primary Jurisdiction Referrals, FED. COMM’N COMM’N (July 29, 2010), https://www.fcc.gov/news-events/blog/2010/07/29/demystifying-primary-jurisdiction-referrals [https://perma.cc/Y6FA-VMJR] (“In the communications law context, a primary jurisdiction referral typically occurs when private litigants raise an issue in court (most often a federal district court) that involves a contested interpretation of the Communications Act, the FCC’s rules, or an FCC order – in other words, a dispute over an issue that the Commission has the congressionally delegated authority to resolve.”).

\(^{110}\) See Reiter, 507 U.S. at 268 n. 3 (“But the ICA (like most statutes) contains no mechanism whereby a court can on its own authority demand or request a determination from the agency; that is left to the adversary system. . . .”)

\(^{111}\) Three district courts petitioned the FDA to respond to an issue in three different, but related, cases. See Barnes v. Campbell’s Soup Co., 12-cv-05185 JSW, 2013 WL 5530017 at *9 (N.D. Cal. July 25, 2013) (“Accordingly, and out of respect for the FDA’s authority, the Court GRANTS Defendant’s motion to dismiss the Plaintiffs’ claims against Defendant’s Natural Vegetable Soups on the grounds of primary jurisdiction and REFERS the matter to the FDA for an administrative determination, and STAYS the action for a period of six months from the date of this Order.”); In Re General Mills, Inc. Kix Cereal Litig., 12-cv-00249-KM-MCA, 2013 WL 5943972 at *1 (D.N.J. Nov. 1, 2013) (“Pursuant to 21 C.F.R. § 10.225(c), this Court hereby refers to the FDA for an administrative determination the question of under what circumstances food products containing ingredients produced using bioengineered corn may be labeled ‘All Natural.’”). The FDA responded to all three petitions in a single letter. See Letter from Leslie Kux, Assistant Comm’r for Policy, U.S. Food & Drug Admin., to Hon. Yvonne Gonzalez Rogers, N.D. Cal., Hon. Jeffrey S. White, N.D. Cal., & Hon. Kevin...
receptive to the idea of doing so, the immediate effect of applying the primary
jurisdiction doctrine is a delay.\footnote{112}

The potential for indefinite delay is a true problem, one which prevents
some courts from applying the doctrine,\footnote{113} and something that critics of the
referral process of the primary jurisdiction doctrine find most troublesome.\footnote{114}
The Fifth Circuit illustrated the concern, saying:

\begin{quote}
[C]ourts should be reluctant to invoke the doctrine of pri-
mary jurisdiction, which often, but not always, results in
added expense and delay to the litigants where the nature of
the action deems the application of the doctrine inappropri-
ate. . . . Likewise, when the agency's position is sufficiently
clear or nontechnical or when the issue is peripheral to the
main litigation, courts should be very reluctant to refer. . . .
Finally, the court must always balance the benefits of seek-
ing the agency's aid with the need to resolve disputes fairly
yet as expeditiously as possible.\footnote{115}
\end{quote}

But given the discretionary nature of the doctrine, even the menace of delay
is not without a solution.

A court can mitigate the negative effects of the inherent delay involved
with applying the primary jurisdiction doctrine by limiting the length of the
stay.\footnote{116} A court may also petition the agency directly by addressing a question
to the agency,\footnote{117} or, if a court believes it “need[s] specific information . . . to
decide [its] case,” it may request that the agency submit an amicus brief.\footnote{118}

\begin{footnotes}
\item[112] McNulty, D.N.J., dated Jan. 6, 2014 at 3. The petitions and letters are discussed in further
detail, \textit{infra}.
\item[113] See Knippa, \textit{supra} note 16, at 1307.
(5th Cir. 2016) (“Thus, at a general level, the primary jurisdiction doctrine requires the district
court to balance the assistance potentially provided by an agency’s specialized expertise
against the litigants’ certainty of delay.”).
\item[115] See, \textit{e.g.}, Winters, \textit{supra} note 24, at 255-57; Knippa, \textit{supra} note 16, at 1307.
\item[116] See, \textit{e.g.}, Miss. Power & Light Co. v. United Gas Pipe Line Co., 532 F.2d 412, 419 (5th
Cir. 1976).
\item[117] See Landis v. N. Am. Co., 299 U.S. 248, 256 (1936) (“[T]he power to stay proceed-
ings is incidental to the power inherent in every court to control the disposition of the
causes on its docket with economy of time and effort for itself, for counsel, and for litigants.”).
\item[118] See, \textit{e.g.}, Cox v. Gruma Corp., 12-CV-6502 YGR, 2013 WL 3828800 at *2 (N.D.
Cal. July 11, 2013) (The court initiated its own administrative proceeding with the FDA pur-
suant to 21 C.F.R. § 10.25(c) asking “whether and under what circumstances food products
containing ingredients produced using bioengineered seed may or may not be labeled ‘Natu-
ral’ or ‘All Natural’ or ‘100% Natural’”).
\item[119] Ryan v. Chemlawn Corp., 935 F.2d 129, 132 (7th Cir. 1991) (In reversing the
district court’s dismissal of the plaintiff’s claim without prejudice pursuant to a primary jur-
isdiction referral to the EPA, the court added, “If the district court believed that it needed
If an agency does not respond, or expresses no interest in addressing the issue, the court can proceed to hear the matter.\textsuperscript{119}

\textbf{PART II – OPIOIDS}

Although courts should consider the wisdom of consulting an agency to promote the doctrine’s three core purposes of uniformity, utilizing agency expertise, and proper allocation of responsibility, in practice, consulting an agency for its expertise resonates the loudest in contemporary jurisprudence.\textsuperscript{120} Indeed, courts have placed heavy emphasis on this core component of the doctrine’s original expression;\textsuperscript{121} applying the doctrine in a wide variety of cases where complicated factual issues necessitate consulting a regulatory body for its expertise.\textsuperscript{122} However, many courts find referral is specific information from the EPA to decide this case, it could have asked the EPA to file an amicus brief.

\textsuperscript{119} See Astiana v. Hain Celestial Grp., Inc., 783 F.3d 753, 761 (9th Cir. 2015) (“Common sense tells us that even when agency expertise would be helpful, a court should not invoke primary jurisdiction when the agency is aware of but has expressed no interest in the subject matter of the litigation.”); see also Bradley W. Pratt, \textit{The Pathway to Primary Jurisdiction}, A.B.A. SEC. LITIG. (Aug. 10, 2015), http://apps.americanbar.org/litigation/committees/products/articles/summer2015-0815-pathway-primary-jurisdiction.html (“In practice, courts are reluctant to apply the doctrine without some express agency interest in the issue at stake.”).

\textsuperscript{120} Leib v. Rex Energy Operating Corp., No. 06–cv–802–JPG–CJP, 2008 WL 5377792, at *14 (S.D. Ill. Dec. 19, 2008) (quoting \textit{In re StarNet, Inc.}, 355 F.3d 634, 639 (7th Cir. 2004)) (“The doctrine of primary jurisdiction allows a federal court to refer a matter extending beyond the ‘conventional experiences of judges’ or ‘falling within the realm of administrative discretion’ to an administrative agency with more specialized experience, expertise, and insight.”).

\textsuperscript{121} See, e.g., Biffar v. Pinnacle Foods Grp., LLC, No. 16-0873-DRH, 2016 WL 7264973, at *1 (S.D. Ill. Dec. 15, 2016); King v. Time Warner Cable, 113 F. Supp. 3d 718, 723-24 (S.D.N.Y. 2015) (appeal pending, No. 15-2474 (filed Aug. 6, 2015)); Chemlawn, 935 F.2d at 131 (drawing upon \textit{Western Pacific}, stating the purpose of the primary jurisdiction doctrine is “to resolve the complexities of certain areas outside the conventional experience of the courts” and to promote judicial economy by allocating responsibility over a matter to an agency for final determination).

\textsuperscript{122} Stevens v. Bos. Sci. Corp., 152 F. Supp. 3d 527, 535-37 (S.D. W. Va., 2016) (“The FDA is in the best position to determine whether Boston Scientific’s mesh device is in compliance with the FDA’s own statutes, regulations, and directives—particularly because the FDA was the very agency that cleared Boston Scientific’s mesh device in the first place.”); SoundExchange, Inc. v. Sirius XM Radio Inc., 65 F. Supp. 3d 150 (D.C. Cir. 2014) (copyright royalty board); Splitrock Props., Inc. v. Qwest Comm’n’s Corp., No. 08-412-KES, 2010 WL 2867126, at *1, *6 (D.S.D.July 20, 2010) (“[A]pplication of Splitrock’s switched access tariff requires interpretation of words used in a technical sense and consideration of extrinsic evidence relating to topics within the expertise of the FCC.”); Langston \textit{ex rel.} Langston v. Iroquois Cent. Sch. Dist., 736 N.Y.S.2d 815, 816 (N.Y. App. Div. 2002) (holding that referral of a matter requesting the annulment of the suspension of a high school student to the Commissioner of Education was appropriate given the Commissioner possessed “the specialized knowledge and experience” required to address the issue); Audiotext Int’l, Ltd. v. MCI
appropriate only for issues of first impression, or complicated issues falling within an agency’s congressional mandate.\textsuperscript{123} While restricting the use of the doctrine only to novel or thorny issues requiring agency expertise seems sensible, both in the context of limited agency resources\textsuperscript{124} and of the preservation of judicial autonomy,\textsuperscript{125} the effect of such a course of action overlooks the important goals of uniformity and promotion of a working relationship between court and agency.

