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Judicial Review of FDA Preemption Determinations

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I. INTRODUCTION

In *Medtronic v. Lohr*,[1] the U.S. Supreme Court held that the Medical Device Amendments[2] to the Federal Food, Drug, and Cosmetic Act (FDCA)[3] did not preempt Lohr's state tort claim for damages. Although the decision has caused lower courts to think twice before holding that state tort laws are preempted by Food and Drug Administration (FDA) regulations, it hardly has settled this area of law. In the time since the *Lohr* decision, courts have disagreed sharply on the question of whether or not FDA approval of medical devices preempts state law.[4]

FDA has taken an active role in the debate. Most significantly, the agency has issued regulations narrowly interpreting the scope of section 360k(a) of title 21 of the *United States Code* — the express preemption provision at issue in the case[5] — and has filed *amicus curiae* briefs, in *Lohr* and in other cases, in support of its interpretation of section 360k(a). Recently, FDA issued a proposed regulation clarifying the narrow reach of section 360k(a),[6] but then rescinded its proposal in response to unfavorable comments.[7]

It is unclear, however, what weight should be given to FDA's construction of the preemption provisions in the FDCA. Normally an agency's interpretation of its own statute is granted *Chevron*[8] deference: if the statute is ambiguous, courts will defer to an agency's reasonable interpretation, even if the court itself would have reached a different conclusion. In *Lohr,* the majority relied heavily on FDA's interpretation of section 360k(a), commenting that FDA's narrow interpretation of the section's preemptive reach "substantially informed" the Court's conclusion.[9] As the four dissenting justices pointed out, however, the majority never explicitly granted "*Chevron* deference" to FDA's interpretation of the statute.[10] In the dissenters' view, the majority shied away from applying *Chevron* because "it is not certain that an agency regulation determining the preemptive effect of *any* federal statute is entitled to deference."[11]

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[1] 518 U.S. 470 (1996).

[2] Pub. L. No. 102-300, 106 Stat. 238 (1992) (codified at 21 U.S.C. §§ 301 note, 321, 331, 334, 346a, 352-353, 356-357, 360c-360d, 360g-360i, 360i notes, 360l, 360mm, 371-372, 372a, 376, 381 (1994); 42 U.S.C. § 262 (1994)).

[3] Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301 et seq. (1994)).

[4] *Compare* Mitchell v. Collagen Corp., 126 F.3d 902 (7th Cir. 1997); Papike v. Tambrands, Inc., 107 F.3d 737 (9th Cir. 1997); Lake v. TPLC, 1 F. Supp. 2d 84, 86-87 (D. Mass. 1998), *with* Goodlin v. Medtronic, Inc., 167 F.3d. 1367 (11th Cir. 1999); Oja v. Howmedica, Inc., 111 F.3d 782 (10th Cir. 1997); Niehoff v. Surgidev, 950 S.W.2d 816, 822 (Ky. 1997); Armstrong v. Optical Radiation Corp., 57 Cal. Rptr. 2d 763 (Cal. App. 1996).

[5] 21 C.F.R. § 808.1(d) (1998).

[6] 62 Fed. Reg. 65,384 (Dec. 12, 1997) (amending 21 C.F.R. § 808.1(d)).

[7] 63 Fed. Reg. 39,789 (July 24, 1998).

[8] Chevron, U.S.A., Inc. v. Natural Resources Defense Council, 467 U.S. 837 (1984).

[9] *Medtronic*, 518 U.S. at 495.

[10] *Id.* at 512.

[11] *Id.*

This article addresses the weight courts should give to FDA's conclusions about the preemptive effect of the FDCA, and the regulations it promulgates. The issue is a complicated one. Although Congress has given FDA considerable authority to issue regulations that may preempt state laws, thereby suggesting that Congress intended to grant FDA authority to make preemption determinations,[12] it nevertheless is troubling to require courts to defer to FDA's opinions on preemption in light of the well-established judicial reluctance to displace state law.[13] Under *Chevron,* courts should defer to agency interpretations of law only when traditional techniques of statutory interpretation, including an awareness of the appropriate roles and capacities of courts and agencies, make it apparent that Congress would have wanted courts to do so.[14] These qualifications cut against granting *Chevron* deference to agency preemption determinations. Agencies have no special expertise in interpreting state laws to determine whether they conflict with federal laws. Moreover, there is a danger that agencies will be too quick to decide that their governing statutes and regulations displace state law because, unlike Congress, agencies are not accountable directly to the states, and therefore lack incentive to restrict their power to preserve state sovereignty.[15]

Part II of this article reviews the theories underlying *Chevron* deference. Part III examines the principles that govern courts' preemption determinations, and discusses the problem of regulatory preemption. Part IV contains the author's views on the degree to which courts should rely on agency preemption determinations. The article concludes that courts should not defer to agencies when their preemption determinations purport to interpret state laws, in part because agencies have no expertise in interpreting state law, and in part because adopting agencies' construction of state laws is disrespectful to state courts and legislatures, raising serious federalism concerns. Some deference is due, however, to agencies' interpretations of the scope and effect of the statutes they administer and the regulations they promulgate, because agencies have the expertise and the authority to make these determinations. In addition, it is always appropriate for courts to defer to agencies' reasonable conclusions that their governing statute or regulations do not displace state laws, because such conclusions do not raise the danger of overreaching by agencies and do not impinge on state sovereignty. Finally, in part V the principles developed in part IV are applied to judicial review of FDA preemption determinations under sections 360k(a) and (b) of the FDCA.

II. THE PRINCIPLES UNDERLYING CHEVRON DEFERENCE

In *Chevron v. Natural Resources Defense Council,* the U.S. Supreme Court made it explicit that if a statute is unclear, courts should defer to the administering agency's reasonable interpretation of the law.[16] The Court established a two-part test for review of an agency's interpretation of its governing statute. The first inquiry is "whether Congress has directly spoken to the precise question at issue."[17] To make this determination, courts should rely on traditional canons of statutory interpretation.[18] If Con-

[12] *Id.* at 506 (Breyer, J., concurring).

[13] *See, e.g.*, Rice v. Santa Fe Elevator Corp., 331 U.S. 218 (1947).

[14] *See* Smiley v. Citibank (South Dakota), N.A., 57 U.S. 735, 741 (1996).

[15] *See* Garcia v. San Antonio Metro. Transit Auth., 469 U.S. 528 (1985); New York v. United States, 505 U.S. 144 (1992); *see also* Cass Sunstein, *Law and Administration After Chevron*, 90 COLUM. L. REV. 2071, 2099-2100 (1990).

[16] *Chevron,* 467 U.S. at 843-44.

[17] *Id.* at 842.

[18] *See id.* at 843 n.9 (noting that courts should "employ traditional tools of statutory construction" in determining if Congress had an intention on the precise question at issue); Dole v. United Steelworkers of Am., 110 S. Ct. 929, 934 (1990); NLRB v. United Food & Commercial Workers Union, Local 23, 108 S. Ct. 413, 421 (1987); INS v. Cardoza-Fonseca, 480 U.S. 421, 447-48 (1987).

gress has made its intent clear, then there is no room for an alternative interpretation; however, "if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute."[19] The agency need only establish that its construction is "reasonable in light of the Act's text, legislative history, and purpose."[20] Although courts have long granted some deference to administrative interpretations,[21] *Chevron* established the formal rule of deference, giving agencies the latitude to develop their own interpretations of the statutes they administer.

Chevron has been viewed as a groundbreaking decision that significantly altered the relationship between the legislative, executive, and judicial branches of government.[22] The decision immediately was recognized as being at odds with the principle first established in *Marbury v. Madison*[23] that the judiciary alone has the authority to "say what the law is."[24] Indeed, *Chevron* has been characterized as the "counter-*Marbury*" for the administrative state.[25] Because *Chevron* altered the balance of power between the branches of government, and particularly because it gave autonomy to the "headless" fourth branch, the reasoning behind its rule of deference has been subject to intense scrutiny.[26] Over the years, courts and commentators have forwarded several different theories to justify judicial deference to agency interpretations of the law.

One view justifies *Chevron* deference as a means of ensuring that policy choices are made by politically accountable actors, thereby retaining the intended separation of powers.[27] Giving meaning to ambiguous statutes necessarily requires making policy choices.[28] Proponents of the separation of powers theory argue that, whenever possible, policy judgments should be made by those who can be held accountable, such as elected officials, and not by judges who are insulated from the will of the people through lifetime tenure and secure salaries.[29] Agency officials are not elected directly by the people, but they are subject to congressional oversight and, in executive agencies, they are appointed and can be removed by the President.[30] Although they are less visible, and thus less accountable, than members of Congress or the President and Vice President, agency officials feel the political pressure that judges are immune to. As the Court in *Chevron* noted, judges, unlike agencies, "are not part of either political branch of the Government," and thus "it is entirely appropriate for this political branch of the Government to make such policy choices — resolving the competing interests which Congress itself either inadvertently did not resolve, or intentionally left to be resolved by the agency. . . ."[31]

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[19] *Chevron*, 467 U.S. at 842-43.

