FEDERAL PREEMPTION

ORIGINS, TYPES AND TRENDS IN THE U.S. SUPREME COURT

Frank Cruz-Alvarez
Jennifer Voss
Jared Sherr
Talia Zucker
Shook, Hardy & Bacon L.L.P.

Foreword
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WASHINGTON LEGAL FOUNDATION
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FOREWORD

By
Daniel E. Troy[1]

The Supreme Court's preemption jurisprudence has long been described as a "muddle." This is a frustrating state of affairs, given the need for clear judicial guidance in an era where states' efforts to nationalize their own public-policy agendas increasingly encroach upon federal regulatory authority.

This Washington Legal Foundation MONOGRAPH examines Supreme Court rulings between 2007 and 2015 and forecasts trends in preemption analysis such as a focus on statutory construction and increased attention to agency rulemaking and the agency's views about the preemptive effect of its regulatory process. The authors, product-liability attorneys with Shook, Hardy & Bacon, summarize important express and implied preemption cases from the Court in each substantive area of the law, and they provide a useful "at a glance" overview for practitioners and policymakers. The authors' work serves as a guide for all those interested in furthering a more consistent and workable preemption doctrine.

One thing is clear: The Court needs to retreat from its ruling in *Wyeth v. Levine,* which rejects preemption for most state-law failure-to-warn claims against brand drug manufacturers absent "clear evidence" that the Food and Drug Administration (FDA) ultimately would not approve

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labeling warnings added by manufacturers under the "Changes Being Effected" rule. This rule allows manufacturers to add warnings to labeling prior to FDA approval of those additions only in very narrow circumstances, and FDA approval still is ultimately required. Fortunately, opportunities to limit *Levine* remain, as illustrated by the authors' discussion of the First Circuit's January 2015 opinion in *In re: Celexa and Lexapro Marketing and Sales Practices Litigation*. *Levine* encourages state-court judges and juries to regularly second-guess, with the benefit of hindsight in a specific plaintiff's case, FDA's expert and reasoned decision making about the appropriate safety information for a drug's labeling.

This state of affairs is bad not just for pharmaceutical companies, but for patients, physicians, and FDA. The failure to recognize preemption in a large subset of brand drug cases undermines both public health and FDA's authority to assure its balancing of risks and benefits is not disrupted. FDA is in the best possible position, consistent with its Congressional mandate, to make safe and effective medicines available to the public in a timely manner to maximize public health benefits. FDA's approval process is based on a comprehensive scientific evaluation of the product's risks and benefits given its intended use. The process is designed to protect consumers from unacceptable risk through extensive government oversight of drugs' testing, formulation, manufacture, marketing, and distribution. FDA labeling regulations require consistent, effectively communicated warnings about all known risks of the drug based on reliable scientific evidence. FDA holds the final say on drug approvals and labeling in the most practical sense and is the best arbiter of what will optimize safety and effectiveness in the interest of public health. Without preemption, FDA loses its ability to control labeling to ensure this balance is maintained.

Tort litigation gives manufacturers a powerful economic incentive to seek FDA approval for changes to drug labeling that are insufficiently grounded in science, interfere with the communication of FDA-mandated safety information, or are otherwise unwarranted. Lay judges and juries are not equipped with the necessary expertise or data to decide what information should be included in a medicine's safety label. Litigation-imposed labeling changes undermine the ability of prescribers to evaluate accurately whether a particular medicine is suited for a specific patient. Such changes can result in "over-warning," which can deter physicians from prescribing—or patients from taking—a potentially beneficial medicine or reduce the impact of warnings about more critical risks. They also can result in "under-warning," where companies may seek to give the same level of emphasis to all risks regardless of their severity to avoid claims they did not emphasize a specific warning enough.

The litigation environment can negatively impact medication adherence if lawsuits, no matter their merit, scare patients away from taking their prescribed medications. And, as has been well-documented, the litigation environment further harms public health by stifling innovation of new health treatments and reducing the availability of potentially beneficial medicines at affordable prices. While some have taken the position that state-tort lawsuits complement FDA regulatory initiatives, it is difficult to ascertain how public-health priorities are served by a multiplicity of private lawsuits that divert significant resources from the innovation and distribution of beneficial products and result in the de facto imposition of additional labeling requirements that potentially conflict with FDA decision making as well as each other. As Dean Prosser wrote in his casebook explaining why prescription drugs should not be subjected to strict liability:

> The argument that industries producing potentially dangerous products should make good the harm,

> distribute it by liability insurance, and add the cost to the price of the product, encounters reason for pause, when we consider that two of the greatest medical boons to the human race, penicillin and cortisone, both have their dangerous side effects, and that drug companies might well have been deterred from producing and selling them.[2]

As is evident in the FDA context, giving preemptive effect to federal regulations is appropriate where agency experts, consistent with their authority, have considered complicated policy issues and reached the optimal balance among those issues to carry out their mandate from Congress, particularly in highly technical fields. Under these circumstances, giving substantial deference to the agency's views on preemption also is appropriate, so long as the agency is not under political pressure to adopt a particular viewpoint. Agency experts are best positioned to determine whether a specific state law will upset the agency's balancing of competing interests. As Justice Breyer said during oral argument in *Williamson v. Mazda Motor of America*:

> Who is most likely to know what 40,000 pages of agency record actually mean and say? People in the agency. And the second most likely is the [Solicitor General's] office, because they will have to go tell them. . . . So if the government continuously says, this is what the agency means and the agency is telling them, yes, this is what it means, the chances are they will come to a better, correct conclusion than I will with my law clerks.[3]

Even though preemption may be most prominent and best known in the context of prescription drugs and other medical

[2]William L. Prosser, HANDBOOK OF THE LAW OF TORTS § 99, at 661 (4th ed. 1971).

[3]Oral Argument at 30, *Williamson v. Mazda Motor of Am.*, 562 U.S. 323 (2011).

products, the rationale behind the need to clarify the doctrine and to give effect to agency decision making in that context applies to a wide range of other products sold nationally, as well as policy issues of national significance. The breadth of the focus of this MONOGRAPH is a testament to the doctrine's broad importance.

FEDERAL PREEMPTION: ORIGINS, TYPES AND TRENDS IN THE U.S. SUPREME COURT

OVERVIEW

The doctrine of federal preemption is messy, its application is inconsistent, and at times it is used as both a sword and a shield by a wide array of actors. One thing is for certain—despite its many complexities and the lack of a consensus on the appropriate framework to analyze preemption problems, federal preemption will continue to challenge the judicial system in light of Congress's increasing desire to enact federal regulatory schemes that implicate many traditional state government powers and functions. Preemption will continue to have its champions and its detractors. Ultimately, this MONOGRAPH's goal is not to advocate for or against preemption, nor is it designed to advocate one theory over another when it comes to the application of preemption. Instead, it is to provide the practitioner with a guide to the competing views on preemption expressed by the United States Supreme Court and to anticipate what participants in the judicial system can expect in the coming years as new preemption problems find their way to the Court.

To achieve this goal, the MONOGRAPH proceeds in four parts. Part I discusses the doctrine of preemption generally and explains its constitutional underpinnings and historical development. Part II discusses the different types of preemption the U. S. Supreme Court has recognized and addresses the paradigms of statutory construction that are regularly employed by reviewing courts, including the

Supreme Court. Part III reviews the preemption-based decisions that the Supreme Court has issued between 2007 and 2015, looking at each within the context of the specific area of law to which it relates (*e.g.*, pharmaceuticals, medical devices, securities, arbitration, aviation, etc.). Part IV assesses trends that have arisen from the Court's preemption jurisprudence and provides some guidance for issues that likely will find their way to the Court in the near future.

I.

ORIGINS OF FEDERAL PREEMPTION

The doctrine of federal preemption is rooted in the Supremacy Clause of Article VI of the United States Constitution, which states that:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.[1]

These sixty-four words are the constitutional mechanism that allows fifty sovereign states in our federalist system to be governed as one nation. At its core, the Supremacy Clause of Article VI means that federal law will displace a conflicting state law. Courts, however, have struggled with the displacement of state law and the scope of such displacement since ratification of the Constitution.

A. Test for Preemption

In *Commonwealth of Pennsylvania v. Nelson*,[2] the Court established a three-part test for courts to follow when confronted with questions of preemption:

- First, whether "the scheme of federal regulation is so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it;"[3]

- Second, whether "the federal statutes touch a field in which the federal interest is so dominant that the federal system must be assumed to preclude enforcement of state laws on the same subject;[4] and

- Third, whether enforcement of the state law "presents a serious danger of conflict with the administration of the federal program."[5]

A more recent formulation of the Court's preemption standard is found in *Pacific Gas and Electric Co. v. State Energy Resources Conservation & Development Commission*[6] where the Court stated as follows:

> Absent explicit preemptive language, Congress' intent to supersede state law altogether may be found from a scheme of federal regulation so pervasive as to make reasonable the inference that Congress left no room to supplement it, because the Act of Congress may touch a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject, or because the object sought to be obtained by the federal law and the character of obligations imposed by it may reveal the same purpose. Even where Congress has not entirely displaced state regulation in a specific area, state law is preempted to the extent that it actually

> conflicts with federal law. Such conflict arises when compliance with both federal and state regulations is a physical impossibility, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.[7]

Under *Nelson* and its progeny, any preemption analysis requires a thorough examination of the federal law under consideration and the intent of the drafters of that law.

B. Presumption Against Preemption

The Court's preemption jurisprudence has generally accepted that a court confronted with a preemption problem should start its analysis of a federal statute with the assumption that "the historic police powers of the States were not to be superseded by the federal act unless that was the clear and manifest purpose of Congress."[8] This starting tool of statutory construction is referred to as the "presumption against preemption." The presumption is rooted in the idea that statutes should be read with an assumption against implied repeals, which means that whenever possible statutes should be interpreted in a manner that harmonizes them with existing law. Just as federal courts will read federal statutes, if at all possible, not to impliedly repeal prior federal statutes, so too courts will read federal statutes not to repeal state laws if at all possible (via implied preemption). This presumption has historically been a counterweight to the Court's broad approach to implied preemption, which in practice should arrive at a "probable" interpretation of a particular federal statute's preemptive scope.

Moreover, and as demonstrated in the review of cases in Part III below, the presumption against preemption has been applied inconsistently, often times influenced by the type of preemption being considered—express or implied

(including field or conflict preemption). For example, in cases where statutes contain express preemption provisions, the Court has applied the presumption to achieve a "narrow" interpretation of the preemption provision. Yet in other cases, the Court does not require a narrow reading of other expressions of federal law when looking at whether there is conflict preemption.

II.

TYPES OF PREEMPTION

Federal preemption normally arises in two forms—express and implied. Under the umbrella of implied preemption fall other forms of preemption, the most common of which are conflict preemption and field preemption. Each form will be discussed below.

A. Express Preemption

Express preemption is derived from the very language of a federal statute and arises when a federal statute includes a clause/provision that explicitly forecloses state action that would conflict with the particular federal statute. When express preemption exists, "there is no need to infer congressional intent to pre-empt state laws from the substantive provisions"[9] of the legislation. Instead, what the reviewing court must do is engage in a two-part analysis: (1) determine the meaning of the clause in question, *i.e.*, the scope of the state action that is being foreclosed; and (2) decide whether Congress has the constitutional authority to foreclose that state action.

B. Implied Preemption

Implied preemption arises even though Congress has not explicitly stated its intent to preempt state law in the text of

the statute and is primarily evaluated as field preemption or conflict preemption.

1. Field Preemption

Federal law may have a preemptive effect through what is known as field preemption. Field preemption arises when Congress regulates an area of law so extensively that no room remains for even complementary state laws. Similarly, the "federal interest" in a field that is regulated by a particular federal statute can be "so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." Despite the fact that there is no express provision from Congress, a presiding court that infers field preemption must nonetheless determine the scope of the implied preemption and whether Congress had the constitutional authority to foreclose state action in the field in question. Although the concept of field preemption continues to be applied, the Supreme Court has become increasingly less willing to infer field preemption in practice absent a clear congressional intent to displace state action.

2. Conflict Preemption

One of the few areas of agreement among scholars, courts, and practitioners is that state laws that actually conflict with federal laws (that Congress was authorized to enact) are preempted. That said, determining when a conflict exists is at times an area rife with disagreement. The Court's preemption jurisprudence suggests that conflicts between state and federal laws can occur in two ways: (1) when simultaneous compliance with both federal and state laws is a physical impossibility; or (2) when the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."

a. Physical Impossibility

The first form of conflict, "physical impossibility," is one that the Court infrequently cites as a basis for preemption.[10] In the case courts most often cite for the proposition of "impossibility," *Florida Lime & Avocado Growers, Inc. v. Paul*,[11] the Court did not find a conflict to exist between the state and federal laws at issue. This form of preemption has been rare because, as one commentator has pointed out, "[t]he Supreme Court has made clear that even if one sovereign's law purports to give people a right to engage in conduct that the other sovereign's law purports to prohibit, the 'physical impossibility' test is not satisfied; a person could comply with both state and federal laws simply by refraining from the conduct, it is physically possible to comply with both unless federal law requires what state law prohibits (or vice versa)."[12]

Preemption on the basis of impossibility, however, regained some prominence through the triad of pharmaceutical liability cases that will be discussed in detail below, *Wyeth v. Levine*, *PLIVA v. Mensing*, and *Mutual Pharmaceutical Co. v. Bartlett*. In those opinions, the justices had to weigh whether it was impossible for brand-name and generic-drug manufacturers to comply both with federal labeling rules and with jury verdicts in state-law failure-to-warn and design-defect lawsuits.

b. Purposes and Objectives

The other form of conflict preemption, namely "purposes and objectives," can be traced back to the Court's 1941 decision in *Hines v. Davidowitz*.[13] In *Hines*, the Court considered whether the federal Alien Registration Act preempted an alien registration law adopted by the Commonwealth of Pennsylvania. The Court ultimately concluded that the two statutes did not directly conflict with

one another. The Court, however, also concluded that its preemption analysis was not limited to merely considering the terms of the relevant federal law. Specifically, it stated that "there is not—and from the very nature of the problem there cannot be—any rigid formula or rule which can be used as a universal pattern to determine the meaning and purpose of every act of Congress."[14] As such, the Court concluded that when confronted with a preemption problem like the one in *Hines*, its "primary function is to determine whether, under the circumstances of this particular case, [state] law stands as an *obstacle* to the accomplishment and execution of the full *purposes and objectives* of Congress."[15]

The "purposes and objectives" test faced criticism from its inception. Justice Stone, in his dissent in *Hines,* observed that the "purposes and objectives" test allows courts, in determining the preemptive effect of a federal statute, to read into the statute notions of congressional intent and policies that are not found in the text of the statute or based on reasonable inferences therefrom.[16] Justice Stone's words are as relevant today as they were in 1941 when he wrote the following:

> At a time when the exercise of the federal power is being rapidly expanded through Congressional action, it is difficult to overstate the importance of safeguarding against such diminution of state power by vague inferences as to what Congress might have intended if it had considered the matter or by reference to our own conceptions of a policy which Congress has not expressed and which is not plainly to be inferred from the legislation which it has enacted.
>
> The Judiciary of the United States should not assume to strike down a state law which is immediately concerned with the social order and safety of its people unless the statute plainly and

> palpably violates some right granted or secured to the national government by the Constitution or similarly encroaches upon the exercise of some authority delegated to the United States for the attainment of objects of national concern.
>
> ***
>
> It is conceded that the federal act in operation does not at any point conflict with the state statute, and it does not by its terms purport to control or restrict state authority in any particular. But the government says that Congress by passing the federal act has 'occupied the field' so as to preclude the enforcement of the state statute and that the administration of the latter might well conflict with Congressional policy to protect the civil liberty of aliens against the harassments of intrusive police surveillance. [17]
>
> ***
>
> Little aid can be derived from the vague but often repeated formula that Congress 'by occupying the field' has excluded from it all state legislation. Every Act of Congress occupies some field, but we must know the boundaries of that field before we can say that it has precluded a state from the exercise of any power reserved to it by the Constitution. To discover the boundaries we look to the federal statute itself, read in the light of its constitutional setting and its legislative history.[18]

Following *Hines* and its progeny, the scope of the inquiry to determine congressional intent grew exponentially. And over time, this broad search for congressional intent has been challenged as speculative, and its application has been inconsistent and in some instances apparently used as a tool to arrive at a pre-determined outcome.