If the primary jurisdiction doctrine is to remain a viable judicial tool, courts must begin to recognize each of the doctrine’s core purposes and, where sufficient reason exists, courts must begin to invoke the doctrine so these purposes may be put into action. The massive opioid addiction problem currently sweeping the United States serves as an excellent backdrop to illustrate this principle. The problem involves the regulatory authority of administrative bodies, important and complex scientific, social, and economic questions, and contentious litigation. In this part, I will lay out a brief history of opioids, discuss the Food and Drug Administration and its role in regulating prescription drugs, and discuss the \textit{parens patriae} suits brought against opioid manufacturers and distributors.

A. The Background of the Opioid Epidemic

Opioids are a class of narcotics, either natural, semi-synthetic, or fully synthetic, which deliver effects ranging from analgesic to euphoric when processed by the brain.\textsuperscript{126} The oldest opioids are the natural opioid products

\textsuperscript{123} See Brown v. MCI WorldCom Network Servs., 277 F.3d 1166, 1172 (9th Cir. 2002).

\textsuperscript{124} See Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. at 2407 (lack of agency resources to address “natural” claims).

\textsuperscript{125} See Chacanaca v. Quaker Oats Co., 752 F. Supp. 2d 1111, 1124 (N.D. Cal. 2010) (holding that the FDA need not be consulted regarding straightforward claims of violation of FDA regulations, noting that courts are “well-equipped” to answer such questions).

\textsuperscript{126} Opioids, 2 \textit{Encyclopedia of Molecular Pharmacology} 903 (Stefan Offermanns & Walter Rosenthal, eds., 2008). The words used to describe this class of narcotics can include “opiates” or “opioids.” In the past, “opiates” was used to refer almost exclusively to naturally derived products, while “opioids” was used to refer to semi-synthetic or synthetic products which operate in a manner substantially like natural products. Today, the colloquial word “opioid” generally refers to both natural and synthetic analogues targeting opiate receptors in the human brain, discussed \textit{infra}. For the purposes of this Note, the term “opioid” or “opioids” will adopt the colloquial definition, unless otherwise specified. For more information, see generally \textit{Opium Derivatives}, Opium.com http://www.opium.com/derivatives/ (last accessed Mar. 16, 2017).
which derive from the milk of the opium poppy plant and include commonly
known drugs such as morphine and codeine. More recent pharmacological
developments yield a variety of synthetic and semi-synthetic medicines and
substances and include the illicit drug heroin as well as mass produced phar-
maceuticals like fentanyl, methadone, and OxyContin. Opioids have long
been known for their therapeutic properties and their widespread use in the
therapeutic treatment of pain, depression, and other ailments in the United
States began in the mid 19th century. Later scientific studies examining
the operation of opioids on neurological functions confirmed what 19th and
early 20th century physicians understood by observation.

Opioids contain a chemical agent that mimics the action of endorphins. Once the chemical agent enters the bloodstream it travels to the
brain where it attaches to opiate sensitive receptors, artificially triggering the
brain’s reward center. The triggering process causes the release of dopa-
mine, creating feelings of intense pleasure which may be strong enough to
overcome and relieve significant pain. However, opioid use absent severe
pain results in a singularly euphoric sensation, and triggering the brain’s re-
ward center in such a manner leads many users to diversion, tolerance, and, ultimately dependence and addiction.


129. Evidence of opiate use in analgesic applications dates back thousands of years. Mention of its use is found in the writings of Homer, ancient Egypt, the Middle East, China, and middle age England. For an excellent summary of opium’s use throughout history, see Martin Booth, Opium: A History, 15-34 (1996).


131. See Amer. Ass’n for the Study and Cure of Intemity, The Disease of Intemity from Alcohol, Opium, and Other Narcotic Drugs: Its Etiology, Pathology, Treatment, and Medico-Legal Relations 317-27 (1893).


134. Id. at 13-14.

135. Id.
Addiction to opioids—especially morphine—became increasingly troublesome in the closing decade of the 19th century and early years of the 20th despite wide acknowledgment of opioids’ legitimate medicinal applications.\(^{136}\) Positive feelings about the efficacy of morphine faded in light of its highly addictive quality, often causing morphine addiction to be equated with alcoholism.\(^{137}\) Thus, spurred by both the Temperance Movement and emerging Progressive Era principles, the scientific community set to work developing new drugs that would retain the beneficial characteristics of morphine while shedding its addictive qualities.\(^{138}\) In 1898, Germany-based Bayer Pharmaceuticals began to claim its new wonder drug distilled from morphine was just what the doctor ordered.\(^{139}\) Bayer asserted its new drug, Heroin, the first semi-synthetic opioid, had all the benefits of morphine but none of the unpleasant side effects like the tendency to encourage addiction.\(^{140}\) Heroin soon hit the worldwide markets where it achieved rapid success thanks in no small part to Bayer’s superior promotional efforts.\(^{141}\) The medical community lauded heroin’s effectiveness, echoing the claims in Bayer’s promotional advertisements by triumphantly touting it as a miracle cure.\(^{142}\) However, the

\(^{136}\) The active ingredient in opium was distilled in 1806 creating the drug Morphine. The invention of the hypodermic needle in the 1850s led to increased medicinal use in the U.S., especially after the Civil War. See Michael J. Brownstein, Review, A Brief History of Opiates, Opioid Peptides, and Opioid Receptors, 90 Proc. Nat’l Acad. Sci. 5391-93 (1993).

Addiction to opioids was a grave concern in late Victorian America and in the early Progressive Era. For a summary of the extent of the opioid addiction problem in the late 19th and early 20th century, see Courtwright, supra note 130, at 1-34.

\(^{137}\) The third wave of the Temperance Movement equated alcoholism to morphine addiction. “There is no more reason in modern science for the beverage use of alcoholic liquor than there is for the same use of opium, morphine, or cocaine. The appetite for liquor is abnormal, unscientific and inexcusable as is the appetite of the morphine fiend, and the user of liquor ought to be as much ashamed of his habit as is the user of morphine.” E.O. Taylor, Science and Legislation of the Alcohol Question, 19 Sci. Temperance J. 84, 85 (1910).


\(^{139}\) See Raymond Cooper & Jeffrey John Deakin, Botanical Miracles: Chemistry of Plants That Changed the World 137 (2016).

\(^{140}\) See id. Heroin was distilled from morphine in 1898 by Germany-based Bayer Pharmaceuticals just two weeks after the same company synthesized the formula of aspirin. Id.

\(^{141}\) See Musto, supra note 138, at 13-14. The very name of heroin was a marketing tactic. Bayer chose the name “heroin,” derived from heroisch, the German word for heroic, because of the way the drug made its users feel. Heroin was widely advertised as safe and effective. It was made available in pastille, lozenge, powder, liquid, and other forms, and was found in children’s cough syrups. See Kenaz Filan, The Power of the Poppy: Harnessing Nature’s Most Dangerous Plant Ally 86 (2011).

\(^{142}\) See Filan, supra note 141; see also James R. L. Daly, A Clinical Study of Heroin, 142 Bos. Med. & Surg. J. 190 (1900) (“It possesses many advantages over morphine . . . it prolongs respiration . . . it is not a hypnotic; [there is an] absence of danger of requiring the habit.”).
drug proved to be just as addictive, and dangerous, as its precursors. The medical community of the 1920s condemned heroin and believed “alkaloids of opium” could achieve heroin’s beneficial effects and avoid its harms.

Progressive era legislators squared up to face the heroin epidemic by crafting several regulatory acts aimed toward stemming the tide of opioid addiction and abuse. The first, the Pure Food and Drugs Act of 1906, was designed to make food and drugs safer by requiring strict label requirements when potentially harmful ingredients, like heroin, were included in over-the-counter medicines. The second major law to address the opioid epidemic was the Harrison Narcotics Act of 1914, a regulatory measure aimed at controlling the distribution of opioids and cocaine by imposing a special tax on individuals in the supply chain. The production of heroin was banned entirely in 1924. Drugs containing opioids could still be sold, however, and their safety and effectiveness were subject only to post-hoc review.

143. See Filan, supra note 141. Heroin eventually lost its favored position within the medical community and is now considered to have no legitimate medicinal use whatsoever. See Drug Scheduling, U.S. Drug Enforcement Admin., https://www.dea.gov/druginfo/ds.shtml (last visited Jan. 12, 2017) (“Schedule I drugs, substances, or chemicals are defined as drugs with no currently accepted medical use and a high potential for abuse. Some examples of Schedule I drugs are: heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), 3,4-methylenedioxymethamphetamine (ecstasy), methaqualone, and peyote.”).

