No. 08-889

In the Supreme Court of the United States

TRI-UNION SEAFOODS, L.L.C.,
D/B/A CHICKEN OF THE SEA,

Petitioner,

v.

DEBORAH FELLNER,

Respondent.

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

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

INTEREST OF THE *AMICUS CURIAE*[1]

The Chamber of Commerce of the United States of America (the Chamber) is the world's largest business federation. The Chamber represents an underlying membership of more than three million companies and professional organizations of every size, in every industry, from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases that raise issues of vital concern to the Nation's business community.

This is such a case. The Chamber's members include millions of businesses that are subject to preemptive federal statutes, regulations, and agency actions. These businesses depend on a robust doctrine of implied preemption as protection against state and local mandates that conflict with federal requirements (including, as in this case, requirements that happen to

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[1] Counsel of record for all parties received timely notice of the *amicus curiae*'s intent to file this brief. S. Ct. Rule 37.2(a). The parties' letters of consent to the filing of this brief have been filed with the Clerk. Under Rule 37.6 of the Rules of this Court, *amicus curiae* states that no counsel for a party has authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity, other than the *amicus curiae*, its members, or its counsel, has made a monetary contribution to this brief's preparation or submission.

be expressed, unambiguously and authoritatively, by an expert administrative agency *outside of* the pages of the Code of Federal Regulation). The Supremacy Clause of the Constitution, which is the fountainhead of the doctrine of implied conflict preemption, serves a vital structural role in our Nation's government by protecting federal laws, programs, policies and prerogatives against encroachment and interference by subordinate governments (including interference by state tort law as applied by lay juries). The Supremacy Clause also helps to create unified markets for nationally distributed goods and services. Further review is needed to clarify several significant issues of preemption law that are raised by the petition. Accordingly, the Chamber and its members have a substantial interest in ensuring that this Court grant the petition and correct the serious errors made by the lower court.

STATEMENT

1. The Supremacy Clause provides that the Constitution and federal laws and treaties "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." U.S. CONST. art. VI, cl. 2. This Court's decisions interpreting the Supremacy Clause – and articulating what has come to be known as the doctrine of implied conflict preemption – stretch back to the earliest days of the Republic. See, *e.g.*, *Gibbons* v. *Ogden*, 22 U.S. (9 Wheat.) 1 (1824); *Houston* v. *Moore*, 18 U.S. (5 Wheat.) 1 (1820); *M'Culloch* v. *Maryland*, 17 U.S. (4 Wheat.) 316 (1819). "[S]ince our decision in *M'Culloch*," the Court has explained, "it has been settled that state law that conflicts with federal law is 'without effect.'" *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 516 (1992).

During the last century (and particularly since the New Deal), in response to fundamental changes in the national economy, there has been a significant expansion of federal law and of the activities of the national government. This includes Congress's creation of dozens of expert, specialized administrative agencies to oversee – and often to comprehensively regulate – complex and important facets of the economy. By virtue of the Supremacy Clause, the inevitable consequence of this expansion of federal authority has been to increase the likelihood of conflicts with the laws and regulatory efforts of state and municipal governments. *New York* v. *United States*, 505 U.S. 144, 159 (1992) ("As the Federal Government's willingness to exercise power within the confines of the Constitution has grown, the authority of the States has correspondingly diminished to the extent that federal and state policies have conflicted."). The risk of conflict is further enhanced by the existence, at last count, of approximately 87,525 local governmental units in the United States, including more than 3,000 counties, more than 19,000 municipalities, and more than 16,000 towns or townships. U.S. CENSUS BUREAU, STATISTICAL ABSTRACT OF THE UNITED STATES 262 (2004). It should come as no surprise that issues of conflict preemption arise with great frequency today.