More recently, Justice Thomas has identified two emerging problems with the Court's "purposes and objectives" preemption jurisprudence.[19] First, "it encourages an overly expansive reading of statutory text."[20] As Justice Thomas observes in *Levine*:

> Federal legislation is often the result of compromise between legislators and 'groups with marked but divergent interests.' Thus, a statute's text might reflect a compromise between parties who wanted to pursue a particular goal to different extents. Therefore, there is no factual basis for the assumption underlying the Court's 'purposes and objective' pre-emption jurisprudence that every policy seemingly consistent with federal statutory text has necessarily been authorized by Congress and warrants pre-emptive effect. Instead, our federal system in general, and the Supremacy Clause in particular, accords pre-emptive effect to only those policies that are actually authorized by and effectuated through the statutory text.[21]
>
> ***
>
> The origins of this Court's 'purposes and objectives' pre-emption jurisprudence in *Hines*, and its broad application in cases like *Geier*, illustrate that this brand of the Court's pre-emption jurisprudence facilitates freewheeling, extratextual, and broad evaluations of the 'purposes and objectives' embodied within federal law. This, in turn, leads to decisions giving improperly broad pre-emptive effect to judicially manufactured policies, rather than to the statutory text enacted by Congress pursuant to the Constitution and the agency actions authorized thereby.[22]

Justice Thomas also highlighted the impact that a federal agency's commentaries on the preemptive scope of a federal statute can have on the Court's analysis. He found

such a practice problematic because a federal agency's use of commentary can provide courts with a reason to "vacate a judgment issued by another sovereign based on nothing more than assumptions and goals that were untethered from the constitutionally-enacted federal law authorizing the federal regulatory standard that was before the Court."[23]

As reflected in the review of cases in Part III, "purposes and objectives" continues to be a point of contention among the justices in preemption cases. On the current Court, Justice Thomas is recognized as a consistent critic of "purposes and objectives" preemption jurisprudence. He advocates a textualist approach to preemption analysis that focuses on the words of federal statutes and provides, in his opinion, a principled and consistent framework for resolving preemption disputes.[24]

III.

PREEMPTION AT THE U.S. SUPREME COURT, 2007-2015

This section surveys Supreme Court preemption cases between 2007 and 2015 and is organized based on the predominant type of preemption in the case—express or implied—and is further categorized by the industry type or area of law (*e.g.*, prescription drug, food safety, etc.).

A. Express Preemption Cases

1. Medical Device Amendments

Riegel v. Medtronic, Inc. *Riegel* addressed whether the preemption clause enacted in the Medical Device Amendments of 1976 ("MDA") bars common-law claims challenging the safety and efficacy of a medical device granted premarket approval ("PMA").[25] Plaintiff underwent

heart surgery in 1996 after suffering a heart attack. The physician performing the surgery inserted the Medtronic Evergreen Balloon Catheter, even though the device's labeling stated that its use was contraindicated when, as in Riegel's case, the patient had a calcified coronary artery. The doctor also inflated the balloon beyond its rated burst pressure. The catheter at issue, a device approved through the PMA process, burst during surgery, forcing plaintiff to be placed on life support, after which he underwent emergency bypass surgery.

Plaintiff, Riegel's wife, sued Medtronic in the Northern District of New York, alleging that the catheter at issue was designed, labeled, and manufactured in a manner that violated New York common law. The complaint raised a number of common-law claims, including strict liability, breach of implied warranty, and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the catheter.

The federal district court held that the MDA preempted plaintiff's common-law claims. It also found that the MDA preempted the loss-of-consortium claims by Riegel's widow to the extent they were derivative of the preempted claims. The Second Circuit affirmed.

Upon review, the Supreme Court held that the MDA preempted the common-law claims challenging the safety and efficacy of the catheter at issue. Justice Scalia wrote the opinion and explained the Court's rationale: Congress passed the MDA in 1976 to combat growing concern over differing state regulations for the many complex medical devices entering the market.[26] The MDA contains an express preemption provision that prohibits states from "establish[ing] or continu[ing] in effect with respect to a device intended for human use any requirement . . . (1) which is different from, or in addition to, any requirement

applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."[27] Under the MDA, devices with a Class III distinction, like the catheter at issue, undergo the most rigorous FDA premarket approval review.[28]

The Court conducted a two-pronged analysis: (a) because the MDA expressly preempts only state requirements "different from, or in addition to, any requirements applicable . . . to the device" under federal law, the Court had to analyze whether the federal government has established requirements for the catheter at issue, and (b) if so, whether plaintiff's claims are based upon New York's requirements with respect to the device that are "different from, or in addition to," the federal ones, and that relate to safety and efficacy.[29]

First, the Court determined that the federal government has established "requirements" for the catheter at issue in that the catheter was a Class III device subject to premarket approval, and those "requirements" entirely concern the safety of the product.[30] Second, the Court determined that the plaintiff's common-law claims relied upon a "requirement" of New York law applicable to the catheter that is "different from, or in addition to," federal requirements and that "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device."[31] The Court noted that the common-law causes of action at issue imposed "requirements" under the MDA context, as the Court had found in other cases as well.[32] Finally, the Court affirmed the lower courts' views that the state "requirements" at issue were "different from, or in addition to" the requirements imposed by federal law.[33]

2. Securities Regulations and Banking

Cuomo v. The Clearing House Ass'n, L.L.C. In this case, the Court considered whether an Office of the Comptroller of the Currency ("OCC") regulation was a reasonable interpretation of the National Bank Act.[34] The New York Attorney General sent letters to several national banks making a request "in lieu of subpoena" for certain non-public information about their lending practices. The Attorney General sought this information to determine whether the banks had violated New York fair-lending laws. The OCC filed suit to enjoin the information request, claiming the regulation prohibited state-law enforcement actions against national banks.

The National Bank Act contains language providing that no national bank would be subject to "visitorial powers," except as authorized by federal law. In interpreting that Act, the OCC issued a regulation declaring that state officials—like the Attorney General—could not exercise "visitorial powers" such as conducting examinations, inspecting or requiring the production of books or records of national banks, or bringing enforcement actions, except in limited circumstances authorized by federal law.

The United States District Court for the Southern District of New York entered an injunction in favor of the OCC, prohibiting the Attorney General from enforcing state fair-lending laws through demands for records or judicial proceedings. The Second Circuit affirmed.

The Supreme Court affirmed the injunction as to the request "in lieu of subpoena" and any executive subpoenas issued by the Attorney General seeking information, but vacated the injunction to the extent it prohibited the Attorney General from bringing judicial enforcement actions under New York fair-lending laws. Justice Scalia explained

in his majority opinion that the resolution of this case turned on the interpretation of "visitorial powers" as used in the National Banking Act and interpreted through the OCC's regulation, and more specifically, whether that term is synonymous with the power to enforce the law. In light of prior Supreme Court jurisprudence, including *Watters v. Wachovia*,[35] Justice Scalia argued that the only reasonable interpretation of "visitorial powers" is that it includes the power to request information, but not the power to bring enforcement actions.

In *Watters*, the Supreme Court held that a state may not exercise general supervision and control over a national bank because multiple audits and surveillance under different oversight regimes would cause uncertainty. The Court made a distinction, however, between oversight and law enforcement, and in so doing implied that a state is always free to enforce its laws. Under this rationale, the OCC is free to limit a state's "visitorial powers" to the extent those powers are being used for oversight, *e.g.*, requests for information. But the OCC cannot limit a state's ability to bring its own enforcement actions under its own laws. Accordingly, the Court affirmed the district court's injunction to the extent it prohibited the Attorney General from making requests for information outside a judicial proceeding, but reversed the injunction to the extent it prohibited the Attorney General from bringing an enforcement action in the state courts of New York.

Chadbourne & Parke LLP v. Troice. The Securities Litigation Uniform Standards Act of 1998 ("SLUSA") forbids plaintiffs from bringing securities class actions alleging a "misrepresentation or omission of a material fact in connection with the purchase or sale of a covered security" that is based on the common or statutory law of any state.[36] A "covered security" includes only securities traded on a national exchange.[37]

In *Troice*, two groups of Louisiana investors filed civil class actions alleging a violation of Louisiana state law and contending that the defendants helped perpetrate a Ponzi scheme by falsely representing that uncovered securities (certificates of deposit in a bank) were backed by covered securities.[38] The district court dismissed the claims under SLUSA.[39] Even though the certificates of deposit were not covered securities, the district court dismissed because the misrepresentation made investments in the uncovered securities *more* protected, which provided the requisite "connection" between the state-law action and transactions in covered securities.[40] The Fifth Circuit reversed, holding that misrepresentations about the holdings in covered securities were not so closely related to the fraud to trigger SLUSA preemption.[41]

The Supreme Court granted *certiorari* and set the question presented as whether SLUSA "encompasses a class action in which the plaintiffs allege (1) that they 'purchase[d] *uncovered* securities...but (2) that the defendants falsely told the victims that the *uncovered* securities were backed by *covered* securities."[42] The Court, per Justice Breyer, affirmed the Fifth Circuit, holding that SLUSA does not preclude the plaintiffs' state-law class-action claims because the misrepresentation never led plaintiffs to buy or sell *covered* securities.[43]

The Court evaluated several factors in holding that SLUSA does not extend beyond misrepresentations that are material to one or more individuals' decisions to purchase or sell a covered security. It noted that its holding is consistent with the Act's focus on transactions in covered, not uncovered, securities and that such an interpretation insists upon a material connection with a transaction in a *covered* security.[44] The Court also stated that a "connection matters where the misrepresentation makes a significant difference to someone's decision to purchase or to sell a covered security,

not an uncovered one, something about which the Act expresses no concern."[45] A fraudulent misrepresentation is not made "in connection with" a purchase or sale of a "covered security" unless it is material to a decision of an individual to buy or sell a covered security.[46] The Court noted that securities cases in which it has found a fraud to be "in connection with" a purchase or sale of a security have involved victims and ownership interests in financial instruments that fall within the statutory definition.[47]

The Court rejected the defendants' argument that the phrase "in connection with" should be given a broad interpretation.[48] It noted that prior cases in which the Court found the phrase to cover a fraud involved the purchase or sale of a statutorily-defined "security" or "covered security" and that the relevant representations were material to a transaction by or on behalf of someone other than the fraudster.[49] The Court also noted that a narrow interpretation would not curtail the Securities and Exchange Commission's enforcement powers under the Securities Exchange Act.[50]

3. Food Safety and Advertising

Some federal food safety laws contain express preemption provisions. One such law is the Federal Meat Inspection Act ("FMIA"),[51] which regulates a broad range of activities at slaughterhouses to ensure both the safety of meat and the humane handling of animals. The FMIA establishes an elaborate system of inspecting live animals and carcasses in order to prevent the shipment of impure, unwholesome, and unfit meat and meat-food products. Since the 1970s, all slaughterhouses have been required to comply with the standards for humane handling and slaughter of animals set forth in the Humane Methods of Slaughter Act of 1958. The FMIA has an express preemption clause.[52]

National Meat Ass'n v. Harris. The Supreme Court reviewed this FMIA provision in *Harris*.[53] It unanimously held that the FMIA expressly preempted a California law concerning slaughterhouses' handling of "non-ambulatory animals." The California law made it illegal to "buy, sell, or receive a non-ambulatory animal;" "process, butcher, or sell meat or products of non-ambulatory animals for human consumption;" or "hold a non-ambulatory animal without taking immediate action to humanely euthanize the animal."[54] A trade association challenged the California law on preemption grounds. The association cited a relevant decision by the Department of Agriculture's Food Safety and Inspection Service ("FSIS"), the agency that administers the FMIA. FSIS had decided that slaughterhouses can make a determination, based on a non-ambulatory animal's condition, on whether it should condemn the animal or set it aside as suspect, a classification that, after a "post-mortem" examination, may allow for its sale for human consumption.[55]

Based on the express preemption provision, which it characterized as "sweep[ing] widely," the Court preempted California's law, as the FSIS clearly determined that slaughterhouses may receive non-ambulatory animals.[56] The Court rejected California's argument that the state law falls outside the "scope" of the FMIA because it excludes a class of animals from the slaughterhouse process.[57] It reasoned that the FMIA's scope includes "animals on a slaughterhouse's premises that will never" be turned into meat.[58]

POM Wonderful LLC v. Coca-Cola Company. In another food-related case, the Court had to resolve a conflict between two federal statutes, without, as it turned out, resorting to federal preemption.[59] However, the Court noted that preemption principles are instructive in an analysis of the interaction of two laws on the same subject.[60] The Court's reasoning, in turn, may be instructive to the application of preemption principles in future case.

One statute was the Lanham Act, which permits competitors to sue for false or misleading commercial advertising, or promotion.[61] The other law, the Federal Food, Drug and Cosmetic Act ("FDCA"), prohibits misbranding.[62] The Food and Drug Administration ("FDA") implements the FDCA through regulations.[63] The law does not permit private-enforcement lawsuits and preempts some state misbranding laws.

POM Wonderful ("POM") produces and sells a pomegranate-blueberry juice-blend drink.[64] It filed a Lanham Act suit against the Coca-Cola Company alleging that a drink marketed by Coca-Cola misled consumers into believing that the Coca-Cola drink contained mainly pomegranate and blueberry juice, a representation POM argued caused it to lose sales of its own drink.[65] The district court granted partial summary judgment to Coca-Cola, ruling that the FDCA precluded Lanham Act challenges to the name and label of Coca-Cola's drink.[66] The Ninth Circuit affirmed in relevant part.[67]

The Supreme Court reversed and remanded, holding that competitors may bring Lanham Act claims challenging FDCA-regulated food and beverage labels.[68] The Court began its analysis by noting that the case before it did not involve federal preemption, but rather concerned the preclusion of a cause of action under one federal statute by the provisions of another federal statute.[69] The Court stated that "[t]here is no statutory text or established interpretive principle to support the contention that the FDCA precludes Lanham Act suits like the one brought by [POM] in this case."[70]

The Court stated that neither the Lanham Act nor the FDCA forbids or limits Lanham Act claims challenging labels that are regulated under the FDCA, indicating that Congress did not intend FDA oversight to be the exclusive means of label monitoring.[71] The Court noted that, if anything,

Congress's express language in the FDCA preempting only some state laws indicates it did not intend for the FDCA to preclude the application of other laws on the subject.[72] The Court also noted that the two acts serve different purposes; the Lanham Act protects commercial interests while the FDCA protects public health and safety.[73]

The Court wrote that the language of the FDCA does not indicate Congress intended to foreclose private enforcement of other federal statutes.[74] The Court also stated that the FDCA's express preemption provision applies to state, not federal, law.[75]

4. Air and Motor Transportation

In 1978, Congress passed the Airline Deregulation Act ("ADA").[76] Prior to the passage of the ADA, states were free to regulate *intrastate* airfares. The ADA sought to curb this practice and also included an express preemption provision that barred states from enforcing any law "*relating to* rates, routes, or services" of any air carrier.[77]

Morales v. Trans World Airlines, Inc. The Supreme Court first addressed preemption under the ADA in *Morales*.[78] The Court considered whether the ADA preempted states from "prohibiting allegedly deceptive airline-fare advertisements through enforcement of their general consumer protection statutes."[79] The National Association of Attorneys General adopted a set of guidelines aimed at "explain[ing] in detail how existing state laws apply to air fare advertising and frequent flyer programs."[80] The attorneys general sent a memorandum to certain airline carriers notifying them of non-compliance with certain provisions of the guidelines, and the carriers filed suit.[81] The carriers alleged that the ADA preempts state regulation of fare advertisements.[82] The district court and appellate court agreed with the airline carriers.