144. Prohibiting the Importation of Crude Opium for the Purpose of Manufacturing Heroin: Hearing on H.R. 7079 Before H. Comm. on Ways & Means, 68th Cong. 32-34 (1924) (statement of Stephen G. Porter, Chairman Foreign Affairs Committee, House of Representatives) (Mr. Porter recited a letter he received from the New York City Department of Health, one relevant portion of which states, “[h]eroin is not a necessity in either medicine or art. All of its useful qualities can be easily and safely replaced by alkaloids of opium.”).


148. Promoting Safe and Effective Drugs for 100 Years, U.S. Food & Drug Admin., https://www.fda.gov/AboutFDA/WhatWeDo
Federal Food, Drugs, and Cosmetics Act of 1938 overhauled the Pure Food and Drugs Act, providing, for the first time, that drugs had to be proven safe before they could be sold. The agency responsible for making safety determinations is the Food and Drug Administration.

B. The FDA and its Regulatory Role

The Food and Drug Administration (FDA) is the federal administrative body responsible for regulating the safety, effectiveness, marketing, and advertisement of prescription drugs. The FDA engages in a variety of direct enforcement activities to achieve its regulatory goals, for example, involuntary recalls of unsafe drugs, seizure of products, and warning letters issued to prescription drug manufacturers whose advertisements are false or misleading.

The FDA’s involvement in regulating prescription drugs increased over time as the need for government regulation in this area became apparent.
The Federal Trade Commission regulated prescription drug advertisements from the onset of the 1938 Act until 1962, when amendments to the act granted the FDA regulatory control over prescription drug advertising.\textsuperscript{157} Placing the authority to regulate prescription drug advertisement with the FDA was the logical outgrowth of the FDA’s existing regulatory responsibilities; it seems only natural that the agency possessing the necessary expertise to determine the safety and efficacy of prescription drugs would be the better choice to regulate prescription drug advertisements. This shift of advertising oversight, and other authority granted in the 1962 amendments, such as new drug approval standards, broadened and strengthened the FDA’s administrative powers.\textsuperscript{158}

The contemporary incarnation of the FDA is at once a gatekeeper and a fence-mender, applying rigorous standards to protect the public from injury and formulating regulations and policy objectives to mend damage not avoided.\textsuperscript{159} In 2011, the FDA’s Division of Drug Marketing, Advertising, and

\textsuperscript{157} An amendment to the Federal Trade Commission Act granted the FTC the authority to regulate the advertisement of drugs, see Act of Mar. 21, 1938, ch. 49, 52 Stat. 111 (codified at 15 U.S.C.A. § 55(a)), but the authority to regulate prescription drugs was vested with the FDA with the passage of the Drug Amendments of 1962, Pub. L. No. 87-781, § 131, 76 Stat. 780 (1962) (codified at 21 U.S.C. § 352(n) (2016)).

\textsuperscript{158} 1962 was a watershed year for the FDA. See, generally, Note, Drug Efficacy and the 1962 Drug Amendments, 60 Geo. L. J. 185 (1971) (discussing the significance of the changes enacted by the 1962 amendments).

\textsuperscript{159} The gatekeeping function of the FDA is acknowledged because of its pre-approval review requirement for drugs and medical devices. See In re Orthopedic Bone Screw Liab. Litig., 159 F. 3d 817, 828 (3d Cir. 1998) (“[T]he FDA is a gatekeeper charged with the responsibility of protecting the public from unreasonable risks of injury from medical devices.”), rev’d on other grounds, 531 U.S. 341 (2001); Mitchell Russell Stern, Note, An Adverse Reaction: FDA Regulation of Generic Drug Labeling, 90 N.Y.U. L. Rev. 2154, 2163 (2015) (“In the context of pharmaceuticals, the FDA functions not only as a regulator, but also as a gatekeeper. Each and every new drug must be approved by the FDA before the drug’s manufacturer can introduce it into the U.S. market.”). The FDA acknowledges that regulatory and policy changes have become necessary in the wake of the opioid crisis sweeping the nation. See FDA Opioids Action Plan, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/NewsEvents/Newsroom/FactSheets/ucm484714.htm [https://wayback.archive-it.org/7993/20170723153345/https://www.fda.gov/NewsEvents/Newsroom/FactSheets/ucm484714.htm].
Communications was reorganized into the Office of Prescription Drug Promotion (OPDP) with two separate divisions: the Division of Direct to Consumer Promotion (DDTCP) and Division of Professional Promotion (DPP).\footnote{160} The primary functions of the DDTCP are to provide advisory review of consumer promotional materials so that marketers of pharmaceuticals and medical devices will avoid violating advertising requirements, and to “\[d\]evelop\[
] and issue\[
] enforcement actions against false and misleading DTCP materials and activities for prescription drugs.”\footnote{161} The functions of the DPP are largely the same as those of the DDTCP, but its regulatory actions are focused on advertisements directed towards medical professionals.\footnote{162}

Another function of the FDA is to receive and answer citizen petitions requesting that the FDA “issue, amend, or revoke a regulation or order, or take or refrain from taking any other form of administrative action.”\footnote{163} Although in recent years citizen petitions have come primarily from pharmaceutical companies seeking to prevent each other’s products from entering the market,\footnote{164} some petitions do come from members of the general public.\footnote{165} Physicians for Responsible Opioid Prescribing (PROP)—an organization outside the pharmaceutical or medical device industry—petitioned the FDA to reevaluate its stance on the long-term use of prescription of opioid analgesics by limiting their use to a “maximum duration of 90-days for continuous (daily) use for non-cancer pain.”\footnote{166} In its response letter, the FDA found the studies and evidence presented by PROP lacked sufficient data and scientific merit to support their request and, thus, expressly refused find opioid use beyond ninety days to be unsafe.\footnote{167} This citizen petition and the FDA’s response are part of a wider discussion about the opioid epidemic in the United States, and both letters played a critical role in the argument for application

161. Id. at 59,409.  
162. See id.  
163. Initiation of Administrative Proceedings, 21 C.F.R. § 10.25(a) (2016); see also Citizen Petition, 21 C.F.R. § 10.30 (2016).  
165. Chen estimates that only 18% of citizen petitions to the FDA between 2001 and 2013 came from individuals or organizations who were not pharmaceutical or medical device manufacturers. See id. at 1.  
166. See Letter from Physicians for Responsible Opioid Prescribing to U.S. Food & Drug Admin. at 2 (July 25, 2012) [hereinafter PROP Pet.].  
of the primary jurisdiction doctrine in the California and Chicago cases, discussed infra.

A. What Happened with Purdue Pharma and OxyContin

Understanding what led California, Chicago, and all the other parens patriae plaintiffs to file suit against opioid manufacturers requires a brief discussion of OxyContin, the drug that some believe started the epidemic.\footnote{168} OxyContin is a controlled release opioid analgesic produced, marketed, and sold since 1996 by Purdue Pharma, a privately owned and operated pharmaceutical developer and manufacturer based in Stamford, Connecticut.\footnote{169} OxyContin was developed to address treatment concerns regarding oxycodone, another opioid analgesic, for longer-term treatment of moderate to severe pain.\footnote{170} Oxycodone is an opioid analgesic that has been used in a clinical setting since 1917.\footnote{171} Oxycodone derives from thebaine, an extremely toxic extract of the Iranian poppy, \textit{papaver bractetum}.\footnote{172} Iranian poppies contain no morphine, unlike their cousins, traditional Opium poppies, \textit{papaver somniferum}, but the oxycodone synthesized from thebaine is free from thebaine’s toxic poison and is similar in both structure and function to morphine, but is twice as potent.\footnote{173}

Oxycodone has been used in the United States since the 1930s for the relief of pain and is commonly mixed with other substances, including aspirin or Tylenol.\footnote{174} Prescription oxycodone is an effective pain reliever, but its

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\footnote{168. See Mike Mariani, \textit{How the American Opiate Epidemic was Started by One Pharmaceutical Company}, THE WEEK (Mar. 4, 2015), http://theweek.com/articles/541564/how-american-opiate-epidemic-started-by-pharmaceutical-company (attributing the current opioid epidemic entirely to the actions of Purdue Pharma).


170. OxyContin was designed to increase the length of time between doses of traditional Oxycodone. See U.S. FOOD & DRUG ADMIN., Approval Package for NDA 20-553/S-002 (1996) (Medical officer review of OxyContin 80).