[20] Southern Cal. Edison Co. v. FERC, 116 F.3d 507,511 (D.C. Cir. 1997); *see also Chevron*, 467 U.S. at 844.

[21] *See, e.g.*, Blum v. Bacon, 457 U.S. 132, 141 (1982); Union Elec. Co. v. Camp, 401 U.S. 617, 626-27 (1971); Investment Co. Inst. v. Camp, 401 U.S. 246, 256 (1971); *see also Chevron*, 467 U.S. at 844-45.

[22] Sunstein, *supra* note 15, at 2074-75.

[23] 5 U.S. (1 Cranch) 137 (1803).

[24] *Id.* at 177.

[25] Sunstein, *supra* note 15, at 2075.

[26] In addition to hundreds of law review articles about *Chevron*, the case has been cited thousands of times since it was decided in 1984. *Id.*

[27] *See, e.g.*, Kenneth W. Starr, *Judicial Review in the Post-Chevron Era*, 3 YALE J. REG. 283, 307-09 (1986).

[28] *See, e.g.*, *Chevron*, 467 U.S. at 864.

[29] *See* Starr, *supra* note 27, at 307-09.

[30] The heads of "independent" agencies are appointed for fixed terms and are not subject to plenary removal power, and thus are insulated from influence by the executive branch.

[31] *Chevron*, 467 U.S. at 865-66.

An alternative theory for *Chevron* deference relies entirely on legislative intent. If Congress is silent or unclear on an issue, it can be reasoned that Congress intended the administering agency to make the final decision. As the Court stated in *Chevron*, "[i]f Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation."[32] Therefore, courts are out of line when they fill gaps themselves rather than leaving the task for the agency, as Congress intended.

From another perspective, *Chevron* deference operates as a default-rule against which Congress legislates. Under this view congressional intent is unclear, not because Congress intended to confer all discretion to agencies, but rather because it failed to think about the issue at all.[33] The rule of deference created in *Chevron* is an improvement on past practice because it provides certainty: Congress knows that if it fails to consider and resolve certain problems, those problems will be resolved not by the courts, but by an agency with policy biases that Congress is familiar with.[34]

Agency expertise is perhaps the most frequently cited rationale for *Chevron* deference. Unlike agencies, "[j]udges are not experts in the field."[35] As Justice Stevens wrote in *Chevron*, the "principle of deference to administrative interpretations has been consistently followed by this Court whenever . . . a full understanding of the force of the statutory policy in a given situation has depended upon more than ordinary knowledge respecting the matters subjected to agency regulations."[36] Agencies are experts because their personnel usually have special training and significant experience in a particular field. Courts cannot match agencies' collective knowledge of their specialty. Because they have an institutional memory of the success and failure of past policies, agencies are uniquely situated to understand the consequences of their actions.[37]

A common thread through these rationalizations is that agencies, unlike courts, are more apt to reach the "correct" outcome by interpreting statutory ambiguities as Congress actually intended, or as Congress would have wanted them to be resolved had it thought about the issue. In other words, an agency's reasonable interpretation of an ambiguous statute supersedes a reviewing court's interpretation because agencies are more likely to get it right. Another theme to these rationales is that agencies, which qualify as one of the political branches of government,[38] are the more appropriate institution to interpret ambiguous statutes.

Chevron has transformed the relationship between the judiciary and administrative agencies. The rule of deference has been applied expansively — at times more expansively than Justice Stevens, the author of the opinion, ever intended.[39] In fleshing out the principle of deference established by *Chevron*, courts have chosen to apply it broadly, finding that it is for agencies, not courts, to make decisions regarding the meaning of their governing statutes.[40] Fifteen years after *Chevron*, it is unquestioned that deference is required whenever an agency construes some ambiguous aspect of its governing statute — that is, deference is required in most administrative law cases.

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[32] *Id.* at 843-44.

[33] Antonin Scalia, *Judicial Deference to Administrative Interpretations of Law*, 1989 DUKE L.J. 511, 516-17.

[34] *See id.*

[35] *Chevron*, 467 U.S. at 865.

[36] *Id.* at 844.

[37] United States v. Shimer, 367 U.S. 374 (1961).

[38] *Chevron*, 467 U.S. at 865.

[39] *See* INS v. Cardoza-Fonseca, 480 U.S. at 446-48; *see also* Young v. Community Nutrition Inst., 476 U.S. 974, 984-88 (1986) (Stevens, J., dissenting).

[40] Sunstein, *supra* note 15, at 2074-76.

Commentators, however, have criticized blanket application of the deference principle, arguing that courts should defer to agencies only when agencies are better situated to fulfill statutory goals.[41] Some courts have agreed, refusing to defer under circumstances that suggest that the courts, and not the agency, are more likely to realize Congress' intent. For example, courts have questioned whether *Chevron* deference is merited when an agency's position is developed for the first time in litigation, and thus may lack the "fair and considered" judgment of agency officials.[42] Some courts have refused to defer to agency interpretations of the scope of their jurisdiction, in light of agencies' obvious self-interest in expanding their jurisdiction beyond what Congress intended.[43] Nor will courts defer, despite statutory ambiguity, when agency actions raise constitutional questions.[44]

III. THE PRINCIPLES UNDERLYING THE PRESUMPTION AGAINST PREEMPTION

The preemption of state law by federal agencies — commonly referred to as regulatory preemption — has been recognized by courts[45] and commentators[46] as a special circumstance under which *Chevron* deference might be inappropriate. The framers of the U.S. Constitution intended for the states to retain autonomous governments that would operate alongside the newly created federal government.[47] There has been debate about the scope of authority retained by the states, and the limits on federal intrusion into state affairs.[48] Although the Supremacy Clause of the Constitution provides the federal government with the power to displace state laws in areas in which the federal government is permitted to act,[49] courts have been reluctant to find such preemption unless Congress clearly has expressed its intent to do so.[50]

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[41] *Id.*; Steven Breyer, *Judicial Review of Questions of Law and Policy*, 38 ADMIN. L. REV. 363, 373 (1986); Clark Byse, *Judicial Review of Administrative Interpretation of Statutes: An Analysis of Chevron's Step Two*, 2 ADMIN. L. REV. 255, 260-61 (1988); Cynthia Farina, *Statutory Interpretation and the Balance of Power in the Administrative State*, 89 COLUM. L. REV. 452, 475-78 (1989).

[42] *See, e.g.*, Public Citizen Health Research Group v. Food and Drug Admin., 997 F. Supp. 56, 66 (D.D.C. 1998) (noting that litigating positions may be unreliable evidence of an agency's policy); *see also* KENNETH C. DAVIS & RICHARD J. PIERCE, ADMINISTRATIVE LAW TREATISE § 3.5 (3d ed. 1994).

[43] *See* The Bus. Roundtable v. Securities and Exch. Comm'n, 905 F.2d 406, 413-14 (D.C. Cir. 1990); New York Shipping Ass'n v. Federal Maritime Comm'n, 854 F.2d 1338, 1363 (D.C. Cir. 1988). The Supreme Court has been unclear about whether courts should defer to agencies on jurisdictional questions. *See, e.g.*, Mississippi Power & Light Co. v. Mississippi, 108 S. Ct. 2428 (1988); Adams Fruit Co. v. Barrett, 110 S. Ct. 1384, 1391 (1990).

[44] *See, e.g.*, Kent v. Dulles, 357 U.S. 116, 130 (1958); DeBartolo Corp. v. Florida Gulf Coast Bldg. & Constr. Trades Council, 485 U.S. 568, 574-75 (1988); Industrial Union Dep't v. American Petroleum Inst., 448 U.S. 607, 645-46 (1980); NLRB v. Catholic Bishop, 440 U.S. 490, 507 (1979).

[45] *See, e.g.*, Teper v. Miller, 82 F.3d 989, 998 (11th Cir. 1996).

[46] Paul E. McGreal, *Some Rice With Your Chevron?: Presumption and Deference in Regulatory Preemption*, 45 CASE W. RES. L. REV. 823 (1995); Damien J. Marshall, *The Application of Chevron Deference in Regulatory Preemption Cases*, 87 GEO. L.J. 263 (1998).

[47] *See* THE FEDERALIST NO. 9 (Alexander Hamilton) (referring to the "sovereign power" of the states), NO. 45 (James Madison) (affirming that the states will retain a significant degree of sovereignty), NO. 51 (James Madison) (assuring the preservation of the states as "distinct governments") (B. Wright ed., 1961).