The Supreme Court affirmed. Writing for the majority, Justice Scalia emphasized that Congress's use of the phrase "relating to" in the provision reflected its intent that the ADA's preemption sweep broadly.[83] This view was supported by the Court's reading of similar preemption provisions, such as one in the Employee Retirement Income Security Act.[84] Here, because it was "obvious[]" that the state attorneys general's guidelines "relate to" fares, the ADA expressly preempted the guidelines.[85] Among other provisions, Justice Scalia pointed to one of the guidelines that sought to regulate print advertisements of fares as an example of a guideline that was clearly related to fares—that guideline attempted to limit the manner in which certain restrictions were published in advertisements, such as refund or exchange rights, time-of-day or day-of-week restrictions, length-of-stay requirements, and more.[86]

American Airlines, Inc. v. Wolens. Three years later, the Court confronted the question of whether the ADA preempts state consumer-fraud and breach-of-contract claims brought by members of American Airlines' frequent-flyer program after the company retroactively modified its program.[87] It held that the plaintiffs' state consumer-fraud claims were preempted, but permitted the breach-of-contract actions.[88] The Court determined that the consumer fraud act at issue served "as a means to guide and police the marketing practices of the airlines,"[89] and that plaintiffs' claims clearly "relate to" rates and services.[90] On the breach-of-contract claims, the Court looked at the language of the ADA and found no "hint" of congressional intention to "channel into federal courts the business of resolving, pursuant to judicially fashioned federal common law, the range of contract claims relating to airline rates, routes, or services."[91]

Dissenting in part, Justice O'Connor explained why the contract claims should have been preempted as well. She emphasized that no material difference existed between the

consumer-fraud action and the breach-of-contract action at issue—"the subject matter of the action relates to airline rates and services."[92] In essence, Justice O'Connor saw no great distinction between the guidelines that *Morales* invalidated and the contract claim allowed to stand in *Wolens*, as neither was an "official, government-imposed policy."[93]

Northwest, Inc. v. Ginsberg. The Court appears to have adopted Justice O'Connor's more expansive view of the ADA's preemptive force in 2014 in *Ginsberg*.[94] It unanimously ruled that the ADA expressly preempted an airline customer's state common-law claims for breach of the implied covenant of good faith and fair dealing after Northwest revoked the customer's membership in the company's frequent-flyer program. It noted that it had previously ruled in *Wolens* that an airline's frequent-flyer program "relates to" the "price, route, or service" under the ADA. The Court rejected the customer's argument that the ADA only applied to actions involving state legislation, and not a common-law rule. It rejected the argument on multiple grounds, including that a common-law rule has the "force and effect of law" as contemplated by the statute.[95] The Court found the customer's claim for breach of implied covenant for terminating his membership in the airline's frequent-flyer program fell squarely within the ADA's express preemption clause.[96]

In 1994, Congress passed the Federal Aviation Administration Authorization Act ("FAAAA") to regulate any "motor carrier" in very much the same way as the ADA operated. The FAAAA contained a preemption provision similar to the ADA's: "[A] state . . . may not enact or enforce a law . . . *related to* a price, route, or service of any motor carrier . . . with respect to the transportation of property."[97]

Rowe v. New Hampshire Motor Transport Ass'n. The Supreme Court evaluated this provision in *Rowe*[98] and again in *Dan's City Used Cars, Inc. v. Pelky*.[99] At issue in *Rowe* was whether the FAAAA preempted Maine legislation prohibiting anyone other than a Maine-licensed tobacco retailer to accept an order for delivery of tobacco.[100] The legislation also mandated that the retailer use a "delivery service" that provided for a series of verification guidelines.[101] The district and appellate courts found that the FAAAA preempted the Maine statute.[102] Using the same analysis as in *Morales* the Court affirmed unanimously: "when judicial interpretations have settled the meaning of an existing statutory provision, repetition of the same language in a new statute indicates, as a general matter, the intent to incorporate its judicial interpretations as well."[103] In other words, because the Congress that drafted the FAAAA copied the language from the ADA, the Court found that Congress must have intended for a broad interpretation.[104]

The Maine statute was preempted because it "focuses on trucking and other motor-carrier services . . . thereby creating a direct 'connection with' motor carrier services."[105] Though conceding that the legislation at issue was not as "direct" as it might be, the Court held that the FAAAA's objective was to bar a state from substituting its own commands for "competitive market forces," and that is precisely what the Maine statute attempted to do.[106] The *Rowe* Court did caution that the FAAAA does have its limits and would not be held to preempt state laws that pertain to prices, routes, or services in "only a tenuous, remote, or peripheral manner, such as state laws forbidding gambling."[107]

American Trucking Ass'n, Inc. v. City of Los Angeles. The Court again assessed preemption under the FAAAA in *American Trucking Ass'n*.[108] At issue in that case was a Los Angeles regulation known as the Clean Truck Program,

which the City Council passed in response to residents' concern that the expansion of the Port of Los Angeles would lead to greater congestion. The Clean Truck Program required any trucking company doing business at the port, including federally-licensed drayage truck companies, to enter into a "concession agreement" accepting certain placard and parking restrictions.[109] The concession agreements were mandatory, and they provided for penalties if signatories did not follow the placard and parking restrictions.[110]

The Supreme Court ruled unanimously that the placard and parking requirements in the concession agreement were expressly preempted by the FAAAA, which supersedes a "state law, regulation, or other provision having the force and effect of law related to a price, route, or service of any motor carrier . . . with respect to the transportation of property."[111] The Court rejected the city's argument that the regulation was a matter of private contract rather than the exercise of regulatory power.[112] The Court found that the punitive element—a terminal operator cannot do business with any truck that had not entered into a concession agreement—clearly made this a "regulation" or "other provision having the force and effect of law."[113]

Dan's City Used Cars, Inc. v. Pelky. During the same term as its ruling in *American Trucking*, the Supreme Court ruled on another FAAAA preemption case, finding that the law did *not* preempt the state-law claims of a car owner. In *Pelky*,[114] a tow company confiscated and eventually sold the plaintiff's car despite his protests.[115] Pelky sued the company under the New Hampshire Consumer Protection Act. The Court rejected the tow company's preemption argument because the FAAAA's preemption provision specifically pertains to "the transportation of property" and the "service" of a motor carrier.[116] The preemption provision does not relate to the disposal and storage of a motor vehicle, which the car owner's claims involved.[117]

5. Rail Transportation

Congress has also demonstrated its intention to supersede state law when regulating activities of railway carriers. Congress enacted the Railroad Revitalization and Regulatory Reform Act of 1976 ("4-R Act") to restore the financial stability of the U.S. railway system.[118] The 4-R Act has an express preemption provision that prohibits states from, among other things, "[i]mpos[ing] another tax that discriminates against a rail carrier."[119]

Burlington Northern Railroad Co. v. Oklahoma Tax Commission. The first case to evaluate the 4-R Act's preemptive scope was *Burlington Northern*.[120] The Court held that the lower courts had improperly dismissed a railway company's claims of discriminatory taxation practices by a state in overvaluing the "true market value" of the company's property.[121] It determined that the language of the statute was "conclusive" in that it plainly forbids states from "assess[ing] rail transportation property at a value that has a higher ratio to the true market value . . . than the ratio that the assessed value of other commercial and industrial property in the same assessment jurisdiction has to the true market value of the other commercial and industrial property."[122] The Court rejected the state's arguments that (1) federal courts could not hear disputes over market value because market value is the "state determined market value," and (2) in order for the railway to make a claim, it had to demonstrate intentional discrimination.[123] Based on the clear language of the statute, the Court ruled that the railway company's case should be allowed to proceed against the state for discriminatory taxation practices.[124]

Department of Revenue v. ACF Industries, Inc. In this case, the Court considered whether the Act preempted an Oregon *ad valorem* property tax that exempted certain classes of business personal property, including agricultural

machinery and equipment, but not railroad cars owned by ACF Industries and other respondent companies that lease railroad cars to railroads and shippers.[125] The companies argued the 4-R Act preempted Oregon's tax because the tax violated subsection 4 of the Act by "impos[ing] another tax that discriminates against a rail carrier providing transportation . . . ."[126] The Court's decision rejecting preemption turned on the meaning of "another tax" in the context of the 4-R Act. It determined Congress intended to "permit States to tax railroad property at a higher rate" than other types of property, including that of agriculture.[127]

CSX Transportation, Inc. v. Alabama Department of Revenue. The Court came to a different conclusion on the preemptive effect of the 4-R Act in this case.[128] It ruled that Alabama's tax on railway carriers' use of diesel gas was expressly preempted by the 4-R Act. First, the Court held that Alabama's law taxing the purchase and consumption of diesel fuel constituted "another tax" under the 4-R Act.[129] Second, it found that Alabama's law was discriminatory because it granted exemptions to the railroad industry's main competitors, namely motor and water carriers.[130] The Court distinguished *ACF Industries* on the ground that the "structural analysis" of that case did not apply to the facts before them in *CSX Transportation*. The case involved "non-property exemptions," rather than "property tax exemptions," which the statute clearly allows for.

6. Tobacco

Altria v. Good. In this case, the Supreme Court held that the Federal Cigarette Labeling and Advertising Act ("FCLAA") did not preempt state-law fraud claims that targeted "lights" advertising.[131] Smokers of "lights" cigarettes sued Altria under the Maine Unfair Trade Practices Act, claiming fraudulent advertising and concealment.[132] The Court reviewed the preemptive language

of the FCLAA and determined that the preemption provision did not prohibit states from barring "deceptive statements in cigarette advertising."[133] It reasoned that the state statute at issue did not concern itself specifically with "smoking and health," but rather a duty not to deceive.[134]

7. Immigration

Chamber of Commerce v. Whiting. In 1986, Congress passed the Immigration Reform and Control Act ("IRCA"), which makes it "unlawful for a person or other entity . . . to hire, or to recruit or refer for a fee, for employment in the United States an alien knowing the alien is an unauthorized alien."[135] The IRCA contains an express provision that preempts "any State or local law imposing civil or criminal sanctions (other than through licensing and similar laws) upon those who employ, or recruit or refer for a fee for employment, unauthorized aliens."[136]

The Supreme Court evaluated this statute for the first time in *Whiting*.[137] In *Whiting*, a divided ruling, the Supreme Court held that the IRCA did *not* expressly preempt an Arizona law instructing courts to suspend or revoke a business license of an in-state employer that employs unauthorized aliens.[138] The Court ruled that because Arizona's law involved licensing conditions it was exempted from the IRCA's preemption tentacles.[139] The Court rejected the Chamber of Commerce's argument that the Arizona law is not a "licensing law" on the grounds that it serves only to suspend and revoke licenses, rather than grant them.[140]

B. Implied Preemption Cases

1. The Pharmaceutical Triad

Wyeth v. Levine. In 2009 the Supreme Court decided the first of three landmark cases regarding manufacturers'

liability under state-law tort theories for harm allegedly caused by prescription drugs.[141]

In *Wyeth*, a plaintiff sued in state court claiming injuries from the use of an anti-nausea drug.[142] The plaintiff claimed that Wyeth violated state law by failing to provide adequate warnings about administering the drug through an "IV-push method."[143] At trial, the jury found for the plaintiff, concluding that the injury at issue would not have occurred had Wyeth placed an adequate warning on the product.[144] The trial court declined to overturn the jury's verdict, rejecting Wyeth's preemption arguments. Wyeth appealed the verdict, arguing that federal law impliedly preempted the plaintiff's claims.[145] The Vermont Supreme Court affirmed, concluding that the claims were not preempted.[146]

The U.S. Supreme Court also affirmed. The Court rejected Wyeth's claim that it was impossible for the company to comply with both federal law governing prescription drugs and its state-law tort duties.[147] Turing first to Wyeth's impossibility argument, the Court focused on the structure of the FDA's approval process.[148] The Court explained that under the regulatory scheme governing such drugs, although a manufacturer typically may only alter warning labels after the FDA approves a requested change, the Changes Being Effected ("CBE") regulation permitted pharmaceutical companies to unilaterally strengthen certain warnings in some circumstances until the FDA either rejected or accepted the change.[149] Because Wyeth had the ability to immediately and unilaterally give greater warnings on the label and there was no "clear evidence" that the FDA "would not have approved the change," the Court concluded the company could comply with both its federal and state-law obligations.[150] This result, the Court reasoned, was consistent with one of the underlying policies of the federal scheme regulating pharmaceuticals: companies, not the

FDA, are primarily responsible for the content of their warning labels "at all times."[151]

The Court likewise rejected Wyeth's argument that a state-law duty-to-warn claim interfered with the FDA's ability to regulate prescription drugs.[152] In support of its argument, Wyeth cited the preamble of an FDA regulation indicating that state-law failure-to-warn claims frustrated the FDA's congressionally delegated ability to regulate drugs.[153] In rejecting the argument, the Court focused on the text and history behind the federal statutory scheme at issue and the manner in which the FDA enacted the regulation.[154] At bottom, the Court explained, because Congress did not delegate to the FDA the ability to preempt state law directly, the rule only served as persuasive authority, and the Court need not defer to it.[155] Instead, the Court focused on congressional intent, and explained that Congress had made clear through its actions and the scheme governing pharmaceuticals that state-law tort claims were to be preserved.[156] For these reasons, the Court affirmed the opinion of the state court.

PLIVA, Inc. v. Mensing. In *Mensing*, the Supreme Court reviewed the impact of implied preemption on state-law failure-to-warn claims brought against *generic* drugmakers.[157] Two plaintiffs brought separate lawsuits against such manufacturers alleging liability for failure to warn.[158] The manufacturers moved to dismiss both cases as a matter of law, arguing the state-law tort claims were preempted by federal statutes and FDA regulations that required generic drugmakers to label their products with the same labels as the "reference listed drug."[159] On appeal in separate federal circuits (the Fifth and Eighth Circuits), both courts rejected the generic manufacturers' preemption arguments.