172. See id.


174. See Kalso, supra note 171; see also Common Errors in the Media About OxyContin (Oxycodone HCL Extended-Release Tablets) CII, PURDUEPHARMA.COM, http://www.purduepharma.com/news-media/common-errors-in-the-media-about-oxycontin-oxycodone-hcl-extended-release-tablets-cii/ [https://perma.cc/B64B-6KGG]; GAO Report at 8 (“The active ingredient in OxyContin tablets is oxycodone, a compound that is similar to morphine and is
analgesic affect typically lasts only around four hours and requires frequent doses to maintain relief.\textsuperscript{175} Purdue’s OxyContin was meant to increase the amount of time between each dose of pain reliever, designed with the specific purpose of delivering a continuous, controlled dose of oxycodone for up to twelve hours.\textsuperscript{176} As such, to ensure longer periods of time between doses, each tablet of OxyContin necessarily contains larger amounts of oxycodone than traditional instant release oxycodone products.\textsuperscript{177} Purdue and the FDA were both well aware that the active ingredient in OxyContin possessed the addictive properties inherent in all opioids, and that OxyContin had the potential for abuse and misuse.\textsuperscript{178} However, both the FDA and Purdue believed that OxyContin’s controlled release properties would reduce the potential for abuse as long as the tablets were ingested without prior manipulation.\textsuperscript{179} OxyContin’s label warned against such manipulation, cautioning that ingesting crushed, broken, or chewed tablets would lead to “rapid release and absorption of a potentially fatal dose of oxycodone.”\textsuperscript{180} But the warnings did little to deter illicit use, and, in fact, may have inadvertently instructed users on how to get high; addicts quickly learned how to achieve an intense high by doing exactly what the label instructed against - crushing the pills to either snort or inject the powder.\textsuperscript{181}

Purdue Pharma was not the only pharmaceutical manufacturer distributing opioid products containing oxycodone, but Purdue’s OxyContin stood

\begin{itemize}
\item \textsuperscript{176} See id.; GAO Report, supra note 173, at 8.
\item \textsuperscript{177} GAO Report, supra note 173, at 8 (“Because of its controlled release property, OxyContin contains more active ingredient and needs to be taken less often.”).
\item \textsuperscript{178} GAO Report, supra note 173, at 8-10.
\item \textsuperscript{179} GAO Report, supra note 173, at 9 (“The OxyContin label originally approved by the FDA indicated that the controlled-release characteristics of OxyContin were believed to reduce its potential for abuse. The labels also contained a warning that OxyContin tablets were to be swallowed whole.”); Letter from Robert F. Bedford, Ctr. for Drug Eval. & Research, U.S. Food & Drug Admin. (Dec. 12, 1995) (FDA original approval of OxyContin, NDA 20-553) (on file with author).
\item \textsuperscript{180} See GAO Report, supra note 173, at 9.
\item \textsuperscript{181} See OxyContin: Its Use and Abuse: Hearing Before H. Sub. Comm. on Oversight and Investigation, Comm. on Energy and Commerce, 107th Cong. 8 (2001) (prepared statement of Terrance W. Woodworth, Deputy Director, Office of Diversion Control, Drug Enforcement Administration) (“The appeal of OxyContin for abusers of controlled substances is related to the larger amounts of active ingredient, oxycodone, in relation to other narcotic products, and to the ability of abusers to easily compromise the controlled release formulation. Simply crushing the tablet can negate the controlled release effect of the drug, enabling abusers to swallow or snort the drug for a powerful morphine-like high. The tablet can also be crushed, mixed with water and injected.”).
\end{itemize}
as a central figure in the wave of opioid addiction and in the surrounding discussion. The rapid spread of opioid abuse garnered the attention of local, state, and federal government officials in the early years of the epidemic. Indeed, in addition to attention from the media and members of Congress, by 2001, the FDA recognized the problems presented by OxyContin, prompting it to contact Purdue about the agency’s concerns. The FDA changed OxyContin’s label to include a “black box” warning of the dangers of the product, the strongest warning label available for an FDA regulated product. Despite enhanced warnings, sales of OxyContin continued to increase, largely due to Purdue’s “aggressive” marketing activities. By 2001, when negative press and increased governmental and regulatory scrutiny began to plague Purdue, the product had earned the company over $2.8 billion in revenue. OxyContin is estimated to have generated revenues in excess


184. See BARRY MEIER, PAIN KILLER: A "WONDER" DRUG'S TRAIL OF ADDICTION AND DEATH 130 (2003) (“FDA officials, alarmed by what they were reading or seeing in television reports, contacted Purdue headquarters and in a teleconference with top company executives expressed their concerns.”).

185. See GAO Report, supra note 173, at 34.

186. See Van Zee, supra note 169, at 221 (“The promotion and marketing of OxyContin occurred during a recent trend in the liberalization of the use of opioids in the treatment of pain, particularly for chronic non–cancer-related pain. Purdue pursued an ‘aggressive’ campaign to promote the use of opioids in general and OxyContin in particular. In 2001 alone, the company spent $200 million in an array of approaches to market and promote OxyContin.”); GAO Report, supra note 173, at 2 (“The Drug Enforcement Administration (DEA) has expressed concern that Purdue’s aggressive marketing of OxyContin focused on promoting the drug to treat a wide range of conditions to physicians who may not have been adequately trained in pain management.”).

of $30 billion since its entry onto the market and has been hailed as “America’s bestselling painkiller.”

B. Parens Patriae Suits

Individual product liability lawsuits and domestic class actions against Purdue and other opioid makers began to surface in the early 2000s as the rate of death from opioids increased, but these lawsuits met with little success, ending primarily in the pleading stage. Conversely, a number of governmental bodies have achieved tangible results in the form of cash settlements by bringing parens patriae suits against Purdue, including the State of West Virginia, twenty-six states participating in a class action in conjunction with Purdue’s 2007 criminal prosecution, and the State of Kentucky. In May of 2007, Purdue and three of its top executives, appearing as individuals, pled guilty to criminal charges of “misbranding” OxyContin by misrepresenting and concealing from regulators, prescribers, and patients the truth about the drug’s operation, effects, and potential for abuse. A consequence of the guilty pleas was a $600 million aggregate settlement, including the forfeiture of millions of dollars and payment of funds to settle the civil cases with twenty-six states. The Kentucky case was filed shortly after Purdue’s guilty plea in October of 2007. A wave of litigation against Purdue and


189. For an excellent summary of cases filed and analysis of defenses and outcomes for lawsuits regarding OxyContin, see Ausness, supra note 30, at 1122-46.


191. See Meier, supra note 187; U.S. DEPT. OF JUSTICE, STATEMENT OF UNITED STATES ATTORNEY JOHN BROWNLEE ON THE GUILTY PLEA OF THE PURDUE FREDERICK COMPANY AND ITS EXECUTIVES FOR ILLEGALLY MISBRANDING OXYCONTIN at 5-6, 9 (May 10, 2007) [hereinafter Brownlee Statement].

192. See Brownlee Statement, supra note 191 at 10.

193. See id. (“The settlement resolves allegations that Purdue Pharma illegally misrepresented and/or concealed the highly addictive nature of OxyContin and encouraged doctors
other opioid manufacturers began seven years later in 2014 after the State of Mississippi, 194 the Counties of Orange and Santa Clara, California, and the City of Chicago, Illinois brought suit. 195 As of this writing, dozens of lawsuits have been filed against opioid manufacturers or distributors by state, county, and local governments. 196 