[48] *See, e.g., Garcia*, 469 U.S. at 528; New York v. United States, 505 U.S. 144 (1992); United States v. Lopez, 514 U.S. 549 (1995); Printz v. United States, 521 U.S. 898 (1997). *See also* DAVID L. SHAPIRO, FEDERALISM: A DIALOGUE (1995).

[49] "It is basic to this constitutional command that all conflicting state provisions be without effect." Maryland v. Louisiana, 451 U.S. 725, 746 (1981) (citing McCulloch v. Maryland, 4 Wheat 316, 427 (1819)).

[50] *See, e.g.*, Gregory v. Ashcroft, 501 U.S. 452 (1991) (holding that the federal Age Discrimination in Employment Act does not preempt state law requiring mandatory retirement of appointed state judges at 70); Cipollone v. Liggett Group, 505 U.S. 504 (1992).

A. *Preemption Doctrine*

Under the federal system, the federal government and the states govern concurrently, subject to the limitations of the Supremacy Clause.[51] The Supremacy Clause provides that federal law "shall be the supreme Law of the Land . . . and any Thing in the Constitution or Laws of any State to the Contrary Notwithstanding."[52] As Justice Marshall first stated in *Gibbons v. Ogden*, state laws that "interfere with or are contrary to, the laws of Congress" are preempted by federal law, and thus must be struck down.[53]

Although Congress, when acting pursuant to its constitutional authority,[54] has the power to preempt state laws, courts have had difficulty determining when Congress intends to utilize that power. To aid in this endeavor, courts have identified three types of preemption: express preemption, conflict preemption, and field preemption.[55] Express preemption occurs when Congress expressly has stated its intent to displace state law.[56] When state and federal laws conflict, preemption is implied.[57] Likewise, preemption is implied if federal law pervades an entire field, indicating congressional intent to occupy the field exclusively.[58] The bottom line in all preemption cases is whether Congress *intended* to preempt the competing state law.[59]

Conflict preemption is the focus of much of this article. There are two types of conflict preemption: direct conflict preemption and obstacle preemption.[60] Direct conflict preemption occurs when "compliance with both federal and state regulations is a physical impossibility."[61] For example, if FDA enacts a regulation requiring hearing aids to have a wire-width of two inches, but Florida enacts a law requiring a wire-width of three inches, hearing aid manufacturers could not obey both laws, and therefore the state law would be in direct conflict and would have to yield to its federal counterpart.[62]

Obstacle preemption is less clear-cut. It occurs "when state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'"[63] State law is preempted even if it is *possible* to obey the command of both federal and state law, because the state law may undermine the purpose of the federal statute. Usually, obstacle preemption arises in cases where a state imposes a stricter standard than the federal law.[64] For example, a state may require drug manu-

[51] *See* Tafflin v. Levitt, 493 U.S. 455, 459 (1990).

[52] This Constitution, and the laws of the United States which shall be made in Pursuance thereof; and all Treatise 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, and any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

U.S. CONST. art VI, cl. 2.

[53] Gibbons v. Ogden, 9 Wheat 1, 211 (1824); *see also* Wisconsin Pub. Intervenor v. Mortier, 501 U.S. 597, 604 (1991).

[54] U.S. CONST. art. 1, § 8. The Constitution also guarantees certain rights to the states with which Congress cannot interfere. *See, e.g.*, U.S. CONST. art IV, § 3 (guaranteeing states' territorial integrity).

[55] Hillsborough County v. Automated Med. Labs., 471 U.S. 707, 713 (1985); Irving v. Mazda Motor Corp., 136 F.3d 764, 767 (11th Cir. 1998); *see also Cipollone*, 505 U.S. at 516.

[56] *Hillsborough County*, 471 U.S. at 713 ("[W]hen acting within constitutional limits, Congress is empowered to preempt state law by so stating in express terms.").

[57] Hines v. Davidowitz, 312 U.S. 52, 67 (1941); English v. General Elec. Co., 496 U.S. 72, 79 (1990).

[58] *See, e.g.*, Silkwood v. Kerr-McGee Corp. 464 U.S. 238, 248 (1994).

[59] *See, e.g., Medtronic*, 518 U.S. at 485.

[60] *See Silkwood*, 464 U.S. at 248; McGreal, *supra* note 46, at 832.

[61] Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142-43 (1963).

[62] This hypothetical is borrowed from Justice Breyer. *Medtronic*, 518 U.S. at 504.

[63] *Silkwood*, 464 U.S. at 248; *see also Hines*, 312 U.S. at 67.

[64] *See* California Fed. Sav. & Loan Ass'n v. Guerra, 107 S.Ct. 683, 689 (1987); *Rice*, 331 U.S. at 241 (Frankfurter, J., dissenting); Cloverleaf Butter Co. v. Patterson, 315 U.S. 148, 172-73 (1942) (Stone, C.J., dissenting).

facturers to develop a more detailed warning label than federal law or FDA regulations require, or may insist that drugs only be used for the purposes for which they are tested, while federal law permits off-label use. State law and federal law can co-exist, but the state law may undercut one of the purposes of the federal law. FDA's decision to limit the contents of the warning label, or to allow off-label use, may reflect the agency's careful balance of health and safety concerns with the need to streamline the process by which new drugs and devices can reach the market. Requiring manufacturers to clear more hurdles before the product can be marketed could upset the compromise struck in the federal law and regulations, and thus the state law presents an impermissible obstacle to the achievement of the federal purpose.

When faced with either direct conflict preemption or obstacle preemption, reviewing courts must compare state and federal law.[65] Direct conflict cases are straightforward: the reviewing court's task is to determine if the letter of the state law conflicts with the letter of the federal law. Cases concerning obstacle preemption, on the other hand, require courts to determine if the state law interferes with the realization of the federal law's purpose.[66]

B. *The Presumption Against Preemption*

The Supremacy Clause leaves no doubt that Congress has the power to preempt state law.[67] At the same time, the preemption of state and local law threatens the Tenth Amendment principle of federalism.[68] The Tenth Amendment provides that "the powers not delegated to the United States by the Constitution, nor prohibited by it to the states, are reserved to the states respectively, or to the people."

On their faces, the Supremacy Clause and the Tenth Amendment appear to complement, rather than conflict with, one another. The Supremacy Clause establishes the superiority of federal laws in those areas in which the Constitution permits the federal government to act, and the Tenth Amendment provides that, until preempted by federal law, states also can exercise control in these areas. In practice, however, it can be difficult to determine whether state law is preempted by federal law. The Constitution only permits preemption of state law when Congress intends to preempt, otherwise the Tenth Amendment reserves to the states the right to legislate even in those areas in which Congress also has spoken. If a court determines that state law is preempted when Congress did not wish it so, the court has violated the states' Tenth Amendment right to retain all powers to govern, save those prohibited to it by the Constitution.

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[65] *See, e.g., Teper*, 82 F.3d at 993.

[66] *Rice*, 331 U.S. at 231.

> A forceful argument is made here for the view that the Illinois regulatory scheme should be allowed to supplement the Federal Act and that the Illinois Commission should not be prevented from acting on any of the matters covered by Rice's complaint, unless what the Commission does runs counter in fact to the federal policy. That is to say, the actual operation of the state system may be harmonious with the "measure of control" over warehousemen which the Federal Act imposes. That, it is said, can only be determined after the Illinois Commission has acted. . . . [U]ntil it is known what the Commission will do, no conflict with the Federal Act can be shown.

Id. (citations omitted).

[67] *See Rice*, 331 U.S. at 229-30 ("It is clear that since warehouses engaged in the storage of grain for interstate or foreign commerce are in the federal domain, Congress may, if it chooses, take unto itself all regulatory authority over them, share the task with the states, or adopt as federal policy state scheme of regulation.") (citation omitted). James Madison told the members of the First Congress "Interference with the power of the States was no constitutional criterion of the power of Congress. If the power was not given, Congress could not exercise it; if given, they might exercise it, although it should interfere with the laws, or even the Constitution of the states." 2 ANNALS OF CONG. 1897 (1791).

[68] *See Garcia*, 469 U.S. at 547.

As discussed above, Congress expressly can preempt state law, or it can do so impliedly by enacting legislation that conflicts directly with state law, or to which state law is an obstacle to the realization of the federal law's purpose. Indeed, state law is preempted even if it does not conflict with federal law if it can be inferred that Congress intended to "occupy the field" onto which the state law intrudes. In cases in which Congress' intention to preempt competing state law arises from inference rather than from its stated intention, courts are caught in the conundrum created by the Supremacy Clause and the Tenth Amendment. On one hand, if a court holds that the state law is not preempted, it risks foiling the legislative purpose, thereby violating the Supremacy Clause's prescription that federal law overrides competing state laws. On the other hand, if a court is too quick to nullify state laws that could operate in unison with the federal law, then the court has infringed needlessly on state autonomy in violation of the Tenth Amendment.