The Supreme Court reversed. The Court explained that the manufacturers' obligations under state and federal laws were in direct conflict.[160] Under state law, when a manufacturer learns of dangers associated with the long-term use of its products, it has a duty to strengthen the product's warning label.[161] At the same time, federal law tied its hands; generic drug companies were required to use the same label as the generic drug's brand-name equivalent.[162]

In reaching this result, the Court rejected Mensing's argument that FDA regulations allowed the generic manufacturers to unilaterally change the labels of their products.[163] Whereas in *Wyeth* the Court rejected the FDA's position that state-law tort claims interfered with its regulatory scheme, in *Mensing* the Court accepted the agency's reading of its own regulations as meaning the generic companies could not change their labels without prior FDA approval.[164] And unlike in *Wyeth*, the regulations governing generic manufacturers permitted them to only *request* a label change in light of new information, which the FDA had discretion to accept or reject.[165]

The standard for determining whether one can comply with both state and federal laws requires examination of whether a party could have complied with both laws by independently doing what was required under both.[166] At bottom, the Court reasoned, state laws cannot be saved from preemption if a party *could have possibly* complied by making a request to the FDA.[167] The Court held that "when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes."[168]

In closing, the Court distinguished the reasoning and outcome of *Wyeth*.[169] The Court noted that *Wyeth* involved a

federal scheme that allowed the drug company to unilaterally make changes to the warning for the branded product at issue and therefore comply with state law, which was simply not the case for generic companies.[170] Though the Court recognized that these different results may seem unfair, it declined to "distort the Supremacy Clause in order to create similar pre-emption across a dissimilar statutory scheme" and expressed that, "[a]s always, Congress and the FDA retain the authority to change the law and regulations if they so desire."[171]

Mutual Pharmaceutical Co. v. Bartlett. In *Bartlett*, the Court returned to preemption in the generic-drug context.[172] The case involved federal laws' preemptive effect on state-law design-defect suits. At the time the plaintiff ingested the medication at issue, the warning label did not caution about the reaction she suffered. Almost a year after her injury, the FDA recommended changing the product's warning to reflect the plaintiff's response to the drug.

Bartlett sued the generic manufacturer under a state-law design-defect theory.[173] A jury found the company liable and awarded the plaintiff $21 million.[174] The generic drug company argued that the design-defect claim was preempted, which both the trial and federal appellate courts rejected.[175] The First Circuit acknowledged that the company could not comply with both federal and state laws and still produce the product, but held that the company could nevertheless comply with duties under both legal regimes by simply not selling the product upon receiving information that the drug caused serious, previously unknown health consequences.[176]

The Supreme Court rejected the First Circuit's reasoning.[177] The Court first examined the company's duties under state and federal laws.[178] State law required the company to design a product that was reasonably safe for users, which was evaluated by using a risk-utility

approach.[179] The approach required a court to determine whether a product's risk could be reduced by either (1) changing its design or (2) altering its warning label.[180] On the other hand, federal law required that the generic drugmaker only produce generic drugs with the same ingredients and bioavailability as the brand-name equivalent, and that the company use the same warning label as approved for the branded drug.[181] Additionally, the federal regulatory scheme barred the generic drug manufacturers from unilaterally changing the label without prior FDA approval.[182] Comparing these duties, the Court concluded the state law acted as an obstacle to the purposes and objectives of the federal law and therefore was preempted.[183]

Because the generic drug at issue was composed of one molecule, redesign would not only be contrary to federal law, it would be impossible.[184] The only way the generic drug company could meet its state-law duty would be to change the warning label, a duty contrary to what was required under federal law.[185] Indeed, *Mensing* already addressed that very situation. The Court concluded the state-law duty was preempted.[186] It also reasoned that the First Circuit's rationale that a company could simply stop selling its product to avoid inconsistent state and federal obligations did not comport with past precedent:[187] "[A]n actor seeking to satisfy both his federal and state-law obligations is not required to cease acting altogether in order to avoid liability."[188] The Court reasoned that in most if not all prior preemption cases a company could have merely stopped selling a product in order to avoid an inconsistency between state and federal laws; the First Circuit's reasoning was therefore inconsistent with the Court's preemption precedent.[189]

2. Arbitration

Businesses' desire to resolve disputes through arbitration, rather than through litigation, has instigated a long-running

conflict between the U.S. Supreme Court and some lower federal courts and state supreme courts over the preemptive impact of the Federal Arbitration Act ("FAA"). The Court has reviewed a series of decisions over the past several years involving arbitration clauses, some of which arose from state supreme courts' invalidation of those contractual provisions on state-law "public policy" grounds.

AT&T Mobility LLC v. Concepcion. In *Concepcion*, the Court affirmed the petitioner's ability to compel arbitration for claims that would typically be pursued through classwide litigation in federal court.[190]

The plaintiffs alleged that AT&T's $30.22 sales tax charge for a mobile phone was contrary to its promotion that it would not charge new customers for their phone.[191] AT&T's purchase agreement required that all disputes be resolved through arbitration, and that claims "be brought in the parties' 'individual capacity, and not as a plaintiff or class member . . . .'"[192] The agreement also provided, among other things, that AT&T was barred from pursuing attorneys' fees and that "in the event that a customer receives an arbitration award greater than AT&T's last written settlement offer, AT&T must pay a $7,500 minimum recovery and twice the amount of the claimant's attorneys['] fees."[193] The plaintiffs filed suit in California federal court, and AT&T moved to compel arbitration.[194]

In response, the plaintiffs argued that the arbitration agreement was unenforceable because California law barred contracts that waived the right to class actions in certain circumstances.[195] The district court agreed.[196] It viewed AT&T's agreement as adequately addressing the class waiver because the $7,500 award served as a "substantial" encouragement to pursue small claims, and it observed that class members would actually be *better off* under the scheme.[197] However, in light of the California Supreme

Court's *Discover Bank v. Superior Court*[198] decision, because the arbitration agreement failed to "adequately substitute[] for the deterrent effects of class actions," the contract was void under state law.[199]

The Ninth Circuit affirmed, agreeing that California law rendered the contract unenforceable.[200] The appellate court rejected AT&T's argument that the FAA preempted the California rule because it was not directed specifically at arbitration agreements; rather, the rule of unconscionability applied equally to all contracts in California.[201]

On appeal, the Supreme Court reversed. The majority concluded that the California rule did in fact discriminate against arbitration clauses and was an obstacle to the twin goals of the FAA: "enforcement of private agreements and encouragement of efficient and speedy dispute resolution."[202] The Court acknowledged that the FAA allows courts to invalidate an arbitration agreement based on certain defenses to enforcement that are equally applicable to all contracts, and that the California rule, on its face, appeared to be such a universally applicable defense.[203] Yet the rule at issue was an obstacle to the FAA and the enforcement of arbitration agreements because "the overarching purpose of the FAA . . . is to ensure the enforcement of arbitration agreements according to their terms so as to facilitate streamlined proceedings. Requiring the availability of classwide arbitration interferes with fundamental attributes of arbitration and thus creates a scheme inconsistent with the FAA."[204]

Marmet Health Care Center, Inc. v. Clayton Brown. The following year the Supreme Court again turned to whether the FAA preempted a state-law rule applicable only to arbitration agreements.[205] The Court issued a *per curiam* opinion holding that the FAA preempts a categorical rule under West Virginia law that barred the enforcement of all

predispute arbitration agreements governing personal-injury or wrongful-death claims against nursing homes.[206]

The case arose from three negligence suits that had been filed against West Virginia nursing homes.[207] A family member of each decedent had signed an agreement to arbitrate all tort claims against the nursing homes.[208] In each case, the trial court upheld the arbitration agreement. On appeal to the Supreme Court of Appeals of West Virginia, the cases were consolidated, and the court reversed.[209]

The court held that "as a matter of public policy under West Virginia law, an arbitration clause in a nursing home admission agreement adopted prior to an occurrence of negligence that results in a personal injury or wrongful death, shall not be enforced to compel arbitration of a dispute concerning the negligence."[210] The court also rejected the argument that the state-law rule was preempted because Congress did not intend to preempt personal-injury or wrongful-death claims that "only collaterally derive from a written agreement that evidences a transaction affecting interstate commerce."[211]

The U.S. Supreme Court soundly rejected the West Virginia court's reasoning as "both incorrect and inconsistent with clear instruction in the precedents of this Court."[212] Adhering closely to the text of the FAA, the Court expressed that the law contains no exception for personal-injury or wrongful-death claims.[213] Instead, the FAA requires that courts enforce the parties' bargain. Seizing upon language from *Concepcion*, the Court explained that when a state-law defense to enforcement takes aim at arbitration agreements in particular and does not apply to all contracts equally, the rule conflicts with and is preempted by the FAA.[214] The Court held that West Virginia's rule discriminating "against predispute agreements to arbitrate personal-injury or wrongful-death claims against nursing homes is a categorical

rule prohibiting arbitration of a particular type of claim" and is therefore preempted.[215]

Nitro–Lift Technologies, L.L.C. v. Howard. Shortly after deciding *Marmet*, the Court again overturned a state-court ruling that ran afoul of the FAA and the Court's arbitration precedents.[216] *Howard* arose out of an employment dispute in Oklahoma. After two employees left Nitro-Lift Technologies, the company served them with a demand for arbitration in order to enforce a non-compete agreement.[217] When the employees brought suit in state court to avoid enforcement of the contract by arguing the agreement was void under state public policy, Nitro-Lift Technologies moved to compel arbitration.[218]

The case eventually reached the Oklahoma Supreme Court, which ruled U.S. Supreme Court precedent allowed review of the validity of the underlying contract on state-law policy grounds prior to an arbitrator's review of the contract.[219] The court concluded that an "exhaustive" review of Supreme Court opinions showed that the FAA did not bar the court from reviewing the underlying validity of the contract prior to compelling arbitration.[220] And with the arbitration clause serving as no obstacle to judicial review of the agreement, the court declared the contract unenforceable on the ground that the non-compete agreement violated Oklahoma's public policy.[221] In reaching its decision, the state court also concluded that its holding rested on adequate and independent state grounds, undoubtedly in an attempt to insulate its opinion from review by the U.S. Supreme Court.[222]

The Supreme Court reversed, writing that the "Oklahoma Supreme Court's decision disregards this Court's precedents on the FAA," and the state court's conclusion "that, despite this Court's jurisprudence, the underlying contract's validity is purely a matter of state law for state-court determination

is all the more reason for this Court to assert jurisdiction."[223] In a pointed opinion, the Court expressed that its precedent examining the FAA "forecloses precisely this type of 'judicial hostility towards arbitration.'" It explained that "when parties commit to arbitrate contractual disputes, it is a mainstay of the Act's substantive law that attacks on the validity of the contract, as distinct from attacks on the validity of the arbitration clause itself, are to be resolved 'by the arbitrator in the first instance, not by a federal or state court.'"[224] Because the state court found the contract at issue contained a valid arbitration clause subject to no valid defense under the FAA, the state court impermissibly assumed the role of the arbitrator by passing upon the validity of the contract in the first instance.[225]

3. Natural Gas

ONEOK, Inc. v. Learjet, Inc. The only preemption case in the Supreme Court's October 2014 term addressed a conflict between the Natural Gas Act ("NGA") and a set of state-law price-fixing class-action lawsuits.[226] Learjet and other entities that purchased natural gas directly from interstate pipelines sued ONEOK and other defendants under state antitrust laws, alleging that the companies illegally manipulated natural gas prices. Petitioner ONEOK argued that by passing the NGA, Congress intended to occupy the field of natural gas regulation, and thus Learjet's suit was preempted under the doctrine of field preemption.

The federal district court granted the Petitioner's motion to dismiss on preemption grounds, but the Ninth Circuit reversed on appeal. The Supreme Court granted *certiorari*.

Justice Breyer, writing for five other justices, acknowledged at the outset that previous Court decisions held that through the NGA, Congress "occupied the field of matters relating to wholesale sales and transportation of

natural gas in interstate commerce."[227] Those decisions recognized a bright line between federal regulation of wholesale natural gas, which crossed state lines, by the Federal Energy Regulatory Commission ("FERC"), and retail gas sales, which occurred entirely within states and were thus subject to state control.

The challenge for the Court in *ONEOK* was that the Petitioner's allegedly anticompetitive behavior affected not just wholesale prices, however, but also retail prices. Congress crafted the NGA, Justice Breyer wrote, "with meticulous regard for the continued exercise of state power,"[228] such as the use of "common law and statutory remedies against monopolies and unfair business practices."[229] In response to the argument of Petitioners and the dissenting justices that the Court provide a "clear division between areas of state and federal authority," Justice Breyer stated, "[T]hat Platonic ideal does not describe the natural gas regulatory world."[230]

Of particular relevance to this survey of broader preemption trends, Justice Breyer noted that ONEOK and the Solicitor General of the United States, in its *amicus* brief, urged the Court to "defer to FERC's determination that field pre-emption bars the respondents' claims."[231] Justice Breyer responded that "they have not pointed to a specific FERC determination that state antitrust claims fall within the field pre-empted by the Natural Gas Act," and the Court would thus accord no weight to the agency's opinion.[232]

4. Rail Transportation

Kurns v. Railroad Friction Products Corp. *Kurns* addressed the scope and application of field preemption in the locomotive industry.[233] A former railroad employee sued a number of corporations for exposure to asbestos, alleging state-law defective-design and failure-to-warn claims.[234] The

companies moved for summary judgment, arguing that the Locomotive Inspection Act ("LIA") preempted the plaintiff's claims. The LIA, the company alleged, occupied the entire field of locomotive equipment regulation leaving no room for state law obligations.[235] The federal appellate court affirmed.[236]

The Supreme Court also affirmed. The opinion relied on a prior case, *Napier v. Atlantic Coast Line Railroad Co.*,[237] in which the Court held that the LIA's broad conferral of regulatory power over locomotive equipment to the Interstate Commerce Commission preempted the field.[238] The Court viewed the scope of field preemption as based not on the objective of the legislation as sought by Congress, but rather on the physical elements affected by the federal scheme.[239] Because the state and federal laws were both directed at locomotive equipment, the state law was field preempted.[240]

The Court explained that *Napier* held that by passing the LIA, Congress manifested its intention to occupy the entire field of locomotive equipment regulation.[241] Napier attempted to evade field preemption by arguing that because the LIA specifically regulated *manufacturers* of locomotive parts, but not the common carriers that purchased the parts, the suit was not preempted.[242] The Court explained that such a result would be inconsistent with its preemption precedent; a railroad company's "ability to equip its fleet of locomotives in compliance with federal standards is meaningless if manufacturers are not allowed to produce locomotives and locomotive parts that meet those standards. Petitioners' claims thus do not avoid pre-emption simply because they are aimed at the manufacturers of locomotives and locomotive parts."[243]

5. Motor Transportation

Williamson v. Mazda Motor of America, Inc. In *Williamson*, the Court considered whether the National Traffic and Motor Vehicle Safety Act regulation that requires vehicles to install either lap only or lap-and-shoulder belts on rear inner seats preempts a state-tort lawsuit alleging that the manufacturer should have installed lap-and-shoulder belts in the rear inner seat.[244] This case arose when Thanh Williamson, a passenger sitting in the rear aisle of a 1993 Mazda minivan, died in a head-on collision. The deceased was wearing a lap-only belt. The family sued Mazda, alleging that it should have installed lap-and-shoulder belts on rear aisle seats.[245]

The California trial court held that Federal Motor Vehicle Safety Standard 208 ("FMVSS 208") preempted the tort claim.[246] The California Court of Appeal affirmed, relying on *Geier v. American Honda Motor Company*.[247]

In *Geier*, the U.S. Supreme Court addressed whether a different portion of the FMVSS 208—one that required manufacturers to install passive-restraint devices—preempted a state-tort lawsuit for failing to install airbags.[248] Justice Breyer, writing for a five-justice majority, utilized a three-step preemption analysis. The majority first examined whether the federal law's express preemption provision preempts state-tort suits. It held that despite the express provision, the Safety Act's savings clause, which dictated that the law "does not exempt a person from liability at common law," left room for state lawsuits.[249] The Court then asked whether ordinary preemption principles could prevent state-tort suits despite the Safety Act's savings clause. It held that nothing in the clause "suggest[ed] an intent to save state-law tort actions that conflict with a federal regulation."[250] Finally, the Court assessed whether under ordinary

preemption principles, the state suit was an obstacle to the federal law's objectives and thus preempted.