The California and Chicago complaints were filed within weeks of each other with the assistance of the same outside counsel and largely contain parallel arguments. 197 The thrust of the allegations is designed to support claims who weren’t trained in pain management to overprescribe the opioid pain reliever to Kentucky patients.”). 194. See Mississippi v. Purdue Pharma L.P., No. 25CH1:15-cv-001814 (Miss. Dec. 15, 2015) [hereinafter Miss. v. Purdue]. The manufacturer defendants in the Mississippi case put forward several motions to stay or dismiss, including asking for dismissal for improper venue and another motion asking to dismiss pursuant to primary jurisdiction. See Joint Motion to Transfer Venue, Miss. v. Purdue (asking for venue transfer and dismissal for failure to state a claim); Joint Motion to Dismiss, Miss. v. Purdue (asking for dismissal pursuant to primary jurisdiction). The issue of primary jurisdiction was not reached because the case was placed under an emergency stay pending the result of an interlocutory appeal to the Mississippi Supreme Court on the denial of the motion to transfer venue. See Order of March 29, 2017, Miss. v. Purdue. 195. See California v. Purdue, supra note 32; Chicago v. Purdue, supra note 32. Purdue objected to the California action on the basis that California was one of the twenty-six states receiving monies following Purdue’s 2007 guilty plea. See Purdue Pharma Demurrer to Second Amended Complaint, California v. Purdue, supra note 32. 196. The list of pending pares patriae suits relating to the opioid epidemic grows by the day and the cases are too numerous to list in a single footnote. However, the following list of selected cases beyond Mississippi, California, and Chicago will illustrate the breadth of the litigation concerning the safety and effectiveness of opioids. For examples of cases brought by state attorneys general, see Missouri v. Purdue Pharma, L.P., No. 1722-cc10626 (Mo. Cir. Ct. June 21, 2017); New Hampshire v. Purdue Pharma L.P., No. 1:17-cv-00427 (Dist. N.H. Aug. 8, 2017) (removed to federal court); New Mexico v. Purdue Pharma L.P., No. D-101-CV-201702451 (N.M. Dist. Ct. Sept. 7, 2017); Ohio v. Purdue Pharma L.P., No. CV 17 CI 000261 (Oh. Ct. Comm. Pleas May 31, 2017); Oklahoma v. Purdue Pharma L.P., No. CJ-2017-816 (Ok. Dist. Ct. June 30, 2017); South Carolina v. Purdue Pharma, No. 2017-CP-400-4872 (S.C. Ct. Comm. Pleas Aug. 15, 2017). For examples of cases brought by county municipal governments, see St. Clair Cty. Illinois v. Purdue Pharma L.P., No. 3:17-cv-00616 (S.D. Ill. June 9, 2017) (removed to federal court); Cty. of Broome v. Purdue Pharma L.P., No. 252/2017 (N.Y. Sup. Ct. May 19, 2017); Staubus v. Purdue Pharma, L.P., No. C41916 (Tn. Cir. Ct. June 13, 2017). For an example of a case brought by a local municipality, see City of Everett v. Purdue Pharma, L.P., No. 17-2-00469-31 (Wa. Super. Ct. Jan. 17, 2017). Although not directly connected to Purdue Pharma, several counties within the State of West Virginia have brought recent suits against wholesale opioid distribution companies, and others, for negligently “flooding” the state with massive amounts of opioids. See Complaint, Cabell Cty. v. AmerisourceBergen Drug Corp., No. 3:17-cv-01665 (D. W.Va. Mar. 9, 2017). 197. In some instances, paragraphs and arguments within the complaints are identical. For example, the first sentence of the introductory paragraph in each complaint states: “A pharmaceutical manufacturer should never place its desire for profits above the health and well-being of its customers.” First Amended Complaint, California v. Purdue, supra note 32, at ¶1; Second Amended Complaint, Chicago v. Purdue, supra note 32, at ¶1.
under state law deceptive acts and practices statutes, arguing that Purdue and the other opioid defendants acted fraudulently by knowingly taking unfair advantage of vulnerable populations and wrongfully influencing the prescribing practices of physicians.\textsuperscript{198} The allegations touch on sales techniques reminiscent of the kind of—aggressive marketing—that led to Purdue’s 2007 guilty plea. Purdue admitted in its plea that between December 1995 and June 2001 it trained and directed its salespeople to mislead healthcare providers by portraying OxyContin as “less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdraw than other pain medications.”\textsuperscript{199} The California and Chicago cases make similar claims, alleging again that the manufacturer defendants misrepresented their products.\textsuperscript{200}

Both cases bear remarkable similarities and, at times, display word-for-word identity in their pleadings.\textsuperscript{201} Both cases make allegations inseparably linked to the regulatory authority of the FDA regarding a class of heavily regulated products,\textsuperscript{202} yet the primary jurisdiction doctrine received different treatment between the two cases. The California Court stayed the action, supporting its decision with rationale clearly adopting at least some of the values of the primary jurisdiction doctrine,\textsuperscript{203} but the Chicago Court flatly rejected the doctrine’s application.\textsuperscript{204} It is in this context, the disparity in treatment and result between the California and Chicago cases, where the need for courts to revise their view of the primary jurisdiction becomes most apparent.

PART III – RECONCILING DISCORDANT HOLDINGS

This part analyzes the holdings of the California and Chicago cases and discusses how proper analysis under the primary jurisdiction doctrine would

\textsuperscript{198} See, e.g., Second Amended Complaint, California v. Purdue, \textit{supra} note 32, at ¶ 13; Second Amended Complaint, Chicago v. Purdue, \textit{supra} note 32, at ¶¶ 7-8.

\textsuperscript{199} See United States v. Purdue Frederick Co., 495 F. Supp. 2d 569, 571 (W.D. Va. 2007).

\textsuperscript{200} Second Amended Complaint, California v. Purdue, \textit{supra} note 32, at ¶¶ 2, 39; Second Amended Complaint, Chicago v. Purdue, \textit{supra} note 32, at ¶¶ 3-4.

\textsuperscript{201} See, e.g., \textit{supra} note 194. The commonality between the two cases is hardly unnoticeable. The two actions were brought by similar plaintiffs represented by the same counsel, against the same group of defendants, alleging virtually the same facts to support remarkably similar causes of action.

\textsuperscript{202} See generally Second Amended Complaint, California v. Purdue, \textit{supra} note 32; Second Amended Complaint, Chicago v. Purdue, \textit{supra} note 32.

\textsuperscript{203} Order of Aug. 27, 2015, California v. Purdue, \textit{supra} note 32, at 2-3. The California court’s stay, on its own, demonstrates the need for courts to reexamine the primary jurisdiction doctrine. The California court issued its stay pursuant to its inherent authority to manage its own cases rather than officially staying the matter under the doctrine, even though the rationale behind its decision clearly echoed principles of the doctrine.

\textsuperscript{204} Order of May 8, 2015, Chicago v. Purdue, \textit{supra} note 32 (first denial); Order of Sept. 29, 2016, Chicago v. Purdue, \textit{supra} note 32 (second denial).
have resulted in unity between the two actions. Before beginning the analysis, however, the criteria for applying the doctrine bear repeating. As discussed in Part I, above, different factors or tests are sometimes used by courts to aid in their analysis of whether to apply the doctrine. Occam’s razor counsels a different approach. First, courts should examine the arguments in the pleadings, whether explicit or implied, to decide whether application of the doctrine will achieve any one of its core purposes: uniformity; proper utilization of agency expertise; or comity between court and agency. Next, courts should consider whether prudence demands the important or complex issue be referred. Finally, if a court decides to refer, the court should choose an appropriate referral path.

A. Pleadings: What are the Allegations?

Each complaint begins with an acerbic opening sentence. "A pharmaceutical manufacturer should never place its desire for profits above the health and well-being of its customers." The California complaint spends over 130 pages on allegations of how Purdue engaged in fraud and deception in marketing opioids for long-term non-cancer ("chronic") pain even though it knew opioids were "too addictive and too debilitating for long-term use." The Chicago First Amended Complaint spends 191 pages making largely the same kind of allegations, echoing, word for word, some of the allegations of the California complaint. The Chicago Second Amended Complaint, although similar to the First Amended Complaint and the California complaint in many respects, spends 326 pages alleging the fraudulent

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205. The term “Occam’s razor” refers to the philosophical principle that the simplest explanation or method should be sought first. *Occam’s razor*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/Occam's razor (last accessed Mar. 25, 2017); see also Samuel M. Bayard, *Chihuahuas, Seventh Circuit Judges, and Movie Scripts: Oh My!*: *Copyright Preemption of Contracts to Protect Ideas*, 86 CORNELL L. REV. 603, 628 n.175 (2001) (expounding upon the definition of the term with examples of its use by the courts).


207. The opening paragraph to the Chicago complaint is identical to the opening paragraph of the California complaint. *Id.* at ¶ 1; Second Amended Complaint, Chicago v. Purdue, supra note 32, at ¶ 1.

208. Second Amended Complaint, California v. Purdue, supra note 32, at ¶ 2. The complaint in this action has been amended three times and the current governing complaint is the Fourth Amended Complaint, filed July 6, 2017. Because the order of stay relates to the Demurrer to the Second Amended Complaint, reference and discussion of the California allegations will be confined to that complaint.

209. See, e.g., First Amended Complaint, Chicago v. Purdue, supra note 32, at ¶ 3, Chicago v. Purdue ("They knew—and had known for years—that, except as a last resort, opioids were too addictive and too debilitating for long-term use for chronic non-cancer pain (pain lasting three months or longer, hereinafter referred to as ‘chronic pain’)").
misrepresentations. The most significant difference in the Chicago complaints is in their respective levels of detail; the Second Amended Complaint pleads allegations with the painstaking particularity one might expect would satisfy FRCP Rule 9, including detailed accounts of exactly what fraudulent misrepresentations were made to specific medical professionals.

The allegations in each of the relevant pleadings detail seven primary types of fraudulent misrepresentations concerning the promotion of opioids for the treatment of chronic pain: that opioids improve function; concealment of the link between long-term use and addiction; misrepresentation that addiction risk can be managed; obfuscate discussion of addiction by coining the term “pseudoaddiction;” falsely claiming withdrawal is easily managed; misrepresentation of the danger of high doses; and deceptive minimization of the adverse effects of opioids and overstatement of the risks of NSAIDs.

The complaints allege these misrepresentations were carried out through indirect sales activities, such as sponsoring unbranded marketing materials that promoted the use of opioids without discussing risks; the cultivation and subversive use of paid agents known as “key opinion leaders” and “front” organizations to deliver pre-approved, biased messages about opioids and direct-to-consumer marketing disguised as “education and support.”

210. See generally Second Amended Complaint, Chicago v. Purdue, supra note 32. As in the California action, the Chicago complaint has been amended three times and the current governing pleading is the Third Amended Complaint, filed October 25, 2016. The Chicago action denied a motion to dismiss pursuant to the primary jurisdiction doctrine in relation to the First Amended Complaint, which was 191 pages, and the Second Amended Complaint, cited here. Because the denials of the motions to dismiss reference and discuss the First and Second Amended complaints, discussion of the primary jurisdiction doctrine in relation to the allegations will be confined to those complaints.