Arguably, the first type of error is less egregious than the second. If a court erroneously lets a competing state law stand, Congress can correct the mistake by clarifying its intention to preempt state laws. If a court erroneously finds that federal law preempts state law, however, the state cannot rectify the error and Congress has little incentive to do so.[69] As a result, courts have demonstrated an "overriding reluctance to infer preemption in ambiguous cases."[70] Before the federal government existed, and before it began actively regulating interstate commerce, the states policed the activities of their citizens. As the Supreme Court stated in *Rice v. Santa Fe Elevator Corporation*,[71] when it comes to preemption, the Court "start[s] 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."[72] By operating under this assumption, the Court hopes to ensure that "the federal-state balance will not be disturbed unintentionally by Congress or unnecessarily by the courts."[73]

Another reason, usually unstated, for courts to hesitate before preempting state law is to slow the transfer of authority from the states to the federal government. The Supremacy Clause permits preemption of state law only when Congress has acted within the enumerated powers set forth in article I of the Constitution. The expansive interpretation of the Commerce Clause that developed over the first half of the century, combined with the rapid growth of the administrative state, has allowed Congress to regulate, in the words of one commentator, "all significant human activity."[74] Although recent Supreme Court decisions have attempted to set some limits on the scope of Congress' Commerce Clause powers,[75] it is fair to say that there exists no identifiable sphere of activities reserved to the states alone, and thus no piece of state legislation that is not at risk of being preempted by a competing federal law. In addition, the Supreme Court's apparent abandonment of the nondelegation doctrine has allowed Congress to delegate its authority to regulate to hundreds of agencies, greatly

[69] McGreal, *supra* note 46, at 846-47.

[70] L. TRIBE, AMERICAN CONSTITUTIONAL LAW § 6-25, at 479; *see also* Chicago & N.W. Tr. Co. v. Kalo Brick & Tile, 450 U.S. 311, 317 (1981); *Florida Lime & Avocado Growers*, 373 U.S. at 142.

[71] *Rice*, 331 U.S. 218 (1947)

[72] *Id.* at 230.

[73] Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977) (citations and quotations omitted) (citing United States v. Bass, 404 U.S. 336, 349 (1971)).

[74] *See* Bruce Ackerman, *Liberating Abstractions*, 69 U. CHI. L. REV. 317, 322 (1992) (describing how the Court's abstraction of commercial competition allowed Congress to place "all significant human activity" within the constitutional grasp of the Commerce Clause); *see also* McGreal, *supra* note 46, at 827 n.22 ("Given the presently expansive reading of the Commerce Clause, it is hardly conceivable that the Court would deny Congress the power to regulate a subject matter because it was unrelated to interstate commerce.").

[75] *Printz*, 521 U.S. at 898; *Lopez*, 514 U.S. at 549; *New York*, 505 U.S. at 144.

expanding the reach of federal law. The presumption against preemption may be one of the judiciary's few remaining tools with which to protect state sovereignty from encroaching federal authority.[76] Although there are few, if any, areas where states have primary authority, courts have strived to allow states room to govern until the federal government has made clear its intent to regulate the area.

An additional cause for concern is that preemption may strip individuals of long-standing remedies available under state law. Often, the plaintiff claims an injury that only state law or the common law can remedy. If a court finds state law preempted, the injured party is left without recourse. By raising preemption as a defense, the defendant is arguing that through the federal enactment, Congress intended to remove these individual rights and remedies that had been available under state law or the common law. Because it is unlikely Congress intended such a result, courts shy away from preempting state law when there is no federal remedy for the alleged wrong.[77]

Thus, to safeguard state sovereignty and injured citizens' remedies, the Supreme Court has emphasized that there is no preemption of state law unless it is the "clear and manifest purpose of Congress"[78] to do so.[79] Congressional intent to preempt is evidenced by persuasive federal regulations that leave no room for states to act, by the dominant federal interest concerned, by an irreconcilable conflict between state and federal law, or by a clear statement from Congress to that effect.[80] In short, before preempting state laws, courts must find either that Congress clearly expressed its intent to preempt state law or that preemption is necessary to fulfill the purpose of the federal law. In either circumstance, the reviewing court applies the presumption against preemption to ensure that it is not disturbing the federal-state balance needlessly, but is following the clear intent of Congress.

The presumption against preemption has been called a "clear statement rule."[81] Courts apply clear statement rules in a number of contexts, most notably to avoid deciding constitutional questions.[83] In part, courts shy away from deciding constitutional issues because judicial pronouncements on the Constitution can be reversed only through the amendment process, or a judicial about-face. Thus, erroneous decisions on constitutional questions are more difficult to undo than erroneous interpretations of statutes. This policy also decreases the number of constitutional amendments and judicial reversals on constitutional questions, each of which can weaken the authority of the Constitution. In addition, by reading statutes to evade constitutional questions, courts avoid conflicts with the other branches of the federal government, as well as with state governments.[84] Less offense will be taken by Congress and the states if courts interpret statutes narrowly, instead of adopting a broad interpretation that

[76] After noting that the Supreme Court no longer enforces the nondelegation doctrine with much vigor, Professor Sunstein writes that "in the wake of the downfall of that doctrine, the use of constitutionally based clear statement principles serves as a narrower and more targeted means of ensuring that Congress, rather than bureaucrats, will deliberate on questions that raise serious constitutional difficulties or intrude into constitutionally sensitive areas." Sunstein, *supra* note 15, at 2111-12.

[77] *See, e.g.*, Symens v. SmithKline Beecham Corp., 152 F.3d 1050, 1055 (8th Cir. 1998) (stating that it is "most reluctant" to infer a preemptive intent that would leave vaccine purchasers and users without any remedy); Medtronic, Inc. v. Lohr, 518 U.S. 470, 486-87 (1996) (plurality opinion); *Silkwood*, 464 U.S. at 251.

[78] *See, e.g.*, New York Blue Cross Plans v. Travelers Ins., 514 U.S. 645, 655 (1995); Hawaiian Airlines, Inc. v. Norris, 512 U.S. 246, 252 (1994); Hillsborough County v. Automated Med. Labs., Inc., 471 U.S. 707, 715 (1985); *Rice*, 331 U.S. at 230.

[79] *Rice*, 331 U.S. at 230

[80] *Id.*

[81] SHAPIRO, *supra* note 47, at 3.

[82] *Rice*, 331 U.S. at 230.

[83] *DeBartolo*, 485 U.S. at 575; *NLRB*, 440 U.S. at 499-501.

[84] *DeBartolo*, 485 U.S. at 575.

requires striking them down. Finally, requiring Congress and state legislatures to speak clearly on constitutional matters ensures that they will have considered the gravity of the issue before acting.

Labeling the presumption against preemption a "clear statement rule" is only partially accurate, however. By definition, a finding of "express preemption" requires that Congress clearly state its intent to negate state law, but conflict and field preemption arise from the implication that Congress would have wanted the letter of its laws fully carried out and the purpose of its laws fully realized. When courts find that preemption of state law is implied, essentially they are adding a codicil to the statute declaring that any state law that impedes the federal statute must give way. Although this is a logical inference, there has been no "clear statement" from Congress on the matter.[82]

In any case, the rationale for the presumption against preemption differ from the rationales underlying clear statement rules. The chief distinction is that although no branch of government has the authority to enact laws that violate the Constitution, Congress does have the authority to preempt state law when it chooses. Courts interpret statutes to elude constitutional questions to save other branches of government from committing constitutional error.[85] In contrast, the presumption against preemption appears to be a judicial strategy to avoid constitutional error by the courts, rather than by Congress. If Congress did not intend to preempt state law, and a court erroneously holds that it did, then the court has violated the state's Tenth Amendment right to govern in the interstices of federal law.[86]

The presumption against preemption serves the additional purpose of forcing Congress to play the central role in protecting the sovereignty of the states.[87] In *Garcia v. San Antonio Metropolitan Transit Authority,*[88] the Supreme Court held that state sovereignty is "more properly protected by procedural safeguards inherent in the structure of the federal system than by judicially created limitations on federal power."[89] The Court explained that the states' interests are protected through their constitutional role as units of political power: members of Congress are elected by states or portions of states, not by regions of the country; the President and Vice President are elected by the electoral college, in which candidates compete to win each state rather than a majority of the population of the entire country; and, most important, the states are represented equally in the Senate, and no state can be deprived of that representation without first giving its consent.[90] James Madison viewed this last provision as the "constitutional recognition of the portion of sovereignty remaining in the individual States, and an instrument for preserving that residuary sovereignty."[91] States also exercise indirect influence over the U.S. House of Representatives through control of electoral qualifications.[92] As Madison saw it, the federal government "will partake sufficiently of the spirit [of the States] to be disinclined to invade the rights of the individual States, or the prerogatives of their governments."[93]

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[85] *Id.* ("The courts will therefore not lightly assume that Congress intended to infringe constitutionally protected liberties or usurp powers constitutionally forbidden it.").