On that final point, the Court held that state common law was an obstacle to the accomplishment of the federal regulatory objective, which offered manufacturers a *choice* to install any of several different restraint devices.[251]

The Supreme Court granted *certiorari* in *Williamson* and unanimously reversed the California Court of Appeal. It held that the federal safety standard did not preempt the state lawsuit because, unlike in *Geier*, choice was *not* a significant regulatory objective regarding a manufacturer's duty to install belts.[252] The Court noted that even though FMVSS 208 contained an express preemption clause, it also contained a savings clause dictating that compliance with a safety standard did not exempt a person from state common-law liability.[253] The savings clause did not foreclose or limit the operation of ordinary preemption principles.

In reaching its conclusion, the Court examined the federal regulation, its history, and its objectives. In 1984, the Department of Transportation ("DOT") rejected a regulation that would have required lap-and-shoulder belts in rear seats.[254] By 1989, however, several factors had changed and the DOT required lap-and-shoulder belts for rear outer seats. As to rear inner seats, manufacturers retained the choice of which type of belt to install. The 1989 rationale for granting manufacturers a choice, however, differed considerably from 1984. By 1989, the DOT was not concerned about consumer acceptance or safety—it was certain that lap-and-shoulder belts would be more effective. Rather, the DOT was concerned that such a belt requirement for rear inner seats would not be cost-effective and could raise design issues. That said, the DOT encouraged the use of lap-and-shoulder belts in rear inner seats where possible.

With this in mind, the Supreme Court found that even though the state-tort lawsuit restricted the manufacturer's choice, it did not, as it had in *Geier*, stand as an obstacle to the accomplishment of the regulation's objective, safety.[255] Furthermore, the Court pointed out that state-tort law does not conflict with a federal minimum standard merely because state law imposes a more stringent requirement, particularly where it has not been determined that the availability of options is necessary to promote safety.[256]

In a concurring opinion, Justice Sotomayor emphasized that "[a] link between a regulatory objective and the need for manufacturer choice to achieve that objective is the lynchpin of implied preemption when there is a savings clause."[257] *Williamson* stands for the proposition that courts should find preemption in cases involving auto safety regulations when there is evidence that achievement of the agency's regulatory objective is dependent on the manufacturer having a choice. That was the case in *Geier*, where the FMVSS 208 deliberately sought to give manufacturers a choice of passive-restraint devices.

6. Immigration

Arizona v. United States. This case involved an Arizona statute, S.B. 1070, enacted in response to an increase in illegal-alien border crossings.[258] The federal government sought to enjoin the law prior to its taking effect, arguing that federal immigration laws impliedly preempted S.B. 1070.[259]

The federal district court agreed, concluding four of the statute's provisions were preempted: (1) Section 3, which made noncompliance with a federal alien-registration requirement a state misdemeanor; (2) Section 5(C), which made an alien's seeking or engaging in work a misdemeanor; (3) Section 6, which gave local and state officers the right to

arrest without a warrant when the officer has probable cause to believe that the person has committed a "public offense," rendering the person removable from the United States; and (4) Section 2(B), which required officers to verify a person's immigration status, under certain circumstances, when conducting a stop, detention, or arrest.[260]

The Supreme Court, with Justice Kennedy writing for the majority, affirmed in part and reversed in part.[261] The majority reasoned that federal law impliedly preempted the first three provisions, but the Court reserved ruling on the fourth provision until it went into effect and Arizona state courts had a chance to construe the provision.

The Court prefaced its preemption analysis by expressing that the federal government has broad power over immigration and the status of aliens.[262] The Court further explained that the scheme Congress designed is extensive and complex, and that control over aliens touches upon the United States' relationship with foreign nations.[263] The Court then addressed whether the four sections of the Arizona statute were preempted.[264]

The Court first examined § 3—which made noncompliance with a federal alien-registration requirement a state misdemeanor—and concluded that Arizona had intruded upon an exclusively federal field of regulation.[265] The Court explained that states can neither "curtail" nor "compl[e]ment" the federal scheme, and are prohibited from passing rules that would "enforce additional or auxiliary regulations."[266] It wrote further, "Were § 3 to come into force, the State would have the power to bring criminal charges against individuals for violating a federal law even in circumstances where federal officials in charge of the comprehensive scheme determine that prosecution would frustrate federal policies."[267] Because "[p]ermitting the State to impose its own penalties for the federal offenses here

would conflict with the careful framework Congress adopted," the intruding section of the Arizona law was impliedly preempted.[268]

The Court then turned to the second provision, § 5(c), which made an alien's seeking or engaging in work a misdemeanor. It held that the rule obstructed the federal scheme created to regulate illegal aliens.[269] The Court again noted, "Congress enacted IRCA as a comprehensive framework for 'combating the employment of illegal aliens,'" and that "the legislative background of IRCA underscores the fact that Congress made a deliberate choice not to impose criminal penalties on aliens who seek, or engage in, unauthorized employment."[270] As a result, allowing states to impose criminal penalties for acts that Congress decided not to punish would create a direct conflict with and stand as an obstacle to federal law.[271]

For similar reasons the Court concluded that the third section at issue, § 6—which gave local and state officers the right to arrest without a warrant when the officer has probable cause to believe that the person has committed a "public offense," making the person removable from the United States—would create an obstacle to federal law.[272] The provision conflicted with the federal scheme under which illegal aliens could only be arrested, for example, when the Attorney General issues a warrant or when an alien is likely to escape before a warrant may be approved.[273] "By authorizing state officers to decide whether an alien should be detained for being removable, the Court held, § 6 violates the principle that the removal process is entrusted to the discretion of the Federal Government."[274]

Finally, the Court turned to § 2(B) of the Act—which requires state officers to verify a person's immigration status, under certain circumstances, when conducting a stop, detention, or arrest. The Court concluded that it would be

premature to pass judgment on this section before the Arizona state courts decided the rule's scope.[275]

IV.

TRENDS IN PREEMPTION

As the review of cases in Section III of this Monograph documents, the Supreme Court has not provided a consistent, predictable preemption jurisprudence over the past decade. Despite this, several trends are emerging that may shape the Court's evaluation of federal preemption arguments and impact the substantive law in the coming years.

A. The Future of Textualism

As some commentators have noted, "the textualist underpinnings of Justice Thomas's approach to preemption, while having not yet gained consistent adherents in preemption cases, have become increasingly influential (though not entirely dominant) on the Supreme Court in other settings."[276] And in the context of preemption, Justice Thomas seems to have persuaded the Chief Justice and Justices Scalia and Alito, and whether he will ultimately convince other justices (*e.g.*, Justice Kennedy) is an open question that may be answered before long. Notably, however, Justice Thomas authored a lone concurrence in *ONEOK*, agreeing with the outcome of the case but reiterating his view that "implied pre-emption doctrines that wander far from the statutory text are inconsistent with the Constitution."[277]

What is evident is that textualist approaches to statutory interpretation are on the rise in non-preemption contexts, and there is some suggestion (*e.g.*, *Mensing*) that in the

coming years this same approach will find majority support in the context of preemption problem solving.

B. Increasing Conflict over the "Presumption Against Preemption"

The Court's application of the presumption against preemption has been attacked for more than a decade as inconsistent with the express language of the Supremacy Clause, and therefore invalid. And in 2011, a plurality of the Court articulated those criticisms in *Mensing*.[278] Although Justice Thomas wrote the opinion for the majority, he was only able to secure a plurality of the Court to join the portion of the opinion where he articulated an interpretation of the Supremacy Clause that suggests that the presumption against preemption is contrary to the express language of the Supremacy Clause. The argument set forth by Justice Thomas was first articulated by Professor Caleb Nelson in an influential article published in the Virginia Law Review in 2000.[279] Justice Thomas explained as follows:

> [T]he text of the Clause—that federal law shall be supreme, 'any Thing in the Constitution or Laws of any State to the Contrary notwithstanding'—plainly contemplates conflict pre-emption by describing federal law as effectively repealing contrary state law. The phrase "any State [law] to the Contrary notwithstanding' is a *non obstante* provision. Eighteenth-century legislatures used *non obstante* provisions to specify the degree to which a new statute was meant to repeal older, potentially conflicting statutes in the same field. A *non obstante* provision 'in a new statute acknowledged that the statute might contradict prior law and instructed courts not to apply the general presumption against implied repeals.' The *non obstante* provision in the Supremacy Clause therefore suggests that federal law should

> be understood to impliedly repeal conflicting state law.[280]
>
> Further, the provision suggests that courts should not strain to find ways to reconcile federal law with seemingly conflicting state law. Traditionally, courts went to great lengths attempting to harmonize conflicting statutes, in order to avoid implied repeals. A *non obstante* provision thus was a useful way for legislatures to specify that they did not want courts distorting the new law to accommodate the old. The *non obstante* provision of the Supremacy Clause indicates that a court need look no further than "the ordinary meanin[g]" of federal law, and should not distort federal law to accommodate conflicting state law.[281]

More recently, the applicability of the presumption greatly divided the Court in *Arizona v. Inter Tribal Council of Arizona*.[282] Justice Scalia, writing for the majority, concluded that the presumption against preemption does not apply to the power conferred to Congress by the Elections Clause. Although Justice Kennedy concurred in the opinion, he wrote separately to criticize the majority's view that the presumption does not apply in that situation. He emphasized that, whether a federal statute concerns congressional regulation of elections or any other subject, "a court must not lightly infer a congressional directive to negate the States' otherwise proper exercise of their sovereign power."

Justice Alito wrote a separate dissent to emphasize his belief that the presumption against preemption "applies with full force" in this case. In his view, the best reading of the National Voter Registration Act "is that the States need not treat the federal form as a complete voter registration application."

Interestingly, although Justice Thomas is critical of the court-created presumption against presumption, he dissented

in *Intertribal Council of Arizona* because he thought that both the plain text and the history of the Voter Qualifications Clause, as well as the Seventeenth Amendment, authorize states to determine the qualifications for voters in federal elections, which necessarily includes the power to determine whether those qualifications are satisfied. Justice Thomas would construe the law as only requiring Arizona to accept and use the Federal Form as part of its voter registration process, leaving the state free to request any additional information it deems necessary.

C. The Increasing Role of Agencies in Preemption

The Court's recognition and acceptance of the growing role of agencies in the field of preemption was illustrated in *Williamson*.[283] In that case, the majority primarily based its holding that a federal safety regulation did not preempt a state-tort law on "the promulgating agency's contemporaneous explanation of its objectives, and the agency's current views on the regulations' pre-emptive effect."[284] Despite the apparent weight given to the agency's interpretation, when the Court released its opinion it came against the backdrop of hesitation from some justices regarding agency preemption, which manifested itself, as discussed previously, in *Levine*.[285] Those decisions could reflect the beginning of a trend where the Court performs more thorough analysis of agencies' statutory interpretations.

That trend is also occurring in the context of an Obama Administration initiative meant to frustrate agency actions that advance federal preemption. President Obama issued a Memorandum for the Heads of Executive Departments and Agencies on May 20, 2009.[286] In this declaration, the President sought to clarify the general policy shift of the Administration, "that preemption of State law by executive

departments and agencies should be undertaken only with full consideration of the legitimate prerogatives of the State and with a sufficient legal basis for preemption."[287] The order directed the heads of departments and agencies to refrain from including in regulatory preambles preemptive language unless such provisions already exist in the codified regulation or would be justified under the current principles governing preemption, "including principles outlined in the Executive order 13132."[288]

Moreover, where such preemptive language had previously been issued, a comprehensive, retroactive, ten-year review was to be conducted to ensure the preemptive language did not run afoul of the current application of the preemption principle, and where it does, the language would have to be amended as necessary.[289] This executive action was not simply a display of authority, but prompted serious internal review and has had wide-ranging effect on preemption policy within the agencies.[290]

As one commentator has noted, with federal agencies playing a more overt role in statutory interpretation and by default preemption analysis, "[t]his shift in institutional power has the potential to reshape the preemption landscape, by directing efforts away from Congress and the courts and toward the administrative rulemaking process within federal agencies."[291] And as such, a stakeholder "with [a] vested interest[] in preemption disputes"[292] cannot ignore the preemptive rulemaking process within federal agencies.

The Court's most recent preemption decision, *ONEOK*, offers one important point of guidance for such stakeholders when seeking support in agency pronouncements. While Justice Breyer did not express aversion to the value of agency statements on preemption, he indicated that such statements must be quite specific for them to have an impact on preemption conflicts. The federal agency at issue, FERC, had

merely "promulgated detailed rules governing manipulation of price indices."[293] What would have been more compelling was a document that Justice Breyer noted the Petitoners did not reference: "[T]hey have not pointed to a specific FERC determination that state antitrust claims fall within the field pre-empted by the Natural Gas Act."[294]

The bottom line is that federal agencies will continue to play an increasingly important role in the Court's preemption analysis. The scope of their role will be governed, in part, by the administration in office but mostly, by the level of allegiance that the Court gives to textualist concepts of statutory construction—which in recent years has been inconsistent and not as widely adopted in preemption analysis as in other contexts of statutory construction.

D. Effect of the Supreme Court's Pharmaceutical Triad

The Court's three most significant cases on brand and generic prescription drugs in recent years—*Wyeth*, *Mensing*, and *Bartlett*—have had a marked impact on the drug liability landscape. Ultimately, a defendant can successfully invoke preemption if a plaintiff pursues defect claims based on a state-law duty to change the composition of a generic drug or to warn of greater risks on its label. However, even after *Wyeth*, *Mensing*, and *Bartlett*, some questions remain and the preemption jurisprudence on pharmaceuticals continues to evolve.

For example, a recent decision from the U.S. Court of Appeals for the First Circuit held that preemption continued to be a viable defense for brand drugs, despite the Court's holding in *Wyeth*, given the circumstances of the case. The case is *In re: Celexa and Lexapro Marketing and Sales Practices Litigation*,[295] which involved allegations that Lexapro's FDA-approved label overestimated the drug's

effectiveness, thereby violating California consumer protection laws.[296] In *Wyeth*, the Court had rejected preemption because the manufacturer had a duty under the CBE regulation to fortify the warning once the manufacturer was aware of the risk. Despite the fact that *In re Lexapro* also involved a brand-name drug, and thus invoked the CBE regulation, the First Circuit concluded that because the manufacturer did not have "newly acquired information" that would have allowed it to independently alter its label, the plaintiff's claims were preempted by the FDCA.[297] The First Circuit's analysis and ultimate holding suggests that branded-drug preemption is not quite as settled as some commentators and courts have suggested.