211. See, e.g., Second Amended Complaint, Chicago v. Purdue, supra note 32, at ¶ 630(a) (describing an account of a specific Chicago prescriber, stating, “Purdue representatives have detailed him on OxyContin, Hysingla, and Butrans. About a year ago, these representatives pushed the message that ‘‘steady-state’ extended release drugs have less potential for abuse.”). The detailed allegations of specific representations made to prescribers are found in paragraphs 296 to 642 of the Chicago pleading. Chicago v. Purdue, supra note 32, at ¶¶ 296-642; see also Fed. R. Civ. P. 9 (heightened pleading required when alleging fraud).

212. Second Amended Complaint, California v. Purdue, supra note 32, at ¶ 214; First Amended Complaint, Chicago v. Purdue, supra note 32, at ¶ 244; Second Amended Complaint, Chicago v. Purdue, supra note 32, at ¶¶ 215-16 (this complaint adds one allegation of misrepresentation against Purdue, singly, alleging it misrepresented “that OxyContin provides a full twelve hours of pain relief.”).

213. Second Amended Complaint, California v. Purdue, supra note 32, at ¶ 40; Second Amended Complaint, Chicago v. Purdue, supra note 32, at ¶ 127. Unbranded marketing materials are not subject to review by the FDA.

214. Second Amended Complaint, California v. Purdue, supra note 32, at ¶ 112; Second Amended Complaint, Chicago v. Purdue, supra note 32, at ¶ 134.

documents which targeted vulnerable populations, such as veterans and the elderly.\textsuperscript{216} The manufacturer defendants argued the allegations touched on deeper, more substantive questions about opioids beyond whether their companies engaged in deceptive practices. The opening paragraph in each complaint alleges that the manufacturers knowingly and deceptively promoted their products, but the thrust of the allegations in each complaint, the manufacturers argued, was that long-term opioid use is inherently unsafe.\textsuperscript{217} Their argument had strong support.

The safety and efficacy of opioids for long-term use were a present theme in both the California and Chicago complaints. Variations of the word “safe” appeared on forty-four pages in the California complaint and on sixty-two pages in the Chicago complaint.\textsuperscript{218} Both complaints implied that the opioids the manufacturer defendants marketed were unsafe in paragraph four, using identical language: “Defendants also knew that controlled studies of the safety and efficacy of opioids were limited to short-term use (not longer than 90 days), and in managed settings (e.g., hospitals), where the risk of addiction and other adverse outcomes was much less significant.”\textsuperscript{219} Both complaints explicitly stated that opioids are unsafe for long-term use, using identical language: “Defendants persuaded doctors and patients that what they had long known—that opioids are addictive drugs, unsafe in most circumstances for long-term use—was untrue.”\textsuperscript{220} Both complaints imply that opioids are not effective for long-term pain relief, using nearly identical language: “Despite the fact that opioids are routinely prescribed, there never has been evidence of their efficacy for long-term use.”\textsuperscript{221} Both complaints allege that the manufacturer defendants created or sponsored false research pointing to the safety of opioids for long-term use.\textsuperscript{222} Both complaints charge, in their

\begin{itemize}
  \item \textsuperscript{216} Second Amended Complaint, California v. Purdue, supra note 32, at ¶¶164-73, California v. Purdue; Second Amended Complaint, Chicago v. Purdue, supra note 32, at ¶ 205-13.
  \item \textsuperscript{217} \textit{See} Second Amended Complaint, California v. Purdue, supra note 32, at ¶¶ 1-6; First Amended Complaint, Chicago v. Purdue, supra note 32, at ¶¶ 1-9; Second Amended Complaint, Chicago v. Purdue, supra note 32, at ¶¶ 1-8.
  \item \textsuperscript{218} \textit{See generally}, Second Amended Complaint, California v. Purdue, supra note 32; Second Amended Complaint, Chicago v. Purdue, supra note 32.
  \item \textsuperscript{219} Second Amended Complaint, California v. Purdue, supra note 32, at ¶ 4; Second Amended Complaint, Chicago v. Purdue, supra note 32, at ¶ 4.
  \item \textsuperscript{220} Second Amended Complaint, California v. Purdue, supra note 32, at ¶ 8; Second Amended Complaint, Chicago v. Purdue, supra note 32, at ¶ 10.
  \item \textsuperscript{221} Second Amended Complaint, California v. Purdue, supra note 32, at ¶ 65. Paragraph 70 of the second amended Chicago complaint is almost identical. \textit{See} Second Amended Complaint, Chicago v. Purdue, supra note 32, at ¶ 70.
  \item \textsuperscript{222} Second Amended Complaint, California v. Purdue, supra note 32, at ¶¶ 102, 118-126; Second Amended Complaint, Chicago v. Purdue, supra note 32, at ¶¶ 150-56.
\end{itemize}
first counts, that the manufacturer defendants misled consumers by misrepre-
senting the safety of opioids.223

The crux of the argument for dismissal or stay was that the FDA is the
expert body charged with deciding the safety of continuous, long-term use of
opioids, not courts or juries,224 and that, in fact, it had already decided.225
Plaintiffs in both actions opposed, responding that they were “not asking the
Court to resolve scientific issues” about the use of opioids for the treatment
of chronic pain and averred that the central issue in both cases was the truth-
fulness of the marketing representations about opioids, which courts are well
equipped to address.226 The manufacturer defendants moved to dismiss or
stay both actions pursuant to the primary jurisdiction doctrine.227 The Cali-
forinia case was stayed in 2015 to allow the parties to pursue the matter before
the FDA and remains to this date under a partial stay.228 Motions to dismiss
or stay the First Amended and Second Amended Chicago complaints were
both denied.229

B. Purposes: Do the Allegations Support One or More Doctrinal Pur-
poses?

Uniformity in administration of law was the first doctrinal purpose of
the primary jurisdiction to be developed, discussed supra, but the manufac-
turer defendants and both courts focused their discussion primarily around

223. Second Amended Complaint, California v. Purdue, supra note 32, at ¶ 391(m); Second Amended Complaint, Chicago v. Purdue, supra note 32, at ¶ 742(g).

224. See supra note 32 at 1-2; supra note 33; Joint Motion to Dismiss First Amended Complaint, Chicago v. Purdue, supra note 32, at 1-2; Joint Motion to Dismiss Second Amended Complaint, Chicago v. Purdue, supra note 32, at 1.

225. See Purdue Pharma Demurrer to Second Amended Complaint, California v. Purdue, supra note 32, at 4-9; Joint Motion to Dismiss First Amended Complaint, Chicago v. Purdue, supra note 32, at 8, 11-12. The motions discuss at length the FDA’s response and denial of a petition from Physicians for Responsible Opioid Prescribing requesting that the FDA limit prescriptions of opioids to a “maximum duration of 90-days for continuous (daily) use for non-cancer pain.” See PROP Pet., supra note 166; FDA Response, supra note 167 (denying petition for a 90-day non-cancer maximum).

226. See Opposition to Demurrer, California v. Purdue, supra note 32, at ¶¶; Opposition to Motion to Dismiss First Amended Complaint, Chicago v. Purdue, supra note 32, at 5, 10.

227. Purdue Pharma Demurrer to Second Amended Complaint, California v. Purdue, supra note 32, at 4-9; Joint Motion to Dismiss First Amended Complaint, Chicago v. Purdue, supra note 32, at 8, 11-12.

228. See Order of Aug. 27, 2015, California v. Purdue, supra note 32; see also Order of Oct. 19, 2016, California v. Purdue, supra note 32, at 3 (lifting stay in part).

utilization of agency expertise. The discussion here will mirror that focus and then expand to consider the other areas of the doctrine.

In the California case, the explicit statements in the complaint convinced Judge Robert J. Moss to stay the case to utilize the expertise of the FDA. Judge Moss stated,

As the second amended complaint clearly shows, this case is about determining what the public and doctors need to be told about opioids. That determination necessary entails much more than determining issues of false and misleading marketing. Underlying every issue here, this case requires this court to become an expert in the field in which it has no expertise. It will have to determine which study, trial, etc. is appropriate and correct as to each issue concerning the use of opioids, and to what extent.

Judge Jorge Alonso in the Northern District of Illinois found all the many allegations in the Chicago complaint relating to the safety and efficacy of opioids ancillary to what he saw as the actual issue in the case: misrepresentation. Despite that the issues of safety and efficacy appeared and reappeared throughout the complaint, Judge Alonso held the FDA’s expertise would not be necessary. He said, “[t]he issue is not whether opioids are prescribed appropriately but whether they are marketed truthfully; specifically, whether defendants misrepresented the risks, benefits and superiority of opioids to treat long-term, chronic pain.” The second dismissal echoed this holding.