[86] The issue is not whether Congress intended to preempt, but whether it has the power to preempt; then the question is analyzed under the clear statement rule for questionable congressional enactments.

[87] TRIBE, *supra* note 70, §§ 5-7, 5-8, 5-20-5-23, 6-26.

[88] 469 U.S. at 528.

[89] *Id.* at 552.

[90] *Id.* at 551; U.S. CONST. art I, § 3, art. V.

[91] THE FEDERALIST No. 62, at 408 (James Madison) (B. Wright ed., 1961).

[92] U.S. CONST. art I, § 2.

[93] THE FEDERALIST No. 46, at 332 (James Madison) (B. Wright ed., 1961).

The judiciary, on the other hand, is ill-equipped to protect state sovereignty. The judicial process requires that courts develop principles applicable to a wide range of cases. Finding such principles to protect the federal-state balance has proven difficult. As Justice Blackmun wrote in *Garcia*, "[w]hat has proved problematic is not the perception that the Constitution's federal structure imposes limitations on the Commerce Clause, but rather the nature and content of those limitations."[94] Justice Blackmun initially believed the Court capable of developing standards to limit Congress' Commerce Clause powers, but he reversed himself — thereby providing the fifth vote to reverse the closely divided Court — after concluding that courts lack the ability to "identify principled constitutional limitations on the scope of Congress' Commerce Clause powers over the States. . . ."[95]

By presuming that Congress does not intend to preempt state law and construing statutes accordingly, courts force Congress to make its intent to displace state law "clear and manifest," thus ensuring that the preemption of state law is deliberate and made with the full knowledge of both the legislative and executive branches. Presumably, those branches will keep the interests of the states in mind when considering whether to abrogate state law. Courts assist the states by displacing state law only in cases in which it is impossible to obey state and federal law, or in cases in which the state law undermines the federal purpose. Presumably, the possibility of such conflicts with state law were foreseen by members of Congress voting to enact the legislation, and thus the states' interests were considered when the law was enacted. By requiring Congress to speak clearly when expressly preempting state law and by narrowly construing "conflicts" between state and federal law, courts force Congress to take full responsibility for the preemption of state law.

C. *Regulatory Preemption*

Regulatory preemption — the preemption of state law by regulations promulgated by federal agencies — creates a special set of problems. These problems are evident particularly in the area of food and drug law, where Congress has delegated much of its lawmaking authority to FDA. FDA has promulgated a detailed set of regulations governing the sale of foods, drugs, cosmetics, and medical devices, and its personnel review new products to ensure they meet agency standards. Absent the ability to delegate to FDA, it is unlikely that Congress could ensure that products are safe and effective for their intended use. Clearly, the Commerce Clause permits Congress to regulate the interstate sale of foods and drugs. Just as clearly, the states have an interest in protecting their citizens from threats to their health and their pocketbooks. Indeed, the states are acting pursuant to their "historic police powers" when protecting the health and safety of their citizens,[96] and courts have taken care not to unnecessarily usurp the states' traditional role.[97] How then, should courts react when FDA promulgates regulations that preempt state law?

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[94] *Garcia*, 469 U.S. at 468.

[95] *Id.* at 469.

[96] *See Medtronic*, 116 S. Ct. at 2245 ("Throughout our history the several States have exercised their police powers to protect the health and safety of their citizens." Because these are "primarily, and historically, . . . matter[s] of local concern. . . ."); *Hillsborough County*, 471 U.S. at 719 ("States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort and quiet of all persons.").

[97] *See, e.g.*, *Rice*, 331 U.S. at 230.

As the Supreme Court repeatedly has held, "[f]ederal regulations have no less preemptive effect than federal statutes."[98] Agencies have the power to preempt even if Congress failed to expressly authorize them to displace state law.[99] Regulatory preemption is suspect only to the degree that any lawmaking by administrative agencies is suspect. Because it is now well-established that agencies have the authority to make law, the preemptive effect of agency-made law should be equally valid.

Nevertheless, agency preemption of state law raises difficult questions for reviewing courts. How should courts apply the presumption against preemption to agency regulations? Should it matter to the reviewing court whether Congress expressly or impliedly delegated the authority to preempt? Finally, should courts apply *Chevron* deference to agency determinations that their governing statute permits preemption just as they would to other agency interpretations of their governing statutes?

The federalism concerns underlying the presumption against preemption are just as strong in the context of regulatory preemption. State sovereignty is no less diminished because it is an agency, and not Congress, that is doing the preempting. In fact, preemption by agencies may prove a greater hindrance to the states' ability to govern their affairs than preemption by congressional enactment. In part, this is because agencies can promulgate far more comprehensive and detailed regulations than Congress — with its limited number of members, lack of expertise, and broad authority — would have the time and inclination to do.[100]

In addition, agencies are a step removed from the political safeguards of federalism that courts rely on to protect state sovereignty. Unlike Congress, agencies are not directly accountable to the states. The heads of agencies are appointed, not elected. Agency decision makers may have little or no connection to the states, and can make decisions without first obtaining state input. Although agencies are accountable to Congress, which controls their budget and defines their mandate, agencies are one-step removed from the pressures and influences that states can exert on members of Congress and the executive branch.[101]

Thus the presumption against preemption should apply to agency preemption determinations. Courts have had difficulty, however, reconciling that presumption with the *Chevron* deference normally granted agency interpretations of their governing statutes. For the most part, courts have chosen to avoid the issue — either being so vague as to leave the question unresolved or sidestepping it completely. For example, in *Medtronic v. Lohr*, the Supreme Court was conflicted about whether *Chevron* required it to defer to FDA's interpretation of the preemptive scope of the Medical Device Amendments to the FDCA.[102] Although the five-member majority discussed FDA's preemption regulations and noted that Congress had delegated substantial discretion to FDA to determine whether particular state laws were preempted by the federal regulatory scheme, the majority did not apply the two-step *Chevron* analysis that normally precedes a discussion of an agency's interpretation of an ambiguous statute.

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[98] Capital Cities Cable, Inc. v. Crisp, 467 U.S. 691, 699 (1984).

[99] Fidelity Fed. Sav. & Loan Ass'n v. De La Cuesta, 458 U.S. 141, 154 (1982) ("A pre-emptive regulation's force does depend on express congressional authorization to displace state law.") (citing United States v. Shimer, 367 U.S. 374, 381-83 (1961)).

[100] *See, e.g.*, Alan B. Morrison, *The Administrative Procedure Act: A Living and Responsive Law*, 72 VA. L. REV. 253, 254-60 (1986).

[101] Marshall, *supra* note 45, at 278.

[102] *Compare Medtronic*, 518 U.S. at 505-07 (Breyer, J., concurring) (stating that absent clear congressional command as to preemption, administrative agencies have a "degree of leeway" to determine which administrative actions has preemptive effect) *with* 518 U.S. at 512 (O'Connor, J., dissenting) (stating that *Chevron* deference is unwarranted).

Moreover, the majority repeatedly stated that its preemption determination rested "primarily" on "a fair understanding of *congressional purpose,*"[103] and not that of FDA. The dissenters, in turn, pointed out that the majority never explicitly granted *Chevron* deference to FDA's regulations interpreting the FDCA. Indeed, the majority questioned whether such deference would have been appropriate. The issue has not been taken up again by the Supreme Court, and remains unresolved.

IV. RESOLVING THE CONFLICT BETWEEN CHEVRON DEFERENCE AND THE PRESUMPTION AGAINST PREEMPTION

To decide what deference, if any, to give agency preemption determinations, the principles underlying *Chevron* deference must be analyzed in conjunction with the principles underlying the presumption against preemption. As discussed in part II, *Chevron* deference is based on theories regarding agency expertise, agency accountability, and congressional intent. The presumption against preemption is derived from concerns for federalism, a reluctance to deprive citizens of the protection of state laws, and the desire to make Congress take responsibility for the preemption of state laws. If these doctrines of judicial decisionmaking are given blanket application, without thought as to whether they are fulfilling their underlying purposes, they inevitably will clash. If applied selectively to further their respective interests, however, they are reconcilable.