Another related question that remained following *Wyeth*, *Mensing*, and *Bartlett* was whether a brand-name drug company could be held liable for harm allegedly caused by a generic company's drug due to the brand-name company's failure to change the warning label. The U.S. Court of Appeals for the Sixth Circuit addressed that issue in *Strayhorn v. Wyeth Pharmaceuticals, Inc.*[298] The court concluded that brand-drug companies could not be held liable for harm caused by generic drugs. The appeal arose out of the consolidation of seven cases filed against the manufacturers of the drug Reglan and its generic equivalent, metoclopramide.[299] The plaintiffs alleged that generic metoclopramide caused them to develop the movement disorder tardive dyskinesia.[300] The district court dismissed plaintiffs' claims against both the generic and brand manufacturers.[301]

The Sixth Circuit affirmed the lower court's dismissal of claims against the generic defendants based on *Mensing* and *Bartlett*.[302] Applying the framework established by *Mensing* and extended by *Bartlett*, the Sixth Circuit held that the plaintiffs' state-law failure-to-warn claims were preempted

by the federal scheme governing generic drugs.[303] The Court explained:

> To the extent that the plaintiffs allege that the Generic Manufacturers should have unilaterally changed the label to reflect any danger posed by long-term use of the drug, this claim is clearly preempted. And to the extent that the plaintiffs allege that the drug itself should have been modified to conform to the properties described in the label, generic manufacturers are prohibited by their federal duty of sameness from designing their drugs differently. . . .[304]

In light of plaintiffs' concession that their design-defect claims did not survive *Bartlett*, the Sixth Circuit concluded that the reasoning of *Mensing* preempted plaintiffs' argument that the generic drug manufacturers should have warned of greater health risks associated with their product.[305]

The Sixth Circuit then examined whether a brand manufacturer may be held liable for providing inadequate warnings that generic manufacturers were then foreseeably obligated to use.[306] The court explained that state law governed the plaintiffs' claims against the brand companies, and those laws required that defendants' product actually injure the plaintiffs.[307] And since plaintiffs had taken the *generic* version of the drug, the brand-name manufacturer's product did not cause the harm and it could not be liable.

Two subsequent cases—one from of the Alabama Supreme Court and another from an Illinois federal district court—rejected the approach of the Sixth Circuit, and virtually every other court,[308] that has addressed the "innovator liability" theory.[309]

In *Wyeth, Inc. v. Weeks*,[310] the Alabama Supreme Court held that a branded drugmaker may be liable for fraud and/or

misrepresentation for injuries sustained when a person takes a generic version of the brand drug in question.[311] In this case, a long-time user of the generic form of Reglan alleged the defendant brand manufacturer misled the physician who prescribed a generic form of the drug about the likelihood that the drug would cause tardive dyskinesia.[312] The court noted that under the Hatch-Waxman Act, the brand manufacturer is responsible for the accuracy and adequacy of its label, which the generic manufacturer is required to use, without alteration.[313] As a result of this framework, brand-name manufacturers could reasonably foresee that a physician prescribing a branded drug to a patient would rely on the warnings drafted by the brand manufacturer even if the patient ultimately consumed the generic version of the drug.[314] Accordingly, in the context of inadequate warnings, the court ruled that "it is not fundamentally unfair to hold the brand manufacturer liable for warnings on a product it did not produce because the manufacturing process is irrelevant to misrepresentation theories based . . . on information and warning deficiencies, when those alleged misrepresentations were drafted by the brand-name manufacturer and merely repeated . . . by the generic manufacturer."[315] The court claimed, however, that it was not "creating a new tort of innovator liability," given that the ruling applied only to brand-name and generic manufacturers who have a "unique relationship."[316]

The Alabama legislature passed a law in April 2015 that effectively overrules the decision. Alabama Act No. 2015-106, signed by the governor on May 1, 2015, expressly states that manufacturers are not liable for injuries resulting from products they did not design, manufacture, sell, or lease.

Likewise, in *Dolin v. SmithKline Beecham Corp.*,[317] a federal district court in Illinois held that a brand-name drug manufacturer owed a duty of care to a patient who took the generic version of its drug. The plaintiff's widow filed a

wrongful death action against GlaxoSmithKline ("GSK"), and the generic manufacturer, Mylan, alleging that GSK failed to warn patients that the active ingredient in Paxil®, paroxetine, carried a greater risk of adult suicide. The court determined that GSK owed a duty to an individual taking the generic brand of its name-brand counterpart because, under the Hatch-Waxman Act, Mylan was compelled to use identical warning labels as its brand-name counterpart.[318]

As these recent cases make clear, despite the Supreme Court's pronouncements with respect to preemption, the scope and application of the Court's rulings are far from certain. In the coming years, these issues will make their way back to the Court for clarification. In the meantime, practitioners should not assume that any particular door has closed with respect to preemption; the story continues to unfold.

E. Distinctions in Immigration Preemption

The Court's decisions over the past several terms related to major immigration disputes reflect the difference between the Court's preemption analysis when the federal scheme at issue touches upon an area that is historically one of state domain, as in *Chamber of Commerce of the U.S. v. Whiting*, or federal schemes that regulate areas that are exclusively federal, as in *Arizona v. United States*.

In *Whiting*, the justices had to decide whether the federal immigration scheme barred states from revoking business licenses based on the hiring of aliens. Deciding that the state law at issue was not within the reach of the federal scheme based, in part, on the express carve-out for such state regulation in the federal statute, the Court also set the stage for its conclusion by noting at the outset of the opinion:

> The power to regulate immigration is unquestionably ... a federal power. At the same time ... the States possess broad authority under their police powers to regulate the employment relationship to protect workers within the State ... [P]rohibit[ing] the knowing employment ... of persons not entitled to lawful residence in the United States, let alone to work here, is certainly within the mainstream of [the State's] police power...[319]

As a result of the area at issue being a matter of historic state concern, the Court was able to distinguish cases offered by the Chamber of Commerce where preemption was found as "all involv[ing] uniquely federal areas of regulation."[320] And the Court ultimately allowed the state law to stand.[321]

In stark contrast, the Court's decision in *Arizona* pertained to an area that is a matter of exclusive federal concern. The Court explained:

> The Government of the United States has broad, undoubted power over the subject of immigration and the status of aliens. This authority rests, in part, on the National Government's constitutional power to 'establish an uniform Rule of Naturalization,' U.S. Const., Art. I, § 8, cl. 4, and its inherent power as sovereign to control and conduct relations with foreign nations.[322]

Though the Court also noted that the "[t]he pervasiveness of federal regulation does not diminish the *importance* of immigration policy to the States," the Court found few of the provisions at issue as implicating the historic police power of the state.[323] As a direct result of these background principles, the Court held that all but one of the Arizona statutory provisions at issue was preempted by the federal scheme.[324]

These cases teach that practitioners would be wise to frame their case as one involving a "historic power of the state" if seeking to shield it from preemption, and conversely for those seeking to wield the preemptive effect of federal law, that the area at issue involves unique and historically exclusively federal concerns.

F. What's Left in Arbitration Preemption?

The willingness of the Supreme Court to accept a relatively large number of arbitration cases can be traced to the very reason the Supremacy Clause exists—inconsistent state-court decisions in an area where Congress sought uniformity and predictability through the FAA. In an effort to assure these ends, the Court's decisions teach a number of lessons.

First, the Court has defined the purposes and objectives of the FAA broadly, which affords the justices a wide degree of latitude when determining whether the FAA preempts a state-law rule. Looking past the plain terms of the FAA, the Court has decided that the Act has twin aims: "enforcement of private agreements and encouragement of efficient and speedy dispute resolution."[325] Of course, the FAA preempts state law through "purposes and objectives" conflict preemption; where the state law at issue, whether statutory or common law, negatively effects either of these ends, the state law is preempted. By defining and adhering to these purposes and objectives, the Court has been able to wield extensive preemptive power. Not only do these ends allow the Court to extinguish any attempts by state courts to create an obstacle to a party's attempt to compel arbitration,[326] they also allow for the rejection of any state-law rules that negatively impact the scope and nature of arbitration proceedings themselves.

Second, any rule that directly and explicitly takes aim at arbitration clauses will be deemed preempted. Recently, the Court has provided extensive, nuanced analysis on why the FAA preempts certain state laws, but the justices have also established a bright-line rule that state laws aimed only at preventing enforcement of arbitration clauses are preempted. In a rare *per curiam* opinion evincing the deep, universal support of arbitration among the justices, the Court expressed once again that "[w]hen state law prohibits outright the arbitration of a particular type of claim, the analysis is straightforward: The conflicting rule is displaced by the FAA."[327]

Third, the justices are eager to assure that arbitrators, and not state courts, are responsible for determining in the first instance whether a contract containing an arbitration clause should be void under *sui generis* state-law policy defenses. There are many reasons for the rule. In certain instances a unique state-law defense that allows for invalidation of a contract—for instance a rule barring the use of pre-dispute arbitration clauses for tort actions against retirement homes—may be more likely enforced by a judge of the state where the action is brought. The parties' bargain to ensure arbitration reflects that reality, as does the Supreme Court's precedent. The Court's recent decisions affirm the now well-established principle that "it is a mainstay of the Act's substantive law that attacks on the validity of the contract, as distinct from attacks on the validity of the arbitration clause itself, are to be resolved 'by the arbitrator in the first instance, not by a federal or state court.'"[328] The Court has thus strengthened the right of parties to arbitrate their dispute by avoiding state court invalidation of contracts on *sui generis* state policy grounds at the initial stage of compelling arbitration.

The Court's preemption cases in the arbitration field have evinced a strong preference for enforcing arbitration

agreements over state-law obstacles. Yet, the bright-line rules the Court has created have left some unanswered questions that lower courts, and likely the Court itself, will eventually have to resolve.

One of the most significant issues left unsettled is whether, and to what extent, state courts or legislatures can fashion a rule that applies equally to all contracts while having an obvious impact on arbitration clauses in particular. On the one hand, the Court has made clear that where a "state law prohibits outright the arbitration of a particular type of claim . . . [t]he conflicting rule is displaced by the FAA."[329] Where a state-law rule is directed at invalidating arbitration clauses in particular and not applicable to all contracts generally, the state-law rule is preempted.[330] On the other hand, where the rule at issue applies to all contracts equally, the preemptive effect of the FAA becomes more uncertain.

It was reasonably clear in *Concepcion*, for instance, why the FAA preempted a state-law rule ostensibly barring the use of class-action waivers in arbitration clauses even when the law applied to all contracts.[331] The question before the Court was "whether § 2 preempts California's rule classifying *most collective-arbitration waivers* in consumer contracts as unconscionable," where "[i]n practice . . . the rule would have a disproportionate impact on arbitration agreements."[332] The Court therefore *did not* address whether and to what extent the FAA preempted *ex post* state-law defenses to enforcement of certain arbitration clauses. As the Court explained:

> Although the [California] rule does not *require* classwide arbitration, it allows any party to a consumer contract to demand it *ex post*. The rule is limited to adhesion contracts, but the times in which consumer contracts were anything other than adhesive are long past. The rule also requires that damages be predictably small, and that the

> consumer allege a scheme to cheat consumers. The former requirement, however, is toothless and malleable (the Ninth Circuit has held that damages of $4,000 are sufficiently small), and the latter has no limiting effect, as all that is required is an allegation.[333]

Thus, the California rule at issue worked to extinguish, for the most post, the enforceability of arbitration agreements including class waivers where the plaintiff wishes to pursue a mass action. What would have been the outcome of the case had the damage element of California's rule been $1,000 and nothing more? Would clearer, less malleable boundaries have repelled AT&T's preemptive challenge by creating more consistency, predictability, and assurances that the exception to enforcement does not swallow the general rule that agreements to arbitrate must be respected? Though unanswered by the Court in *Concepcion*, the Court may address in a more clear fashion under what circumstances a generally-applicable defense to contract formation will be enforced despite obvious impacts on arbitration agreements, now that it has granted *certiorari* in *Imburgia v. DirecTV*, [334] a case involving class-action waiver in California. In *Imburgia*, the plaintiff filed a class-action complaint against DirecTV alleging that DirecTV improperly charged early termination fees to its customers.[335] The company has an arbitration provision in its contract, which includes a class waiver. The provision stated that if class arbitration procedures are deemed unenforceable under the "law of the state," then that section would be invalid.[336] The next provision of the agreement, however, stated that the class-arbitration provision shall be governed by the FAA.[337] Prior to the decision in the case, the Ninth Circuit decided *Murphy v. DirecTV, Inc.*,[338] in which the court held that a similar arbitration provision waiving class-action procedures was enforceable under *Concepcion*, preempting any state law to the contrary.

The California Court of Appeal rejected the Ninth Circuit's opinion in *Murphy* and determined that DirecTV's arbitration class waiver was unenforceable under California law without considering the preemptive effect of the FAA.[339] The California court reasoned under the law of contracts that the contract's provisions in question created ambiguity and inconsistency, justifying the application of California law.[340] The Supreme Court will now weigh in, and hopefully provide some clarity to this body of law.

CONCLUSION

As our economy becomes more complex and Congress continues to struggle with crafting broad federal regulatory schemes that impact states' regulatory authority, preemption jurisprudence will continue to evolve to address the needs of our modern federal republic. Although over the course of the last decade the Court's preemption jurisprudence has been inconsistent, the stage is set for a renaissance in the Court's interpretation and application of the preemption doctrine within our federal system.

The Court's decisions over the last decade reveal an intellectual tug-of-war among the justices, which promises to bring new ideas and conceptual tools into the preemption analysis. And while these developments are intellectually interesting and important to the framework of our federal system, the Court's lack of predictability in preemption jurisprudence will continue to frustrate the marketplace and legal practitioners eager for certainty.

APPENDIX:

Additional Implied Preemption Cases

Below are summaries of Supreme Court rulings decided during the past eight years which, though they arose within areas of regulation unrelated to business litigation, are still notable.

Hillman v. Maretta (Federal Employees' Group Life Insurance)

In *Hillman*, the Supreme Court considered whether a Virginia statute conflicts with the Federal Employees' Group Life Insurance Act of 1954 ("FEGLIA") to the extent that the Virginia statute revokes a former spouse's beneficiary designation in a life insurance policy.[341]

Congress enacted FEGLIA to offer low-cost group-life insurance to federal employees. FEGLIA provides that life insurance benefits from a FEGLIA policy shall be paid in a specified order of precedence—first, to the beneficiary designated by the policyholder in a signed and witnessed document. In 1998, Congress amended FEGLIA to create a limited exception, which provides that benefits will be paid to another person if and to the extent expressly provided for in the terms of a divorce or separation decree, so long as it is received before the employee dies.[342] FEGLIA also contains an express preemption provision.

Section 20-111.1(A) ("Section A") of the Virginia Code provides that a divorce or annulment revokes a beneficiary designation in a then-existing policy for death benefits. If a subsequent federal law preempts Section A, Section 20-111.1(D) ("Section D") of the Virginia Code applies. Section D creates a cause of action for the individual who would have received benefits had Section A continued in effect against a former spouse for the principal amount of the insurance proceeds.