2. This case arises against the backdrop of longstanding regulation by the Food and Drug Administration (FDA) of food safety under the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq*., as amended, and, more specifically, of the health risks associated with methylmercury in fish.[2] As petitioners demonstrate

[2] In the area of food safety, Congress has often used preemption clauses to ensure national uniformity of federal regulation. Examples include the Nutritional Education and Labeling Act, 21

(Pet. 4-11), for more than a decade the FDA has carefully examined the scientific data concerning the risks of human consumption of methylmercury in fish and, on the basis of that analysis (as well as the agency's study through focus groups of the effect of various communications on consumers), has devised a balanced and nuanced regulatory program aimed at informing consumers of those risks. In particular, the FDA has undertaken to balance comprehensively the societal health benefits of eating fish (which might be reduced by warnings aimed in blunderbuss fashion at the general population) against the potential risks to specific subgroups of consumers, including nursing mothers, pregnant women, and young children (risks that FDA has concluded can and should be conveyed through more targeted communications). Because of its scientific and public-health expertise, the FDA is uniquely qualified to make these delicate judgments.

Congress has armed the agency with broad authority to act in a wide variety of ways, both formal and informal, to carry out the agency's responsibility of protecting the public health. Over the years, the FDA has carried out its extensive and balanced program concerning methylmercury in fish through a series of regulatory actions, including (1) the issuance of consumer advisories; (2) the denial of a "citizen" petition submitted by Martek Biosciences Corporation, which had requested that FDA mandate that qualified health claims relating to the health benefits of consuming

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U.S.C. § 343-1, the Poultry Products Inspection Act, *id.* § 467e, the Federal Meat Inspection Act, *id.* § 678, and the Egg Products Inspection Act, *id.* § 1052. Even where no express preemption clause applies, Congress legislates – and administrative agencies regulate – against the backdrop of ordinary principles of implied conflict preemption.

omega-3 fatty acids be accompanied, in the case of fish products, with additional mercury-related warnings; and (3) the FDA Commissioner's issuance of a letter to the California Attorney General making clear that certain warnings sought by the latter in litigation under California law would be impossible for manufacturers to provide without violating the FDA's requirements and rendering products "misbranded" in violation of federal law.

3. Respondent filed this lawsuit in New Jersey state court, alleging among other things that petitioner, which manufactures Chicken-of-the-Sea tuna products, violated several New Jersey statutes by committing fraud and by failing to provide adequate warnings of the risks of mercury consumption. In respondent's view, New Jersey law imposed a duty to warn of the hazards that might arise if someone (such as respondent) elected to follow a "fad" diet of eating only (or mostly) canned tuna fish for years on end. After petitioner removed the case to federal court, the district court granted petitioner's motion to dismiss on the ground that respondent's statutory claims were preempted by federal law. See also Pet. 13 n.4. Citing the "FDA's ten-year deliberately balanced approach to the issue of methylmercury in fish," the district court explained that "it would be impossible for [petitioner] to comply with the FDA" as well as with "New Jersey law." Pet. App. 52a-53a.

The Third Circuit reversed. Pet. App. 1a-37a. As a threshold matter, it ruled that a "presumption against preemption" was applicable here because, notwithstanding the FDA's longstanding regulatory activities concerning mercury in fish, respondent's "tort-like action" falls "squarely within the realm of traditional state regulation." *Id.* at 19a. Although acknowledging that the Supreme Court "has applied the presumption in few

conflict preemption cases of late," the Third Circuit declared its intent to continue to apply that presumption in conflict preemption cases "until the Supreme Court provides guidance to the contrary." *Id.* at 21a. Applying the presumption, the court of appeals proceeded to reject the preemption defense, reasoning that the FDA's various regulatory actions – including the FDA Commissioner's letter to the California Attorney General – were not sufficiently "formal" to give rise to preemption of state law. *Id.* at 11a-24a.

INTRODUCTION AND SUMMARY OF ARGUMENT

The petition in this case squarely and cleanly raises two issues of federal preemption law that are of surpassing doctrinal and practical importance. Both issues are recurring and have produced significant disagreements in the lower courts – conflicts that only this Court can resolve. The Third Circuit decided both issues incorrectly, and its rulings are inconsistent with the results and analysis in some of this Court's own decisions. Ordinarily this would be more than enough to justify further review by this Court. But here there is even more reason to grant the petition.