The disparity in the holdings regarding promoting proper utilization of agency expertise is irreconcilable given the parties’ pleadings. One of the FDA’s stated purposes is to ensure the safety and efficacy of prescription drugs. The complaints do turn to a significant degree on the safety of opioids for long-term use, both by explicit allegations and by inference. If the FDA were to decide that opioids were safe and effective for long-term use, the force of each plaintiff’s argument would necessarily decrease, if not

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230. Joint Motion to Dismiss First Amended Complaint, Chicago v. Purdue, supra note 32, at 1-2; Joint Motion to Dismiss Second Amended Complaint, Chicago v. Purdue, supra note 32, at 1.
233. Id.
236. See What Does FDA Do?, supra note 152.
237. See, e.g., Second Amended Complaint, California v. Purdue, supra note 32, at ¶¶ 102, 118-126; Second Amended Complaint, Chicago v. Purdue, supra note 32, at ¶¶ 150-156.
altogether disappear. Neither of the Chicago denials recognized the significance of the allegations of dangerousness or what it would mean for the case if the FDA were to weigh in on the issue. The utility of requesting the FDA’s expertise need not have *controlled* the decisions in the Chicago denials, but it at least should have been acknowledged. A stay or dismissal to utilize agency expertise could have been supported in both cases.

Both actions could have been stayed or dismissed under rationale supporting the need for uniformity in administration of laws. The Chicago holdings never analyzed this doctrinal purpose, but Judge Moss’s rationale in sustaining the Defendants’ demurrer and instituting a stay in the California action noted the need for uniformity.\(^{238}\) If the case were to continue, he reasoned, “[t]his action could lead to inconsistencies with the FDA’s findings, inconsistencies among the States, a lack of uniformity, and a potential chilling effect on the prescription of these drugs for those who need them most.”\(^{239}\) Not only is this rationale supported by the fact that the FDA had already at least partially addressed the issue of safety and efficacy of opioids for long-term chronic pain,\(^{240}\) but also by the assumption that the California court was most probably made aware of the parallel proceedings in Chicago litigating largely the same issue, against the same defendants, by the assistance of common outside counsel. Support for the proposition that applying the doctrine will promote the purpose of uniformity can also be found in examining how judicial determinations could run contrary to the FDA’s stated objectives regarding its intent to regulate opioids, including those used in the treatment of long-term, chronic pain.\(^{241}\) FDA representatives have made statements to Congress, the press, and the public about its intent to regulate opioids.\(^{242}\) One representative testified before a House Committee that the “FDA recognizes the serious problem of prescription drug abuse. The Agency will continue to take steps to curb abuse and misuse of prescription drugs.”\(^{243}\)

However, the strength of rationale supporting uniformity necessarily fades if a court does not fully invoke the doctrine. Indeed, most, if not all, of Judge Moss’s rationale in instituting the stay pulls directly from the principles supporting application of the doctrine, but he stayed the California action


\(^{239}\) *Id.*

\(^{240}\) See FDA Response, *supra* note 167.


\(^{242}\) *Id.*

pursuant to “the court’s inherent authority to manage its own cases,” not pursuant to the FDA’s primary jurisdiction.\footnote{244} For this reason, Judge Alonso was unpersuaded that his court should fall in line with the California Superior Court in deciding the second motion to dismiss in the Chicago case.\footnote{245} Notwithstanding the California Court’s decision to institute a stay pursuant to its own power while using rationale supporting the primary jurisdiction doctrine,\footnote{246} the arguments presented in the litigation and an assessment of the surrounding factual context can support the doctrine’s purposes of promoting uniformity in administration of laws.

Neither the California nor the Chicago court considered whether the case should be referred to promote a proper working relationship between courts and the FDA.\footnote{247} Judge Moss in California stopped at agency expertise and uniformity, and the Chicago court held twice that the FDA’s views on the safety and efficacy of prescription opioids were wholly unnecessary.\footnote{248} In the FDA’s own regulations, however, it considered its working relationship with courts in the context of primary jurisdiction.\footnote{249}

FDA has \textit{primary jurisdiction} to make the initial determination on issues within its statutory mandate, and will request a court to dismiss, or to hold in abeyance its determination of or refer to the agency for administrative determination, any issue which has not previously been determined by the agency or which, if it has previously been determined, the agency concluded should be reconsidered and subject to a new administrative determination. The Commissioner may utilize any of the procedures established in this part in reviewing and making a determination on any matter initiated under this paragraph.\footnote{250}

\footnotesize
\begin{itemize}
  \item \footnote{244}{Order of Aug. 27, 2015, California v. Purdue, \textit{supra} note 32, at 2.}
  \item \footnote{245}{Order of Sept. 29, 2016, Chicago v. Purdue, \textit{supra} note 32, at 6-8 (stating the Court was unpersuaded dismissal was warranted because of the California court’s decision to stay pursuant to its own inherent power, and that the Court found no other facts had changed which would warrant a stay under the primary jurisdiction doctrine).}
  \item \footnote{246}{\textit{Id.}}
  \item \footnote{247}{\textit{See Order of Aug. 27, 2015, California v. Purdue, \textit{supra} note 32; Order of May 8, 2015, Chicago v. Purdue, \textit{supra} note 32; Order of Sept. 29, 2016, Chicago v. Purdue, \textit{supra} note 32.}}
  \item \footnote{248}{\textit{See Order of Aug. 27, 2015, California v. Purdue, \textit{supra} note 32; Order of May 8, 2015, Chicago v. Purdue, \textit{supra} note 32; Order of Sept. 29, 2016, Chicago v. Purdue, \textit{supra} note 32.}}
  \item \footnote{249}{\textit{See 21 CFR § 10.25(b) (2018).}}
  \item \footnote{250}{\textit{Id.} (emphasis supplied).}
\end{itemize}
The safety and efficacy of prescription drugs clearly fall within the FDA’s statutory mandate, and the pleadings in both cases relied on allegations that could have supported referral to promote the working relationship between the courts and the agency.

A. Prudence: Should the Matter be Referred?

Once a court has decided that an issue can be referred, it must decide whether it should be referred. The very nature of the California and Chicago suits suggests the issue of opioid safety should have been referred to the FDA. The California and Chicago actions were two of only three parens patriae suits of their kind pending at the time Judge Moss issued the stay, but the potential for more suits making similar allegations must have been clear. Each complaint alleges that the misrepresentations of the defendants were associated with the recent dramatic increase in opioid related addiction and death nationwide.

The significance of the number of prescription overdoses leading to death lies not only in its size but in its finer details—the number of prescription opioid overdoses has increased at least fourfold since 1999. Even more significant is that the rate of both death and addiction from opioid abuse began to accelerate after Purdue Pharma’s OxyContin entered the United States market in January of 1996. The opioid addiction problem was arguably

252. The Mississippi, California, and Chicago cases were active at the time the California case was stayed. See supra note 192. The Kentucky action against Purdue Pharma for misrepresentations regarding OxyContin was still pending at the time of the California stay; however, the Kentucky suit alleged Purdue misrepresented OxyContin in violation of the Federal Food, Drugs, and Cosmetics Act, 21 U.S.C. § 331(a) unlike the California and Chicago cases. See First Amended Complaint, Kentucky v. Purdue Pharma LP, supra note 190, at ¶¶ 33-72.
253. See, e.g., First Amended Complaint, Chicago v. Purdue, supra note 32, at ¶ 14 (“One Defendant’s own 2010 internal data shows it knew that the use of prescription opioids gave rise to 40% of drug-related emergency department visits in 2010 and 40% of drug poisoning deaths in 2008, and that the trend of opioid poisonings was increasing from 1999-2008.”); Second Amended Complaint, Chicago v. Purdue, supra note 32, at ¶ 15 (same); Second Amended Complaint, California v. Purdue, supra note 32, at ¶ 381 (“Defendants’ creation through false and misleading advertising of a virtually limitless opioid market has imposed significant burdens on the community at large. Defendants’ success in extending the market for opioids to new patients and chronic conditions has created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury.”).
254. See Understanding the Epidemic, supra note 28.
255. See generally, Underlying Cause of Death, supra note 27; Understanding the Epidemic, supra note 28. Purdue emphasizes that the opioid addiction problem cannot be attributed solely to its product alone, claiming that the media, and others, improperly equate any product containing oxycodone to be OxyContin. See Common Errors in the Media About OxyContin (Oxycodone HCL Controlled-Release) Tablets, PURDUEPHARMA.COM,
sufficiently great and sufficiently well known before the California and Chicago complaints were ever filed that a court should have anticipated the need for regulatory action. Deciding that the FDA should be asked to weigh in on the issue of opioid safety for long-term use would have been proper.