The Petitioner's husband, Warren Hillman, designated his first wife, Judy Maretta, as the beneficiary of his FEGLIA policy. The marriage ended in divorce and Mr. Hillman remarried but failed to

change the beneficiary designation on his life insurance policy. Upon Mr. Hillman's death, his widow attempted to claim the benefits under her husband's policy. Her claim was denied, and Ms. Maretta, the named beneficiary received the benefits. Mrs. Hillman sued Ms. Maretta in Virginia state court under Section D for the full amount of death benefits.

The state court rejected Ms. Maretta's federal preemption argument and granted summary judgment for Mrs. Hillman. The Virginia Supreme Court reversed, finding that FEGLIA preempts Section D because it "stand[s] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[343]

The U.S. Supreme Court affirmed. Writing for a unanimous Court, Justice Sotomayor utilized a conflict preemption analysis, which requires consideration of the federal law's purpose.[344] Her opinion drew upon two previous preemption cases with similar issues and statutes.[345] The laws considered in those cases, like FEGLIA, gave priority to the named beneficiary.[346] In each case, the Court had found that the federal law preempted the conflicting state law. Justice Sotomayor concluded that Virginia's Section D interferes with Congress' federal regulatory scheme because "it directs that the proceeds actually 'belong' to someone other than the named beneficiary by creating a cause of action for their recovery by a third party."[347]

WOS v. E.M.A. (Federal Medicaid)

In *WOS*, the Supreme Court considered a conflict between an anti-lien provision of the federal Medicaid statute and a North Carolina law that grants the state a claim on a Medicaid recipient's malpractice damages.[348] Under the North Carolina law, the North Carolina Department of Health and Human Services ("NCDHHS") has a right to recover either the total amount the state spent on the patient's health care or one-third of the patient's recovery payment, whichever is less.[349] Section 1396p(a)(1) of the federal Medicaid law preempts a state's effort to take any portion of a Medicaid beneficiary's tort judgment or settlement not "designated as payments for medical care."[350]

North Carolina's Medicaid program paid for part of the minor plaintiff's ongoing medical care needed after she suffered serious injuries during childbirth. Her parents and guardian (collectively "E.M.A.") sued the physicians who performed the delivery for medical malpractice and the case settled for $2.8 million. The NCDHHS placed a lien on the plaintiff's settlement.

E.M.A. brought suit in federal court against the NCDHHS, claiming that the federal Medicaid law prevents the NCDHHS from taking her proceeds. The district court rejected E.M.A.'s preemption argument and dismissed the claim. The Fourth Circuit vacated the district court's decision and remanded.[351]

The Supreme Court granted *certiorari* and held that the federal anti-lien provision preempts North Carolina's irrebuttable statutory presumption that one-third of a tort recovery is attributable to medical expenses. The Court explained that a previous decision, *Arkansas Dept. of Health and Human Services v. Ahlborn*,[352] held the Medicaid statute sets both a floor and a ceiling on a state's potential share of a tort recovery and also precludes attaching or encumbering the remainder of any settlement.[353] Federal law requires an assignment to the state for "that portion of a settlement that represents payments for medical care."[354] However, *Ahlborn* did not determine what portion of a settlement necessarily represents payment for medical care.[355]

The Court determined that the North Carolina law is preempted insofar as it would permit the state to take a portion of a Medicaid beneficiary's tort judgment or settlement that is not designated for medical care.[356] It noted that the state law has "no process for determining what portion of a tort recovery is attributable to medical expenses" but that the state has instead picked an arbitrary percentage.[357] The Court found this incompatible with the Medicaid Act's clear mandate that a state may only demand a share that is attributable to medical expenses.[358]

Tarrant Regional Water District v. Herrmann (Water Rights)

In *Herrmann*,[359] the Court addressed whether a provision of the Red River Compact, a congressionally-approved water apportionment agreement, preempts Oklahoma laws that prevent other states from accessing waters allocated by the Compact.

Tarrant Regional Water District ("Tarrant"), a Texas state agency responsible for providing water to north-central Texas, applied to the Oklahoma Water Resources Board (OWRB) for rights to divert water from a tributary of the Red River located in Oklahoma. Anticipating that its request would be denied, Tarrant sought an injunction against the OWRB in federal court, arguing that the Compact preempted Oklahoma water statutes.

The district court granted summary judgment for the OWRB, a decision affirmed by the Tenth Circuit. The Supreme Court granted Tarrant's petition for writ of *certiorari* and held that the Compact does not preempt Oklahoma's water statutes. Justice Sotomayor explained that the ruling turned on an interpretation of the Compact's provision that granted the signatory states "equal rights" to use water from one of the river's tributaries within certain limits. The provision did not mention whether a state could cross state lines to divert water. Tarrant argued that the subsection creates a borderless common in which each state can cross borders to access water, thus conflicting with Oklahoma's statutes preventing such access. The OWRB argued that the provision's silence on cross-border rights indicates the Compact's drafters had no intention to create any such right and therefore does not conflict with Oklahoma law.

Agreeing with the OWRB, the Court analyzed the Compact's silence to mean the drafters did not intend to create cross-border rights. The Court focused on three factors: (1) the well-established principle that states do not easily cede their sovereign powers; (2) the fact that other interstate water compacts have treated cross-border rights explicitly; and (3) the parties' prior course of dealing.

Arizona v. Inter Tribal Council of Arizona (Voting Rights)

The Court addressed whether the National Voter Registration Act of 1993 ("NVRA") preempts Arizona's state-law requirement that officials "reject" the applications of voters who submit the federal registration form unaccompanied by documentary evidence-of citizenship.[360] The NVRA requires states to "accept and use" a uniform federal form to register voters for federal elections. The "Federal Form," created by the Election Assistance Commission ("EAC"), only requires applicants to aver, under penalty of perjury, that they are citizens. In 2004, Arizona enacted a law, Proposition 200, under which voters must present proof of citizenship when they register to vote and present identification when they vote. Respondents, groups of Arizona residents and nonprofit organizations, filed separate suits seeking to enjoin the Arizona law.

The district court consolidated the cases and denied plaintiffs' motions for a preliminary injunction. The Ninth Circuit then enjoined the Arizona law pending appeal. The Supreme Court vacated that order and allowed the impending 2006 election to proceed with the new rules in place. On remand, the Ninth Circuit affirmed the district court's initial denial of a preliminary injunction. The district court then granted Arizona's motion for summary judgment on the claim the NVRA preempts Proposition 200. The Ninth Circuit affirmed in part and reversed in part, holding that Proposition 200's documentary proof of citizenship requirement conflicts with the NVRA's text, structure, and purpose.

The Supreme Court granted *certiorari* and held that Arizona's evidence-of-citizenship requirement, as applied to Federal Form applicants, is preempted by the NVRA's mandate that States "accept and use" the Federal Form. Arizona could, however, request that the EAC include an evidence-of-citizenship requirement among the Federal Form's state-specific instructions.

Justice Scalia emphasized that Congress has the power to regulate elections. The Court has previously held that this power extends to providing regulations relating to registrations. The

question, therefore, was whether Proposition 200's proof-of-citizenship requirement conflicted with the NVRA's mandate that Arizona "accept and use" the Federal Form.

The opinion rejected Arizona's argument that the presumption against preemption should dictate the outcome of the case. The Elections Clause confers the power to preempt, the Court explained. Because Congress, when it acts under this Clause, is always on notice that its action will displace some element of a state's legal regime, the reasonable assumption is that the statutory text accurately communicates Congress's preemptive intent.

Justice Scalia reasoned that the NVRA does not conflict with Arizona's constitutional authority to establish qualifications for voting. The Elections Clause empowers Congress to regulate how elections are held, but not who may vote in them. The NVRA, however, could be read not to preclude a state from obtaining information necessary to enforce voter qualifications. Since the NVRA permits a state to request that the EAC include state-specific instructions on the Federal Form, and may challenge a rejection, no constitutional doubt is raised.

ENDNOTES

[1]U.S. CONST. art. VI.

[2]*Commonwealth of Pennsylvania v. Nelson*, 350 U.S. 497 (1956).

[3]*Id.* at 503 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)) (internal quotations omitted).

[4]*Nelson*, 350 U.S. at 504.

[5]*Id*. at 505.

[6]*Pacific Gas and Electric Co. v. State Energy Resources Conservation & Development Commission*, 461 U.S. 190 (1983).

[7]*Id*. at 204.

[8]*Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

[9]*Cal. Fed. Savings & Loan Ass'n v. Guerra*, 107 S. Ct. 683, 690 (1987).

[10]Interestingly, even though the Court rarely invokes preemption due to "impossibility," that was the basis for the Court's recent holding in *PLIVA v. Mensing*, 131 S. Ct. 2567 (2011), which is discussed in more detail in Part III.

[11]*Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132 (1963).

[12]Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 228 n.15 (2000).

[13]*Hines v. Davidowitz*, 312 U.S. 52 (1941).

[14]*Id*. at 67.

[15]*Ibid*.

[16]*See, e.g., id*. at 74-81.

[17]*Id*. at 75.

[18]*Id*. at 78-79.

[19]*Wyeth v. Levine*, 555 U.S. 555, 601 (2009).

[20]*Ibid*.

[21]*Ibid* (internal citations omitted). Justice Thomas' concerns are undoubtedly based on the growing role that federal agencies are playing in the Court's interpretation of federal statutes. Some commentators have suggested that politics is the reason behind the growing trend within federal agencies to promulgate regulations that provide their own interpretation of the preemptive scope of the laws they are charged with executing; that analysis, however, does not account for the fact that the Court routinely looks to federal agencies' interpretation of statutes when deciding preemption problems. *See* Catherine M. Sharkey, *Inside Agency Preemption*, 110 MICH. L. REV. 521 (2012).

[22]*Levine*, 555 U.S. at 597 (internal citations omitted).

[23]*Id.* at 600.

[24]*Id*. at 583.

[25]*Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

[26]*Id*. at 316.

[27]21 U.S.C. § 360k(a).

[28]*Riegel*, 552 U.S. at 317.

[29]*Id*. at 321-22.

[30]*Id*. at 322. This was different from the medical device at issue in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), where the Court found that a medical device entering the market through § 510(k) of the MDA does not involve so-called "requirements" necessary to invoke the preemption provision.

[31]*Ibid* (quoting 21 U.S.C. § 360k(a)).

[32]*Id*. at 324; *See, e.g., Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005); *Cipollone v. Liggett Group*, *Inc*., 505 U.S. 504 (1992).

[33]*Riegel*, 552 U.S. at 329.

[34]*Cuomon v. The Clearing House Ass'n, L.L.C.*, 557 U.S. 519 (2009).

[35]*Watters v. Wachovia*, 550 U.S. 1 (2007).

[36]*Chadbourne & Parke LLP v. Troice,* 134 S. Ct. 1058, 1062 (2014); 15 U.S.C. § 78bb(f)(1).

[37]15 U.S.C. § 78bb(f)(5)(E), 77r(b)(1).

[38]*Id*. at 1059.

[39]*Ibid*.

[40]*Ibid*.

[41]*Ibid*.

[42]*Id*. at 1062 (emphasis in original).

[43]*Ibid*.

[44]*Id*. at 1066.

[45]*Ibid*.

[46]*Ibid*.

[47]*Ibid*.

[48]*Id*. at 1069.

[49]*Id*. at 1069-70.

[50]*Ibid*.

[51]21 U.S.C. § 601.

[52]*Ibid.* The provision states: "Requirements within the scope of this [Act] with respect to premises, facilities and operations of any establishment at which inspection is provided under . . . this [Act] which are in addition to, or different than those made under this [Act] may not be imposed by any State."

[53]*National Meat Ass'n v. Harris*, 132 S. Ct. 965 (2012).

[54]*Id*. at 971 (citing § 599f(a) of California Laws).

[55]*Id*. at 968-69 (citing 9 CFR § 309-311).

[56]*Id*. at 970.

[57]*Id*. at 973. This argument carried the day at the appellate level, where the Ninth Circuit determined that the California law at issue avoided the scope of the Act "by . . . removing nonambulatory pigs from the slaughtering process." In other words, the Ninth Circuit determined that "states are free to decide which animals may be turned into meat." *Nat'l Meat Ass'n v. Brown*, 599 F. 3d 1093, 1098 (9th Cir. 2010).

[58]*Harris*, 132 S. Ct. at 973.

[59]*POM Wonderful LLC v. Coca-Cola Company*, 134 S. Ct. 2228 (2014).

[60]*Ibid*.

[61]15 U.S.C. § 1125.

[62]21 U.S.C. §§ 321(f), 331.

[63]*POM Wonderful*, 134 S. Ct. at 2234-35.

[64]*Ibid*.

[65]*Ibid*.

[66]*Id*. at 2235-36.

[67]*Ibid*.

[68]*Id*. at 2233.

[69]*Id*. at 2236-37.

[70]*Ibid*.

[71]*Id*. at 2237-39.

[72]*Ibid*.

[73]*Ibid*.

[74]*Ibid*.

[75]*Ibid*.

[76]49 U.S.C. App. § 1301.

[77]49 U.S.C. App. § 1305(a)(1) (emphasis added).

[78]*Morales v. Trans World Airlines, Inc.*, 504 U.S. 374 (1992).

[79]*Id*. at 378.

[80]*Id*. at 379.

[81]*Ibid*.

[82]*Ibid*.

[83]*Id*. at 384.

[84]*Ibid*.

[85]*Ibid*.

[86]*Ibid*.

[87]*American Airlines, Inc. v. Wolens*, 513 U.S. 219 (1995).

[88]*Id*. at 226.

[89]*Id*. at 228.

[90]*Id*. at 226.

[91]*Ibid*.

[92]*Id*. at 240-41.

[93]*Id*. at 241.

[94]*Northwest, Inc. v. Ginsberg*, 134 S. Ct. 1422 (2014).

[95]*Id*. at 1429.

[96]*Id*. at 1430-1431.

[97]49 U.S.C. § 14501(c)(1).

[98]*Rowe v. New Hampshire Motor Transport Ass'n*, 552 U.S. 364 (2008).

[99]*Dan's City Used Cars, Inc. v. Pelky*, 133 S. Ct. 1769 (2013).

[100]*Rowe*, 552 U.S. at 367-69.

[101]*Ibid*.

[102]*Ibid*.

[103]*Id*. at 370 (quoting *Merrill Lynch, Pierce Fenner & Smith, Inc. v. Dabit*, 547 U.S. 71, 85 (2006)).

[104]*Rowe*, 552 U.S. at 370.

[105]*Ibid*.

[106]*Ibid*.

[107]*Id*. at 383-384. *See, e.g.*, *City of Columbus v. Ours Garage and Wrecker Serv., Inc.*, 536 U.S. 424, 440 (2002), where the Court held that the FAAAA did not preempt a particular regulation of a municipality governing tow truck safety because the regulation concerned the "safety regulatory authority of [the] state."

[108]*American Trucking Ass'n, Inc. v. City of Los Angeles*, 133 S. Ct. 2096 (2013).

[109]*Id*. at 2100.

[110]*Ibid*.

[111]*Id*. at 2100-01 (citing 49 U.S.C. § 14501(c)(1)).

[112]*Id*. at 2103.

[113]*Ibid*.

[114]133 S. Ct. 1769 (2013).

[115]*Id*. at 1775.

[116]*Id*. at 1778 (quoting 49 U.S.C. § 14501(c)(1)).

[117]*Id*. at 1778-81.

[118]Section 101(a), 90 Stat. 33. The Act's purpose, as stated in the congressional declaration of policy, was "to provide the means to rehabilitate and maintain the physical facilities, improve the operations and structure, and restore the financial stability of the railway system of the United States."