As the Third Circuit correctly noted in applying the presumption against preemption over petitioners' objections (and in conflict with decisions of two other circuits, see Pet. 29-31), this Court in recent years "has applied the presumption in few conflict preemption cases." Pet. App. 21a. Despite this Court's recent practice of *not* relying on the presumption in conflict preemption cases, and the existence of various good arguments for why "the conflict preemption analysis subsumes or supplants the presumption," *ibid.*, the Third Circuit declined to examine the validity of the

presumption in this setting. "[W]e will continue," the court instead declared, "to apply the traditional presumption *until the Supreme Court provides guidance to the contrary*." *Ibid.* (emphasis added). Further review is especially warranted to provide that needed guidance not only because this Court's *own decisions* are the source of confusion but also because the Third Circuit has declared an unwillingness to follow this Court's example in recent conflict preemption cases. Moreover, this issue arises at the threshold of *every* conflict preemption case. It deserves a clear answer, which only this Court can provide.

There are additional reasons for granting review of the other issue raised by the petition as well. Just last Term, in *Altria Group, Inc.* v. *Good*, 129 S. Ct. 538 (2008), this Court granted review of an implied preemption issue that included whether an administrative agency's policy that was not embodied or reflected in a formal regulation (but rather only in less formal agency actions) could trigger implied preemption. See No. 07-562 Pet. i, 20-24. In *Good*, the First Circuit had rejected the conflict preemption defense in part because the Federal Trade Commission (FTC) "has never issued a formal rule specifically defining which cigarette advertising practices violate the [Food, Drug and Cosmetic] Act." *Good* v. *Altria Group, Inc.*, 501 F.3d 29, 51 (1st Cir. 2007). At the same time, the First Circuit acknowledged that "[o]ther courts . . . have held that an agency *can* preempt state law through action short of formal rulemaking." *Ibid.* (emphasis added) (citing the decisions of several federal courts of appeal as well as *Dowhal* v. *SmithKline Beecham Consumer Healthcare*, 88 P.3d 1 (Cal. 2004)). This Court granted review to resolve that disagreement even though there was no

conflict in the "light" cigarette cases over the validity of the implied preemption defense.

Because this Court's decision in *Good* resolved the implied preemption issue on other grounds (the nonexistence of any FTC policy), the broader doctrinal conflict identified in the *Good* petition persists. Indeed, the Third Circuit's decision in this case significantly compounds the confusion because it creates a direct conflict with the California Supreme Court's decision in *Dowhal*, a case cited by the First Circuit and by the certiorari petition in *Good*, over whether an FDA letter can trigger conflict preemption. As just explained, this Court has *already* determined that the agency preemption issue raised in this case warrants further consideration. And the reasons for granting review have become only more persuasive since the petition was granted in *Good*. The Court should take this opportunity to address an issue that is of utmost importance to regulated entities.

ARGUMENT

I. THIS COURT SHOULD DECIDE WHETHER THE PRESUMPTION AGAINST PREEMPTION APPLIES TO CONFLICT PREEMPTION

A. The Decision Below Deepens A Circuit Split And Departs From This Court's Methodology In Recent Conflict Preemption Cases

The Third Circuit parted company with the Fifth and Eleventh Circuits when it applied a "presumption against preemption" in this case. The lower court held that the presumption applies across-the-board to *all* preemption cases, including those involving the defense of implied conflict preemption. See Pet. App. 18a-21a. The Fifth and Eleventh Circuits have reached exactly the opposite view, ruling that the presumption is

irrelevant to the analysis of potential conflicts between state and federal law. See *Perry* v. *Mercedes Benz N. Am., Inc.*, 957 F.2d 1257, 1261-62 (5th Cir. 1992) ("We do not begin with an assumption against conflict preemption."); *Irving* v. *Mazda Motor Corp.*, 136 F.3d 764, 769 (11th Cir. 1998) ("When considering implied preemption, no presumption exists against preemption."); see also Pet. 29-31. This clear rift in the circuits warrants this Court's review.