A. *Accountability*

Agencies' political accountability, and the courts' lack thereof, is one of the bases for deferring to agencies' interpretations of their governing statutes. As the Court wrote in *Chevron*,

> While agencies are not directly accountable to the people, the Chief Executive is, and it is entirely appropriate for this political branch of the Government to make such policy choices — resolving the competing interests that Congress either inadvertently did not resolve, or intentionally left to be resolved by the agency charged with the administration of the statute in light of everyday realities.[104]

In the preemption context, however, it is not only political accountability that matters, but accountability specifically to the states as units of political power within the federal system. In *Garcia*, the Court explained that it was abandoning its previous efforts to protect state sovereignty through judicially-crafted limitations on Congress' Commerce Clause powers because it believed state interests were protected by the "structure of the Federal government itself."[105] Locating agency preemption power in ambiguous federal statutes undermines the structural safeguards of federalism. Congress' failure to authorize an agency to preempt state laws could mean that it did not foresee the possibility of preemption. Alternatively, Congress may have left the language of the statute ambiguous because it wanted the agency to make the final decision on the issue. Under *Chevron*, such lack of foresight, or intentional indecision, is

[103] *Id.* at 2250 (quoting *Cipollone*, 505 U.S. at 530 n.27) (emphasis in original).
[104] *Chevron*, 467 U.S. at 865.
[105] *Garcia*, 469 U.S. at 550-51.

viewed as an invitation to the agency to fill the "gaps" in the statute. In contrast, the presumption against preemption requires reading an ambiguous statute as a bar to preemption, because state laws should only be displaced by a deliberative act of Congress, in which the states' interests are represented and taken into account.[106] Indeed, a recognized benefit of the presumption against preemption is that it prevents the legislative and executive branches from evading responsibility for displacing state laws.[107] Where the preemption of state law is concerned, congressional silence or ambiguity should not lead automatically to the conclusion that the agency is empowered to act in Congress' stead.[108]

Agencies, however, are not completely insulated from the political influence of the states. As the Court noted in *Chevron*, all agencies are accountable to Congress, which oversees their activities and controls their budgets. Executive agencies are also accountable to the President, who appoints their top personnel and maintains some control over policymaking.[109] Agencies are thus subject, at least indirectly, to the political pressures applied to Congress and the executive branch by the states. To the degree that the legislative and executive branches are persuaded to protect state sovereignty, agencies will feel some pressure to do the same. Thus, the states have an opportunity to make their concerns known to agencies through Congress, through directives from the executive, or through comments submitted directly to agencies on proposed regulations. As a result, even though agency rulemakings lack some of the political safeguards of federalism that are present when a bill preempting state law is passed, agencies are not immune completely from pressure to act in the states' interests.

Nevertheless, regulatory preemption should not be equated with statutory preemption and its attendant opportunities for states to protect their interests. When an agency is affirmatively asserting the authority to preempt state law, courts should not defer unless the agency has given notice of its intention and provided an opportunity for interested persons to comment. Normally, courts grant *Chevron* deference to agency interpretations of their governing statute as long as those interpretations reflect the agency's "fair and considered judgment on the matter;"[110] there is no requirement that agencies undertake formal notice and comment before deference is accorded.[111] Thus, courts have deferred to agencies' litigating positions, and to informal articulations of agency policy in letters or policy statements.[112] Decisions by an agency to preempt state law, however, should be subject to a higher standard. If an agency has formulated its preemption determination without notice and comment — such as in a nonbinding policy statement or a preamble to a regulation — then the political safeguards of federalism are absent and reviewing courts should take care to attend to the federalism concerns that otherwise might be neglected.

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[106] *See* TRIBE, *supra* note 70, at 480 ("to give the state-displacing weight of federal law to mere congressional *ambiguity* would evade the very procedure for lawmaking on which *Garcia* relied to protect states' interests") (emphasis in original); *The Supreme Court, 1987 Term — Leading Cases*, 102 HARV. L. REV. 143, 296 (1988) ("A rule that distills displacement of state law from congressional *silence* divests states of even *Garcia's* slender procedural guarantee.") (emphasis in original). *Cf.* California State Bd. of Optometry v. Federal Trade Comm'n, 910 F.2d 976, 981-82 (D.C. Cir. 1990) (refusing to defer to the Federal Trade Commission's argument that it could issue rules interfering with sovereign acts of states in the face of congressional silence because to do so would "short-circuit the protections offered States by the political process").

[107] *See id.*

[108] *Silkwood*, 464 U.S. at 251 (finding Congress' silence on the preemption question to be significant).

[109] *Chevron*, 467 U.S. at 865.

[110] Tax Analysts v. Internal Revenue Serv., 117 F.3d 607, 613 (D.C. Cir. 1997) (quoting Auer v. Robbins, 117 S. Ct. 905, 912 (1997)).

[111] *Id.*

[112] *See id.*

In the past, courts have expressed concern about the formality of agency action in the preemption context. In *Fidelity Federal Savings and Loan Association*, the Supreme Court had to decide whether the Federal Home Loan Bank board regulations allowing federal savings and loan associations to use the due-on-sale clauses in their mortgage contracts preempted a California law prohibiting such clauses.[113] The preamble that accompanied the Board's regulations permitting use of due-on-sale clauses stated that "Federal [savings and loan] associations shall not be bound by or subject to any conflicting State law which imposes different . . . due-on-sale requirements. . . ."[114] Although the Court used this expressed intention to preempt as support for its conclusion that the regulation conflicted with — and thus preempted — state law, the Court was careful to note that it was not relying on the preamble alone as a basis for its decision, because the preamble had not been subject to notice and comment and it lacked the force of law. Similarly, in *United States v. Walter Dunlop & Sons, Inc.*,[115] the Third Circuit held that state law governed the status of a lien on collateral for a loan made by the Farmers Home Administration (FmHA), despite an FmHA regulation that conflicted with state law. The regulation at issue was an interpretive rule, promulgated without notice and comment, and thus lacked the force and effect of law.[116] The court concluded that interpretive rules "do not constitute the sort of explicit 'congressional directive' that will displace the application of state law. . . ."[117]

There are two reasons to require agencies to act formally through notice and comment before granting any deference to their preemption determinations. First, formal agency action will ensure that the "political safeguards of federalism" have a chance to work. Agencies are accountable indirectly to the states, whose interests are represented by the legislative and executive branches, and agencies also can be influenced by direct input from the states. The states' influence over agencies is at its weakest when agencies take informal action. If agencies have not provided notice that they have taken a stand regarding preemption or given interested persons an opportunity to comment, the legislative and executive branches, as well as the states, will be unable to make their preferences known. Moreover, by failing to provide for a period of public comment, agencies lack the input from states that might persuade them that preemption is unnecessary or unwarranted. In short, informal agency action deprives states of the political influence that protects states from federal overreaching.

Second, when agencies preempt state law informally, they show a lack of respect for state sovereignty. Although federal agencies have the power to preempt, they should not do so cavalierly, without the long deliberation that accompanies the promulgation of a legally-binding rule. State laws deserve the respect of federal agencies. These laws are enacted by democratically elected state legislatures. Oftentimes, the state laws threatened by preemption concern the health and safety of the state's citizens — an area that traditionally has been the domain of the states. Moreover, usually it is not just one state whose laws are threatened, but a number of states that have similar laws on the books. In

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[113] 458 U.S. at 141.

[114] *Id.* at 158.

[115] 800 F.2d 1232 (3d Cir. 1980).

[116] *Id.* at 1238.

[117] *Id.* at 1239. Without noting any conflict with its previous decision in *Walter Dunlop & Sons*, a split panel of the Third Circuit preempted state law on the ground that it conflicted with an interpretive rule issued by the Secretary of Health and Human Services. *See, e.g.*, Elizabeth Blackwell Health Ctr. for Women v. Knoll, 61 F.3d 170, 182 (3d. Cir. 1995). The majority defended its decision by noting that Chevron deference applies to informal, as well as formal, agency action, but failed to consider the possibility that deference to agency preemption determination taken without notice and comment, even if appropriate in other contexts, is at odds with the rationale underlying the presumption against preemption. *See id.* at 182, 196 (Nygaard, J., dissenting).

contrast to state law makers, the decision makers in federal agencies are appointed, not elected. Agency officials lack knowledge of the special circumstances that exist in the individual states. Allowing agencies to preempt state law without notice and comment creates needless friction between the states and the federal government, and deprives citizens of the protection from state laws that they expect.

If agencies use informal means to declare their intent *not* to preempt state law, however, neither of the above two concerns apply. Because the states lose nothing by an agency determination that federal law does not displace state law, they need not participate in such decisions. Nor does an agency show any lack of respect for the states when it informally concludes that state laws should be left in place. Thus, an informal agency statement that it does not intend to preempt state law should be granted the same deference as any "fair and considered" agency judgment would be accorded under *Chevron*.