[119]49 U.S.C. § 11501. Pursuant to the 4-R Act, states cannot:

> (1) Assess rail transportation property [***7] at a value that has a higher ratio to the true market value of the rail transportation property than the ratio that the assessed value of other commercial and industrial property in the same assessment jurisdiction has to the true market value of the other commercial and industrial property.
>
> (2) Levy or collect a tax on an assessment that may not be made under paragraph (1) of this subsection.
>
> (3) Levy or collect an ad valorem property tax on rail transportation property at a tax rate that exceeds the tax rate applicable to commercial and industrial property in the same assessment jurisdiction.
>
> (4) Impose another tax that discriminates against a rail carrier.

[120]*Burlington Northern Railroad Co. v. Oklahoma Tax Commission*, 481 U.S. 454 (1987).

[121]*Id*. at 460.

[122]*Id*. at 461.

[123]*Id*. at 461-63.

[124]*Id*. at 464.

[125]*Department of Revenue v. ACF Industries, Inc.*, 510 U.S. 332 (1994).

[126]*Id*. at 340.

[127]*Id*. at 338-41.

[128]131 S. Ct. 1101 (2011).

[129]*Id*. at 1107.

[130]*Id*. at 1109.

[131]*Altria v. Good*, 555 U.S. 70 (2008).

[132]*Id*. at 72-73.

[133]*Id*. at 80.

[134]*Id*. at 81.

[135]8 U.S.C. § 1324a(a)(1)(A). This statute is primarily concerned with immigration law rather than employment or labor law. While there is no express preemption provision in the National Labor Relations Act, this MONOGRAPH has addressed the tangential relationship between express preemption and labor law in other contexts. *See Dilts v. Penske Logistics, LLC*, 757 F.3d 1078 (9th Cir. 2014) (finding that California's labor law pertaining to meal and rest breaks is not preempted by the FAAAA); *see also Perry v. Thomas*, 482 U.S. 483 (1987) (finding that rights to pursue labor disputes in court were preempted by the Federal Arbitration Act where agreements to arbitrate were negotiated).

[136]8 U.S.C. § 1324a(h)(2).

[137]*Chamber of Commerce v. Whiting*, 131 S. Ct. 1968 (2010).

[138]*Whiting* also implicates implied preemption.

[139]131 S. Ct. at 1978.
[140]*Id*. at 1979.
[141]*Wyeth v. Levine*, 555 U.S. 555 (2009).
[142]*Ibid*.
[143]*Id*. at 558-64.
[144]*Ibid*.
[145]*Ibid*.
[146]*Ibid*.
[147]*Id*. at 563-64.
[148]*Id*. at 568-73.
[149]*Ibid*.
[150]*Ibid*.
[151]*Ibid*.
[152]*Id*. at 573-81.
[153]*Ibid*.
[154]*Ibid*.
[155]*Ibid*.
[156]*Ibid*.
[157]*PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).
[158]*Id*. at 2572-73.
[159]*Id*. at 2573.
[160]*Id*. at 2573-74.
[161]*Ibid*.
[162]*Id*. at 2574.
[163]*Id*. at 2575-76.
[164]*Ibid*.
[165]*Ibid*.
[166]*Id*. at 2580-81.
[167]*Ibid*.
[168]*Ibid*.
[169]*Id*. at 2581-82.
[170]*Ibid*.
[171]*Ibid*.
[172]*Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013).
[173]*Id*. at 2472.
[174]*Ibid*.
[175]*Ibid*.
[176]*Ibid*.

[177]*Id*. at 2470.

[178]*Id*. at 2437.

[179]*Id*. at 2473-76.

[180]*Ibid*.

[181]*Id*. at 2476.

[182]*Id*. at 2476-77.

[183]*Ibid*.

[184]*Id*. at 2475.

[185]*Ibid*.

[186]*Id*. at 2476.

[187]*Id*. at 2478.

[188]*Id*. at 2477.

[189]*Id*. at 2477-78.

[190]*AT&T Mobility LLC v. Concepcion*, 131 S. Ct. 1740 (2011).

[191]*Ibid*.

[192]*Ibid*.

[193]*Ibid*.

[194]*Id*. at 1745.

[195]*Ibid*.

[196]*Ibid*.

[197]*Ibid*.

[198]*Discover Bank v. Superior Court*, 113 P.3d 1100 (2005).

[199]131 S. Ct. at 1745 (citing *Laster v. T–Mobile USA, Inc.*, 2008 WL 5216255, at *14 (S.D. Cal. Aug. 11, 2008)).

[200]*Ibid*.

[201]131 S. Ct. at 1745 (citing *Laster v. AT&T Mobility LLC*, 584 F.3d 849, 855 (9th Cir. 2009)).

[202]*Id*. at 1749 (ellipses omitted).

[203]*Id*. at 1746-47.

[204]*Id*. at 1748.

[205]*Marmet Health Care Center, Inc. v. Clayton Brown*, 132 S. Ct. 1201 (2012).

[206]*Id*. at 1202.

[207]*Ibid*.

[208]*Ibid*.

[209]*Ibid*.

[210]*Id*. (quoting *Brown v. Genesis Healthcare Corp.*, No. 35494, 2011 WL 2611327 (W.Va. June 29, 2011)).

[211]*Ibid* (citation and ellipses omitted).

[212]*Ibid*.
[213]*Ibid*.
[214]*Ibid*.
[215]*Id*. at 1204.
[216]*Nitro–Lift Technologies, L.L.C. v. Howard*, 133 S. Ct. 500 (2012).
[217]*Id*. at 502.
[218]*Ibid*.
[219]*Id*. at 502-03.
[220]*Ibid*.
[221]*Ibid*.
[222]*Ibid*.
[223]*Id*. at 503-04.
[224]*Ibid* (citations omitted).
[225]*Ibid*.
[226]*ONEOK, Inc. v. Learjet, Inc.*, 135 S. Ct. 1591 (2015).
[227]*Id.* at 1594.
[228]*Id.* at 1599.
[229]*Id*. at 1601 (citations omitted).
[230]*Ibid*.
[231]*Id*. at 1602.
[232]*Ibid*.
[233]*Kurns v. Railroad Friction Products Corp.*, 132 S. Ct. 1261 (2012).
[234]*Ibid*.
[235]*Ibid*.
[236]*Ibid*.
[237]*Napier v. Atlantic Coast Line Railroad Co.*, 272 U.S. 605 (1926).
[238]*Kurns*, 132 S. Ct. at 1266.
[239]*Id*. at 1266-70.
[240]*Ibid*.
[241]*Id*. at 1267-68.
[242]*Ibid*.
[243]*Ibid*.
[244]*Williamson v. Mazda Motor of America, Inc.*, 131 S. Ct. 1131 (2011).
[245]*Id*. at 1134.
[246]*Ibid*.
[247]*Geier v. American Honda Motor Company*, 529 U.S. 861 (2000).
[248]*Williamson*, 131 S. Ct. at 1137; *see also Geier*.
[249]*Geier*, 529 U.S. at 868.

[250]*Id*. at 869.

[251]*Id*. at 870.

[252]*Williamson*, 131 S. Ct. at 1137.

[253]*Id*. at 1138.

[254]*Id*. at 1137.

[255]*Id*. at 1139-40.

[256]*Id*. at 1139

[257]*Id*. at 1140.

[258]*Arizona v. United States*, 132 S. Ct. 2492, 2497 (2012).

[259]*Id*. at 2947-98.

[260]*Ibid*.

[261]*Id*. at 2492.

[262]*Id*. at 2498-99.

[263]*Id*. at 2499-2500.

[264]*Id*. at 2501.

[265]*Id*. at 2501-04.

[266]*Ibid*.

[267]*Ibid*.

[268]*Ibid*.

[269]*Id*. at 2504-06.

[270]*Ibid*.

[271]*Ibid*.

[272]*Id*. at 2505-08.

[273]*Ibid*.

[274]*Ibid*.

[275]*Id*. at 2507-10.

[276]Daniel J. Meltzer, *Preemption and Textualism*, 112 MICH. L. REV. 2, 3-4 (2013).

[277] *ONEOK*, 135 S. Ct. at 1603.

[278]In *Mensing*, the Court was asked to decide whether the Hatch-Waxman Amendments to the federal Food, Drug and Cosmetic Act preempt state-law failure-to-warn claims brought against manufacturers of generic drugs. The Court concluded that because federal law prohibits generic drug manufacturers from unilaterally changing the warning labels on their products, it would be impossible for generic manufacturers to comply with a state law duty to change their warning and at the same time meet their federal obligation to keep the warning labels the same. As such, the FDCA preempted the state-law failure-to-warn claims.

[279]Nelson, *supra* note 12.

[280]*Mensing*, 131 S. Ct. 2567, 2579 (2011) (internal citations omitted).

[281]*Id*. at 2579-80 (internal citations omitted).

[282]*Arizona v. Inter Tribal Council of Arizona*, 133 S. Ct. 2247 (2013), discussed *infra* at Appendix.

[283]131 S. Ct. 1131 (2011).

[284]*Id*. at 1137.

[285]Sharkey, *supra* note 21 at 525.

[286]*Preemption: Memorandum for the Heads of Executive Departments and Agencies,* 74 Fed. Reg. 24,693, 24,693-94 (May 20, 2009).

[287]*Ibid*.

[288]Federalism, Exec. Order No. 13132, 3 C.F.R. § 206 (2000), which President Clinton issued on August 4, 1999, serves as the crux of multiple reform proposals for agency preemption of state law. This executive order revoked President Reagan's Exec. Order No. 12612 on Federalism. The Order imposes certain requirements on agencies when preempting state law, emphasizes consultation with state and local governments, and encourages sensitivity to their concerns.

[289]*Preemption: Memorandum for the Heads of Executive Departments and Agencies,* 74 Fed. Reg. at 24,693.

[290]Sharkey, *supra* note 21 at 531.

[291]*Id*. at 595.

[292]*Ibid*.

[293]*ONEOK*, 135 S. Ct. at 1602.

[294]*Ibid*.

[295]779 F.3d 34 (1st Cir. 2015)

[296]*Id*. at 37-38.

[297]*Id*. at 42-43.

[298]737 F.3d 378 (6th Cir. 2013).

[299]*Id*. at 383.

[300]*Ibid*.

[301]*Ibid*.

[302]*Id*. at 390-98.

[303]*Ibid*.

[304]*Id*. at 396 (citations omitted).

[305]*Id*. at 406.

[306]*Id*. at 401-06.

[307]*Id*. at 401-03.

[308]*Ibid*. Prior to *Dolin* and *Weeks*, only two states had issued opinions embracing "innovator liability" claims: (1) California (*Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299 (Cal. Ct. App. 2008)); and (2) Vermont (*Kellogg v. Wyeth*, 762 F. Supp. 2d 694 (D. Vt. 2010)).

[309]The Supreme Court recently denied *certiorari* in *Huck v. Wyeth*, which is another case involving the drug Reglan. *PLIVA, Inc. v. Huck*, 850 N.W.2d 353 (Iowa 2014), *cert. denied*, 135 S. Ct. 1699 (2015). In that case, the Iowa Supreme Court found a plaintiff's labeling claims against PLIVA were not preempted to the extent they were based on PLIVA's failure to include additional warning language approved by the FDA after a consumer began taking the drug in question. *Id*. at 364. In February 2004, an individual started taking the generic form of the drug Reglan. *Id*. at 359. In July 2004, the FDA approved a new warning for Reglan, which its manufacturer, Wyeth, implemented. The statement warned against the use of Reglan for more than a twelve-week period, due to the increased risk of developing tardive dyskinesia. *Id*. The generic manufacturer, PLIVA, did not update its label and the plaintiff developed the condition. *Id*. The court found the plaintiff's claims survived preemption "to the extent they are based on PLIVA's failure to adopt the additional warning language approved by the FDA in 2004." *Id*. at 362. The court emphasized the "narrow path around *Mensing*," given that PLIVA did not need FDA approval to revise its warning label to match its brand-name counterpart, and in fact had a duty to do so. *Id*. at 364.

[310]159 So.3d 639 (Ala. 2014)

[311]*Id*. at 677.

[312]*Id*. at 653.

[313]*Id*. at 660-61.

[314]*Id*. at 669.

[315]*Id*. at 677.

[316]*Ibid*.

[317]62 F. Supp. 3d (N.D. Ill. 2014).

[318]*Id*. at 714-15.

[319]*Chamber of Commerce of U.S. v. Whiting*, 131 S. Ct. 1968, 1974 (2011).

[320]*Id*. at 1983 (citations omitted).

[321]*Id*. at 1987.

[322]*Arizona v. United States*, 132 S. Ct. 2492, 2498 (2012).

[323]*Id*. at 2500 (emphasis added).

[324]*Id*. at 2510.

[325]*AT&T Mobility LLC v. Concepcion*, 131 S. Ct. 1740, 1789 (2011).

[326]*See, e.g.*, *Concepcion*, 131 S. Ct. 1740, 1789 (2011); *Nitro-Lift Technologies, LLC, v. Howard*, 133 S. Ct. 500 (2012); *Marmet Health Care Ctr., Inc. v. Brown*, 132 S. Ct. 1201 (2012).

[327]*Brown*, 132 S. Ct. at 1203-04 (citation and quotation marks omitted).

[328]*Nitro-Lift Technologies, LLC*, 133 S. Ct. at 503.

[329]*Concepcion*, 131 S. Ct. at 1747 (citation omitted).

[330]*Ibid*.

[331]*Ibid*.

[332]*Id*. at 1746-47 (emphasis added).

[333]*Id*. at 1750 (emphasis in original).

[334]225 Cal. App. 4th 338 (Cal. App. 2014), *review denied* (July 23, 2014), *cert. granted*, 135 S. Ct. 1547 (2015).

[335]*Id*. at 340-41.

[336]*Id*. at 341.

[337]*Id*. at 342.

[338]724 F.3d 1218 (9th Cir. 2013).

[339]225 Cal. App. 4th at 346-47.

[340]*Id*. at 347.

[341]*Hillman v. Maretta*, 133 S. Ct. 1943 (2013).

[342]*Id*. at 1948.

[343]*Maretta v. Hillman*, 283 Va. 34, 37 (2012) (internal quotation marks omitted).

[344]*Hillman*, 133 S. Ct. at 1948. The cases were *Wissner v. Wissner*, 338 U.S. 655 (1950), and *Ridgway v. Ridgway*, 454 U.S. 46 (1981).

[345]*Id*. at 1950-51.

[346]*Id*. at 1946.

[347]*Ibid*.

[348]*WOS v. E.M.A.*, 133 S. Ct. 1391 (2013).

[349]*Id*. at 1395.

[350]42 U.S.C. § 1396p(a)(1).

[351]*E.M.A. v. Cansler*, 674 F.3d 290 (2012).

[352]*Arkansas Dept. of Health and Human Services v. Ahlborn*, 547 U.S. 268 (2006).

[353]133 S. Ct. at 1396.

[354]*Ibid*.

[355]*Id*. at 1397.

[356]*Id*. at 1398.

[357]*Ibid*.

[358]*Id*. at 1399.

[359]*Tarrant Regional Water District v. Herrmann*, 133 S. Ct. 2120 (2013).

[360]*Arizona v. Inter Tribal Council of Arizona*, 133 S. Ct. 2247 (2013).

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