Moreover, the Third Circuit's decision reflects the widespread confusion in the lower courts about critical aspects of *this Court's* conflict preemption jurisprudence. As the lower court candidly acknowledged (Pet. App. 21a), its decision to apply the presumption strays from the vast majority of this Court's recent conflict preemption decisions, which make no mention of the presumption. See also Pet. 32 (identifying such cases). The confusion in the lower courts about where this Court stands is also compounded by *Crosby* v. *Nat'l Foreign Trade Council*, 530 U.S. 363 (2000), in which this Court said it was "leav[ing]" the consideration of this issue "for another day." *Id.* at 374 n.8.[3]

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[3] This Court's recent 5-4 decision in *Altria Group, Inc.* v. *Good*, 129 S. Ct. 538 (2008), is unlikely to dispel the confusion in the lower courts – and may even exacerbate it. On the one hand, the majority opinion states, albeit only in passing, that "[w]hen addressing questions of express *or implied* pre-emption, we begin our analysis 'with the assumption that the historic police powers of the States [are] not superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Id.* at 543 (emphasis added) (quoting *Rice* v. *Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). On the other hand, the majority's rejection of Altria's implied conflict preemption arguments later in the opinion does not invoke or in any way rely upon any such "assumption." Beyond that, the four dissenting Justices in *Good* criticized the majority for applying the presumption to the *express* preemption issue before the Court, arguing that the majority's

Without a clear resolution to this important issue, some lower courts have seized on snippets of language in a few of this Court's decisions to find support for applying the presumption. In this case, for example, the Third Circuit invoked one of the rare conflict preemption decisions where this Court mentioned (but did not rely on) the presumption. See Pet. App. 21a (citing *Hillsborough County* v. *Automated Med. Labs., Inc.*, 471 U.S. 707, 715 (1985)); see also Pet. 32 n.14. The lower court also quoted a passage from *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996) – an *express* preemption case – which appeared to suggest that the presumption applies in "all" preemption cases. See Pet. App. 18a-19a (quoting 518 U.S. at 485). Insofar as such dicta have sown confusion and provided daylight for the proponents of the presumption, this merely underscores the need for this Court finally to address the issue and provide clarification to the lower courts.

Without such clarification, there is no doubt that the lower courts will remain hopelessly divided on this issue. The court of appeals recognized that "arguments have been raised that the conflict preemption analysis subsumes or supplants the presumption," but declined even to consider those arguments and declared that it would continue reflexively to apply the presumption

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analysis was impossible to reconcile with *Riegel* v. *Medtronic*, 128 S. Ct. 999 (2008), but made no mention of the majority's dicta concerning the presumption's use in implied preemption cases. See *Good*, 129 S. Ct. at 555-58 (dissenting opinion). The majority in *Good* did not explain how *Riegel* and *Good* could be reconciled, nor did it address the recent scholarship (brought to this Court's attention in several recent cases by the Chamber and other business *amici*, see pages 11-15, *infra*), which demonstrates, based on newly uncovered historical evidence, that a presumption against preemption *in any setting* is inconsistent with the clear historical understanding of the Supremacy Clause.

"until the Supreme Court provides guidance to the contrary." Pet. App. 21a. Given the split among the circuits and evident confusion about the meaning of its past decisions, this Court should wait no longer to provide the much-needed clarification.

B. The Issue Arises At The Threshold Of Every Conflict Preemption Case

As the scope of the federal government's activities has grown, so too have opportunities for conflicts between state and federal authority. New federal statutes and regulatory activity frequently generate conflicts with state and local law, requiring the courts to resolve issues of conflict preemption. In each case involving a claim of conflict preemption, a court must as a threshold matter face the very question that has so sharply divided the circuits: Does the analysis begin with a judicial thumb on the scales *against* a finding of conflict preemption?