B. *Default Rule*

Another rationale for *Chevron* deference is that it serves as a default rule against which Congress legislates. According to this theory, when Congress is ambiguous or silent, it is not explicitly delegating policy decisions to the agencies, but rather has failed to foresee the issue at all or has failed to gather a majority to support one position or another.[118] Establishing the rule of deference is useful because it provides certainty — Congress knows that if it fails to be clear, the agency entrusted with administering the statute will make the final decision. Because Congress has some idea of the policy preferences and biases of the agencies for which it legislates, Congress knows how an unclear statute likely will be interpreted.[119]

The default rule theory for deference is at odds with preemption doctrine. If Congress failed to foresee the possibility of preempting state law, then there was no clear intent on Congress' part to authorize the agency to do so. Without congressional intent to preempt, or congressional delegation of the preemption power, agencies are acting on their own initiative when preempting state law. Preempting state law is substantively different from general agency interpretations of ambiguous statutes, or agency policymaking to fill statutory gaps. To defer to an agency's conclusion that preemption is within its mandate, when Congress never decided the issue, would violate the states' Tenth Amendment right to regulate the activities of their citizens.

Even more problematic is the idea that Congress left the statute ambiguous because it could not form a coalition to vote in favor, or against, the delegation of preemption power to the agency. If Congress cannot muster a majority to support preemption, then allowing the agency to preempt state law regardless is at odds with the rationale underlying the presumption against preemption. Indeed, under such circumstances, deference to an agency's conclusion that it is authorized to preempt state law creates a presumption in *favor* of preemption. If agencies are permitted to preempt state law even when a majority of Congress refused to speak in favor of it, then deferring to agency preemption determinations is equivalent to finding congressional intent to preempt in the absence of a clear statement to the contrary. Such an outcome conflicts with the Tenth Amendment's prohibition against unnecessarily interfering with the autonomy of the states.

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[118] Deference is appropriate even when Congress "simply did not consider the question at this level" or when "Congress was unable to forge a coalition on either side of the question." *Chevron*, 467 U.S. at 865.

[119] *See supra* notes 33-34 and accompanying text.

Again, these federalism concerns do not arise when agencies interpret their governing statutes to avoid preempting state law. An agency's decisions not to preempt reads congressional ambiguity or silence as a bar to preemption of state law, letting Congress know that if it wishes a particular agency to displace state law, it must delegate that power clearly and without reservation. Such a judgment by an agency merits *Chevron* deference. By deferring to agency decisions not to preempt, courts promote the policies behind the presumption against preemption because Congress will quickly come to realize that without a clear delegation the agency will let state law stand and the courts will affirm the agency's interpretation.

C. *Expertise*

Agency expertise, one of the most frequently cited rationales for *Chevron* deference, fails to justify blanket deference to agency preemption determinations. Agencies are granted deference when construing their governing statutes because they understand how the statutes work in practice, and because Congress intended, or at least was aware, that agencies would fill in the missing gaps. Most preemption determinations, however, require agencies to construe state law, and then determine if these laws conflict with federal law. Agencies have no comparable familiarity with state laws, nor are they the institution entrusted with applying those laws. State agencies, legislatures, and courts, not federal agencies, are experts on their own laws. State and local governments never intended to leave the interpretation of their statutes to federal agencies. Courts should deny deference to agency interpretations of state law, just as they would deny deference to agency interpretations of federal statutes that they are not responsible for administering.[120]

Moreover, Congress cannot delegate to agencies the authority to interpret state laws; state courts, not Congress, are the final authority on the interpretation of state laws.[121] Federal agencies have only those powers delegated to them by Congress, and Congress cannot delegate powers it does not possess. Because Congress has no authority to interpret state laws, agencies lack that authority as well. [122]

Of the three branches of government, only the judiciary is in a position to construe state laws, and then under the most limited of circumstances. Federal courts interpret state laws only when those laws are tied to a federal question,[123] or when the parties before it have diversity of citizenship. Even then, federal courts go to great effort to avoid passing on state law or reviewing decisions by state courts so as to avoid intruding in the states' affairs. For example, federal courts routinely abstain from deciding cases when the state law at issue is uncertain, preferring to certify the state law questions for a determination by state courts. Indeed, abstention and certification doctrines are defended as the judicial creation of common law rules necessary to protect the position of the states in the federal system.[124] Federal courts abstain so that the states can interpret their laws, which promotes harmony between state and federal

[120] Courts do not owe deference to an agency's interpretation of statutes that are "outside the agency's particular expertise and special management charge to administer." Professional Reactor Operator Soc. v. U.S. NRC, 939, F.2d 1047, 1051 (D.C. Cir. 1991) (rejecting deference for NRC's interpretation of the Administrative Procedure Act).

[121] *See* Cooper v. Aaron, 358 U.S. 1, 19 (1958).

[122] *See, e.g.,* Murdock v. City of Memphis, 87 U.S. (20 Wall.) 590 (1875) (holding that a state's highest courts are final interpreters on questions of state law).

[123] *See, e.g.,* Indiana *ex rel.* Anderson v. Brand, 303 U.S. 95 (1938); Broad River Power Co. v. South Carolina, 281 U.S. 537, 540 (1930); Standard Oil Co. v. Johnson, 316 U.S. 481 (1942).

[124] *See* Michael Wells, *Why Professor Redish is Wrong About Abstention*, 19 GA. L. REV. 1097 (1985).

courts.[125] As Justice Frankfurter wrote when the Court first established the practice of abstention, "few public interests have a higher claim upon the discretion of a federal chancellor than the avoidance of needless friction with state policies."[126]

Federal agencies' interpretations of state laws raise the same federalism concerns that motivated the federal courts to develop the abstention and certification doctrines. Every time an agency concludes that a state law must be preempted because it is in conflict with federal law, or because it stands as an obstacle to the achievement of a federal purpose, the agency has made a determination regarding the scope and effect of the state law. Just like courts, agencies risk misinterpreting state laws, creating needless friction between state and federal governments.

D. *Congressional Intent*

Chevron deference also has been justified as a means of realizing congressional intent. Proponents of this theory argue that Congress intended agencies, not courts, to fill the gaps in ambiguous or silent statutes. This theory is most persuasive when an agency is interpreting an ambiguous word or phrase in a statute that relates directly to its area of expertise. For example, it makes sense to conclude that Congress intended the Environmental Protection Agency, and not the federal courts, to determine the exact compass of the term "stationary source" in the Clean Air Act Amendments of 1977.[127] The same assumption does not apply to agency preemption determinations. As discussed above, agencies are not experts in determining the scope of state laws, or if those laws conflict with federal law or pose an obstacle to the achievement of a federal purpose. Determining when and if statutes conflict for preemption purposes is the type of question that courts, not agencies, are best positioned to address. Moreover, agencies have an institutional interest in deciding the question in favor of preemption, for then the agency establishes itself as the sole authority in its field. Considering the lack of agency expertise in determining whether preemption of state law is required, combined with the risk of agency aggrandizement, it is far from clear that Congress intended agencies, not courts, to make preemption determinations.

E. Guidelines for Judicial Review

A comparison of the rationales underlying the presumption against preemption and *Chevron* deference reveals that courts should modify the usual rule of deference when reviewing agency preemption determinations. Below are guidelines for judicial review of agency preemption determination that were derived from the previous analysis.

1. As a threshold matter, if an agency asserts a right to preempt a state law, courts should not grant deference unless the agency has articulated its position formally, through notice-and-comment rulemaking. Otherwise, the legislative and executive branches, and the states, are left without a voice in the agency's decision, undermining the structural safeguards of federalism.

2. Even when acting through formal rulemaking, however, agencies are less susceptible to the states' influence than Congress because they are one step removed from political process, and thus agencies are less accountable to state interests. Accordingly, courts should not accept an agency's assertion of preemptive power without

[125] *See* Davies, *Pullman and Buford Abstention: Clarifying the Roles of Federal and State Courts in Constitutional Cases*, 20 U.C. DAVIS L. REV. 1, 9-10 (1986).

[126] *Hines*, 312 U.S. at 396, 500.

[127] Pub. L. No. 95-95, 91 Stat. 685.

first determining, independent of the agency's view of things, if Congress intended the agency to have such power. If courts defer to any reasonable agency position, as *Chevron* dictates, states would lose some of the protections of the political safeguards of federalism.

An agency's natural desire to expand its authority is another reason for courts to review agency preemption determinations with concern. When agencies conclude that they are authorized to preempt state laws, courts should keep in mind that agencies may be acting out of self-interest, rather than a principled belief that preemption is necessary. Courts should retain a degree of skepticism when reviewing the validity of regulatory preemption.