B. Path: Which Referral Method is Appropriate?

The California case was stayed so that the matter could be pursued before the FDA. The problem with the revolving stay, however unlikely, is that it could continue indefinitely; although the FDA has a procedure for addressing primary jurisdiction doctrine referrals, the FDA is under no time constraints to review or respond. Indeed, the California case remains under at least a partial stay to this date, with status conference hearings roughly every 180 days. The California court could have used its discretion to stay

http://www.purduepharma.com/news-media/2011/12/common-errors-in-the-media-about-oxycontin-oxycodone-hcl-controlled-release-tablets/ (last accessed Mar. 22, 2017) (“Media reports frequently and erroneously use the terms oxycodone and OxyContin interchangeably, creating the misimpression that all oxycodone abuse involves OxyContin.”). Indeed, overdose and addiction data sets do not differentiate between different oxycodone products, lending some credence to Purdue’s defensive argument, but, aside from other arguments, the timing alone of OxyContin’s entry onto the market and the dramatic rise in opioid addiction and overdose deaths suggests that Purdue’s involvement in the opioid epidemic is more than merely incidental. See, e.g., Mike Mariani, How the American Opiate Epidemic was Started by One Pharmaceutical Company, THE WEEK (Mar. 4, 2015), http://theweek.com/articles/541564/how-american-opiate-epidemic-started-by-pharmaceutical-company.

256. See Order of Aug. 27, 2015, California v. Purdue, supra note 32, at 2-3 (staying the action). The case remained under a full stay until October 2016, when the stay was partially lifted. See Order of Oct. 19, 2016, California v. Purdue, supra note 32, at 3 (lifting stay in part). Purdue Pharma requested the full stay to be reinstated after the plaintiff filed its fourth amended complaint. See Demurrer to Fourth Amended Complaint, California v. Purdue, supra note 32, at 2-17.

257. See 21 C.F.R. § 10.25(c) (2018) (“The Commissioner will institute a proceeding to determine whether to issue, amend, or revoke a regulation or order, or take or refrain from taking any other form of administrative action whenever any court, on its own initiative, holds in abeyance or refers any matter to the agency for an administrative determination and the Commissioner concludes that an administrative determination is feasible within agency priorities and resources.”); Winters, supra note 24.

the matter for a definite period, or it could have petitioned the agency itself and given the FDA a deadline to respond.\textsuperscript{259} Some courts have, in fact, petitioned the FDA to submit a brief or otherwise respond, and the FDA has responded \textit{within the timeframe} identified by the courts.\textsuperscript{260} For example, three different U.S. District Court judges in three different cases sent a question to the FDA pursuant to the primary jurisdiction doctrine regarding whether and how the term “natural” could be used to describe genetically modified ingredients in food.\textsuperscript{261} The FDA responded to all three courts via a letter dated January 4, 2014, less than six months after the first question had been sent, declining to make a determination.\textsuperscript{262} The exchange between the three courts and the FDA demonstrates not only that the FDA is willing to engage the courts in answering primary jurisdiction questions, but that it will respond in a timely manner. Had either of the courts in California or Chicago elected to use this method of referral, the FDA’s disposition on the matter might already have been established, thus allowing both courts to proceed having been put in a better, more knowledgeable position about the FDA’s views.

\section*{Conclusion}

Analysis of the primary jurisdiction doctrine’s guiding decisions reveals that the core considerations a court must scrutinize in deciding whether the doctrine should apply are whether application of the doctrine will promote at

\textsuperscript{259} See Landis v. N. Am. Co., 299 U.S. 248, 254 (1936) (“[T]he power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants.”).

\textsuperscript{260} See, e.g., N.Y. State Rest. Ass’n v. N.Y.C. Bd. of Health, 556 F.3d 114, 130 (2d Cir. 2009) (“As previously noted, prior to oral argument in this appeal, we invited the FDA to submit an amicus brief to enlighten us as to its views on preemption. It did so and we may consider the views expressed therein for persuasive value.”); Perry v. Novartis Pharma Corp., 456 F. Supp. 2d 678, 682-83 (E.D. Pa. 2006) (“Because the FDA has, at our request, filed an amicus brief in this case, before moving on to the preemption analysis itself, we must determine the degree of deference to afford the FDA’s statements regarding the preemptive effect of its regulations.”).

\textsuperscript{261} See Barnes v. Campbell’s Soup Co., 12-cv-05185 JSW, 2013 WL 5530017, at *9 (N.D. Cal. July 25, 2013) (“Accordingly, and out of respect for the FDA’s authority, the Court GRANTS Defendant’s motion to dismiss the Plaintiffs’ claims against Defendant’s Natural Vegetable Soups on the grounds of primary jurisdiction, REFERS the matter to the FDA for an administrative determination, and STAYS the action for a period of six months from the date of this Order.”); In Re General Mills, Inc. Kix Cereal Litig., 12-cv-00249-KM-MCA, 2013 WL 5943972, at *1 (D.N.J. Nov. 1, 2013) (“Pursuant to 21 C.F.R. § 10.225(c), this Court hereby refers to the FDA for an administrative determination the question of under what circumstances food products containing ingredients produced using bioengineered corn may be labeled ‘All Natural.’”)

\textsuperscript{262} Letter from Leslie Kux, Assistant Comm’r for Policy, U.S. Food & Drug Admin., to Hon. Yvonne Gonzalez Rogers, N.D. Cal., Hon. Jeffrey S. White, N.D. Cal., & Hon. Kevin McNulty, D.N.J., 3 (Jan. 6, 2014).
least one of the doctrine’s three core purposes, and whether the issue referred is important or complex enough to make referral prudent and sound. Once referral is decided, a court must choose an appropriate referral method that will accomplish the purpose for referral without exposing the litigants to undue hardship. Analysis of the opioid epidemic and the California and Chicago opioid litigation show that the cases can support all three doctrinal purposes of promoting uniformity, properly utilizing agency expertise, and promoting comity between court and agency, and that the matter probably should be referred to the FDA. If courts engage in analysis of pleadings to identify whether referral serves a doctrinal purpose, whether referral is prudent, and whether the referral path is appropriate, the amorphous, borderless character of the doctrine will begin to take definite shape.

A few observations must be made before this effort concludes. First, it is hardly disputable that the primary jurisdiction doctrine asks much of the courts. Primary jurisdiction asks courts to engage in decision-making regarding a doctrine that lacks definite boundaries and has received inconsistent judicial treatment. Second, application of the doctrine in parens patriae litigation could offend principles of federalism and the power of states to protect the health and safety of their citizens, especially where such a complicated, important, deep, and painful problem like the opioid epidemic is concerned. Third, a finding that the doctrine can be applied does not mean that it must be applied—the doctrine is and should remain discretionary—but courts should attempt to apply the doctrine where there is clear and legitimate need. Last, litigants should be cautioned that asking a court to invoke the doctrine does not come without risk.

Opioid manufacturers engage in a dangerous gamble by asking courts to push the FDA to determine whether opioids are safe for long-term use. The FDA has the power to remove unsafe products from the market or to place significant restrictions on their use. Recently, the FDA used its power to remove from the market one of the opioids being litigated in the California and Chicago cases. On June 8, 2017, the FDA requested Endo Pharmaceuticals to voluntarily recall Opana ER, an extended-release opioid

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analgesic which was reformulated from its original version to “deter abuse.” Opana ER was deemed too dangerous:

After careful consideration, the agency is seeking removal based on its concern that the benefits of the drug may no longer outweigh its risks. This is the first time the agency has taken steps to remove a currently marketed opioid pain medication from sale due to the public health consequences of abuse.266

Even after the FDA removed Opana ER, the opioid manufacturers still requested courts to stay litigation pursuant to the primary jurisdiction doctrine.267 Dozens of parens patriae lawsuits against the manufacturer defendants have been filed since California and Chicago brought suit, and the number may continue to grow.268 If enough of the opioid courts make use of the primary jurisdiction doctrine to refer the issue of long-term opioid safety to the FDA, the FDA might be convinced to subject all opioid products to greater scrutiny. The FDA could decide that more opioids should be removed from the market, because, like Opana ER, the risks of opioids used to treat chronic pain outweigh their benefits.269

One thing is certain; for the primary jurisdiction doctrine to retain its utility in the present wave of opioid litigation—and in all consumer protection litigation—courts should analyze whether referral will achieve any one of the doctrine’s three core purposes instead of focusing analysis solely on the necessity of an agency’s expertise. Upon finding referral is proper, courts should evaluate and explain what core purposes referral will achieve and why the matter is important enough to be referred. Finally, courts should utilize any means within their power to craft referral procedures that minimize prejudice to the parties, including the ability to limit the length of a stay. The primary jurisdiction doctrine is already a viable judicial tool, but its utility will become even more clear if courts employ this simplified approach.

265. Id. See also Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Research, U.S. Food & Drug Admin., to Robert Barto, Vice President of Regulatory Affairs, Endo Pharm., 2 (May 10, 2013) (FDA declined to label Opana ER as having abuse-deterrent properties even though it was intended to be abuse-deterrent).
266. See FDA REQUESTS REMOVAL OF OPANA ER, supra note 264 (emphasis supplied).
267. See, e.g., Demurrer to Plaintiff’s Fourth Amended Complaint at 2-17, California v. Purdue, supra note 32.
268. See collected cases, supra note 196.
269. See FDA REQUESTS REMOVAL OF OPANA ER, supra note 264.