Given the increasing frequency with which the courts must face this question, and the importance of its answer for millions of businesses and individuals regulated at both the state and federal levels, it is no surprise that the Chamber and other national business groups have filed *amicus* briefs in many of this Court's recent cases criticizing the presumption against pre-emption on multiple grounds. See, *e.g.*, Chamber Br., *Watters* v. *Wachovia Bank*, No. 05-1342, 2006 WL 3203256, at *10-14; Br. of the Product Liability Advisory Council, Inc., and the Chamber, *United States* v. *Locke*, Nos. 98-1701 and 98-1706, 1999 WL 966527, at *4-12; Chamber Br., *Geier* v. *Am. Honda Motor Co.*, No. 98-1811, 1999 WL 1049891, at *25-26.

In *Warner-Lambert Co.* v. *Kent*, 128 S. Ct. 1168 (2008), the Chamber recently argued at length that the presumption is categorically inapplicable to conflict

preemption cases. See No. 06-1498 Chamber Br., 2007 WL 4205141, at *8-20. In *Warner-Lambert*, the Second Circuit had relied heavily on the presumption in holding that federal law did not impliedly preempt a Michigan statute. See *Desiano* v. *Warner-Lambert & Co.*, 467 F.3d 85 (2006). This Court granted review but affirmed by an equally divided court, 128 S. Ct. 1168, thus leaving the issue unresolved. See *Exxon Shipping Co.* v. *Baker*, 128 S. Ct. 2605, 2616 (2008) (explaining that such a disposition "is not precedential"). This case presents another, excellent opportunity to resolve this important and recurring question.[4]

C. The Use Of A Presumption In This Setting Is Contrary To The Supremacy Clause

The text of the Constitution provides no basis – none – for applying a presumption against preemption in any circumstance. Indeed, it points in exactly the opposite direction. A fundamental principle of the Constitution is that Congress may legislate preemptively pursuant to its enumerated powers, and federal law "shall be the supreme Law of the Land . . . *any* Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. CONST. art. VI, cl. 2 (emphasis added). As scholars have persuasively demonstrated, eighteenth century lawyers and judges would have recognized the concluding phrase of the Supremacy Clause as a "*non obstante*" provision "telling courts *not* to apply the traditional presumption against implied repeals in determining whether federal law contradicts state law." Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 255 (2000) (emphasis added); see also

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[4] More recently, the Chamber also addressed this issue in its brief as *amicus curiae* in *Wyeth* v. *Levine*, No. 06-1249 (oral argument held on November 3, 2008). See No. 06-1249 Chamber Br. 27-28.

Jack Goldsmith, *Statutory Foreign Affairs Preemption*, 2000 S. CT. REV. 175, 182, 184 (arguing that "the Supremacy Clause's *non obstante* clause . . . was designed precisely to eliminate any residual presumption" against implied repeals).

By its very nature, the Supremacy Clause thus directs courts to avoid precisely the evil that a presumption *against* preemption introduces: that they "might strain the federal law's meaning in order to harmonize it with state law." Nelson, 86 VA. L. REV. at 255; see also Viet Dinh, *Reassessing the Law of Preemption*, 88 GEO. L.J. 2085, 2092 (2000) (explaining that any "systemic favor[ing]" of state law in analyzing preemption questions "risk[s] an illegitimate expansion of the judicial function" by "disrupt[ing] the constitutional division of power between federal and state governments, rewrit[ing] the laws enacted by Congress, or both"). As the Eleventh Circuit explained in declining to apply the presumption in a conflict preemption case,"[f]ederal law is not obligated to bend over backwards to accommodate contradictory state laws, as should be clear from the Supremacy Clause's blanket instruction." *Florida State Conference of the NAACP* v. *Browning*, 522 F.3d 1153, 1168 (2008); see also Pet. 30. Placing a thumb on the scale in favor of state law over federal law is precisely opposite to the approach dictated by the Supremacy Clause's text.