3. Nonetheless, courts should continue to give some degree of deference to some parts of an agencies' preemption analysis. To determine the preemptive effect of federal law, courts and agencies must conduct a three-part review. They must: a) determine the scope of the federal law at issue, b) analyze the state law that allegedly is preempted, and c) determine the extent to which they are in tension.[128] Agency views on each of these questions should be granted varying degrees of consideration by a reviewing court.

a) Courts should continue to give some degree of deference — even if not full-fledged *Chevron* deference — to agencies' conclusions regarding the scope of their governing statute and implementing regulations. The principles of *Chevron* apply to an agency's construction of its statute and regulations; an agency is better positioned than a court to make judgments about the extent of its regulatory authority because it has more expertise and experience in the area, and because Congress likely intended that the agency, not the court, make the determination.

b) Reviewing courts, however, should not rely on agencies when conducting the second step of the preemption review. Agencies are no more expert in interpreting state laws than they are in interpreting federal statutes that they are not charged with administering. Moreover, Congress has no authority to interpret state laws; therefore, it cannot delegate that power to federal agencies.

c) The third step of judicial review requires comparing state law to federal law and determining if state law must give way. Courts should not defer to an agency's conclusions that federal and state laws conflict. Agencies have no expertise in making such determinations, nor is this the kind of decision that Congress should be encouraged to leave to agencies to decide. By deferring to an agency's determination that state law is in conflict with federal law, rather than reaching that conclusion on their own, courts are saying that although a finding of preemption is reasonable, it is not the only possible conclusion. In fact, by deferring to the agency's interpretation, courts leave agencies free to change their minds, deciding in the next administration that the statute does not preempt the state law at issue after all. If agencies do vacillate, the states are in limbo, never sure which of their laws will be preempted.

All federalism concerns can be set aside when agencies conclude that federal and state laws do not conflict. *Chevron* requires courts to defer to such decisions as long as they are reasonable. If the agency's determination not to preempt is reasonable, then the presumption against preemption also favors deference to the agency. In such situations, the doctrines of *Chevron* deference and the presumption against preemption operate in tandem, each providing independently valid reasons for deferring to the agency's conclusion that preemption is not required.

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[128] *See Teper*, 82 F.3d at 993.

V. APPLYING THE GUIDELINES: JUDICIAL REVIEW OF FDA PREEMPTION DETERMINATIONS

These guidelines resolve some of the questions raised by courts and litigants concerning the degree of deference that should be given to FDA preemption determinations. In *Medtronic v. Lohr* the majority fell short of asserting the two-step *Chevron* analysis, although it did profess to give FDA's narrow interpretation of the express preemption provision "substantial weight." Seizing on the majority's hesitancy, the dissent questioned whether deference is appropriate at all in the area of preemption. Although the dissent correctly noted that *Chevron* deference and preemption are sometimes in conflict, *Lohr* was not such a case. In *Lohr*, FDA argued against preemption of state law. FDA clearly stated its position both in its regulation and in the *amicus curiae* brief that it filed with the Court.[129] Thus, there was no reason not to grant FDA *Chevron* deference.

FDA's regulation in *Lohr* did not tell the Court when preemption of state law is required, but instead merely delineated the scope of the express preemption provision in its governing statute. FDA interpreted the preemption provision narrowly, concluding that:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.[130]

Under FDA's view, expressed in its regulation, the "different from or in addition to requirement" applies only in the narrow circumstances stated in its regulation. This view assists a reviewing court's understanding of the scope of the express preemption provision, and should be given *Chevron* deference. The agency is the expert in determining the scope and effect of its governing statute, and is in a better position than a reviewing court to determine Congress' intent in enacting the express preemption provision. Moreover, because FDA's interpretation of the preemption provision is a narrow one, there is no fear that the agency's view is biased in its own favor. Finally, FDA's narrow interpretation is the safest one for the court to adopt. If the agency is wrong, Congress' intentions have not been realized, but the court and FDA have not committed constitutional error. On the other hand, if courts adopt a broader interpretation of the preemption provision than Congress intended, the states' Tenth Amendment right to govern their affairs has been violated. It is better for courts to err on the side of misinterpreting the statute than impinging on states' autonomy.

FDA's regulations narrowly interpreting the express preemption provision comprise one aspect of the agency's role in determining if and when state laws concerning medical devices are preempted. In the Medical Device Amendments, Congress gave FDA the unusual task of prescreening state laws to determine whether or not they are preempted by the FDCA.[131] Even if a state or local requirement is preempted, states

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[129] 21 C.F.R. § 808.1(d); Brief for the United States as Amicus Curiae supporting respondent/cross-petitioner, *Lohr*, 518 U.S. 470.

[130] 21 C.F.R. § 808.1(d).

[131] *Id.* § 808.1(e).

and localities may apply to FDA for exemptions from preemption under section 360k(b) of title 21 of the *United States Code*. At its discretion, FDA may allow a state law to stand that otherwise would have been preempted, as long as the state requirement is "more stringent" than federal requirements, or an exemption is required by compelling local conditions and compliance with the requirement would not cause the device to be in violation of any federal requirements.[132] States may petition for an exemption before their laws go into effect, and thus before there has been any conflict between federal and state law. In short, section 360k(b) gives FDA the task of "vetting" state laws to determine first whether they are preempted, and second whether they merit an exemption from the preemption provision — even before any conflict between state and federal law has arisen.

FDA has enacted regulations detailing its procedures for reviewing applications under section 360k(b) for exemption from preemption. First, FDA analyzes the state law or local requirement at issue. FDA does not limit its analysis to the "literal language" of the state law, but instead looks at "how the requirement is interpreted and applied."[133] To aid in the endeavor, FDA requires that states submitting their laws for review send relevant background material, including legislative histories, hearing reports, and any other information that will "enable the Commissioner to determine the intent of the State or local ordinance or statute."[134] When considering a formal application for exemption from preemption, FDA requires the submission of all the materials listed above, with a letter to the Commissioner signed by an individual authorized to request the exemption on behalf of the state or political subdivision.[135] FDA will not issue its decision until after holding a public hearing and permitting the public to comment on the application.

FDA has a separate and less formal procedure for issuing advisory opinions concerning the preemption of state or local regulations. Upon request by any "interested person," FDA will review a state or local regulation — even if it is not yet law — and issue an advisory opinion predicting if the requirement will be preempted.[136] FDA does not require the "interested person" to submit all the materials required for a formal application for exemption from preemption. Although these advisory opinions lack the force of law of a section 360k(b) determination, at the Commissioner's discretion, a request for an advisory opinion also can be treated as a formal application for an exemption from preemption.[137]

If a case arises concerning a statute that FDA already has analyzed under section 360k(b), reviewing courts must decide what weight to give FDA determinations. For the reasons discussed in part IV, FDA's conclusions regarding the meaning of state statutes and local ordinances are entitled to no deference by a reviewing court. In attempting to determine how a statute or ordinance operates, FDA is performing the task of a state court or state agency, but without the experience or information of those institutions. Moreover, if FDA has been asked to issue an advisory opinion by someone who is not a state or local official, to grant FDA's review *Chevron* deference would be inappropriate. Such an advisory opinion can be issued before the state or local law goes into effect, and thus before the state has had an opportunity to educate the agency regarding its intended application. In addition, the more informal advisory

[132] 21 U.S.C. § 360k(b).

[133] 43 Fed. Reg. 18,661, 18,663 (1978).

[134] 42 Fed. Reg. 30,383, 30,385 (June 14, 1977).

[135] *Id.* at 30,385.

[136] *Id.*

[137] *Id.*

opinion process does not ensure that the agency has all the relevant information about the state law before making its decision. Finally, the informality of FDA's review means that the state may not have an opportunity to participate in the agency's decisionmaking.

Although courts should not defer to FDA's construction of state law, deference should be given to FDA conclusions that state and federal law do not conflict, even if FDA might have misconstrued state law in the process. If FDA reads a state law narrowly to avoid preemption, then it has acted as courts do when faced with constitutionally troubling legislation. Courts prefer to interpret statutes so as to uphold them, even if the interpretation is somewhat strained, and courts should allow agencies to do the same. Until a state makes it clear that FDA's interpretation is wrong, FDA's reading of a state law should stand.

Even though deference should not be granted to FDA preemption determinations under section 360k(b), that is not to say that the process set up under section 360k(b) is illegitimate. To the contrary, the process allows FDA to exempt certain state laws from preemption, and thereby avoid the necessity for judicial intervention. In addition, the advisory process is beneficial to the states, which get the opportunity to prescreen potentially conflicting legislation with FDA and perhaps alter the law to meet FDA's concerns before final enactment. These benefits, however, do not mean that courts should defer to FDA conclusions regarding state laws or the existence of a conflict, when the federal courts themselves would have decided the issue differently.