Implied conflict preemption cases are a *particularly* strange place to apply a presumption against preemption. The presumption is typically – though controversially – articulated as a safeguard against too lightly inferring that Congress *intended* to preempt state law in an area of *traditional state regulation*. See *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 347-48 (2001). But where an actual conflict exists between

state and federal law, it is simply irrelevant that the offending state law falls within an area of traditional state authority. See *Fidelity Fed. Sav. & Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141, 153 (1982) ("The relative importance to the State of its own law is not material when there is a conflict with a valid federal law, for the Framers of our Constitution provided that the federal law must prevail.") (internal quotation marks omitted). By the same token, where federal and state law stand in direct conflict, no inference about Congress's preemptive intent is necessary. Indeed, Congress acts against the backdrop of the well-settled assumption that its handiwork preempts any and all conflicting state law.

In this regard, "conflict pre-emption is different," *Geier* v. *American Honda Co.*, 529 U.S. 861, 884 (2000), from express and implied *field* preemption. In express preemption cases, courts look to the text of an express preemption clause and infer from it the scope of Congress's preemptive intent. See *English* v. *Gen. Elec. Co.*, 496 U.S. 72, 79 (1990). Likewise, in implied field preemption cases the substantive provisions of federal law must support an inference that Congress intended federal law to occupy a given field. See *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 517 (1992). Regardless of whether the presumption against preemption applies where courts must infer Congress's intent, it is entirely inapplicable to the determination of whether state and federal laws stand in conflict with each other. Cf. *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 504 (1996) (Breyer, J.) (explaining that conflict preemption is possible "[w]here Congress likely did not focus specifically on the matter"). That is a question not of Congress's preemptive intent but rather of the Supremacy Clause's meaning. And where such conflicts between federal and state law do exist, any "federalism concerns," *Lohr*, 518 U.S. at 485, that arguably might be

invoked as a justification for the "presumption against preemption" already have been conclusively resolved – by the Supremacy Clause.

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In *Crosby*, this Court left "for another day" consideration of whether a presumption against preemption applies to conflict preemption. 530 U.S. at 374 n.8. That day has arrived. This case presents an excellent vehicle for the Court to finally answer this important and recurring question of constitutional law – one that intractably divides the courts of appeals and is implicated in every case that presents a conflict between expanding federal laws and regulatory activities and proliferating state and local regulation. Beyond that, the time really has come for this Court to address head on the detailed historical critique of the presumption against preemption that has been so carefully developed in recent years by Caleb Nelson, Jack Goldsmith, and Viet Dinh, not to mention other legal scholars. The alternative of invoking the presumption in some cases but ignoring it in others – and doing so in the face of, but without ever responding to, vigorous dissenting opinions that accuse the Court of methodological inconsistency (see note 3, *supra*) – has the effect of sowing more confusion in the lower courts and creating the impression that this Court is more concerned about outcomes in individual cases than about articulating and applying a consistent methodology that would promote the rule of law.

II. THIS COURT SHOULD DECIDE WHETHER AGENCY ACTIONS OTHER THAN ADJUDICATION AND RULEMAKING CAN PREEMPT STATE LAW, AN ISSUE GRANTED BUT NOT REACHED IN *ALTRIA* v. *GOOD*

A. The Decision Below Squarely Conflicts With A Decision Of The California Supreme Court And Deepens The Confusion In The Circuits

In *Dowhal* v. *SmithKline Beecham Consumer Healthcare*, 88 P.3d 1, 11 (2004), the California Supreme Court unanimously held that (1) the FDA prohibited nicotine replacement therapy products from bearing any warnings other than those approved by the agency, and (2) the FDA's policy preempted a claim that state law required those products to carry different warnings. In reaching these conclusions, *Dowhal* specifically rejected the position adopted by the Third Circuit in this case: that the FDA's regulation of product warnings, as articulated in a letter from the FDA Commissioner, could not preempt contrary state law because that letter was not the product of a full-blown rulemaking or adjudicatory proceeding. *Id.* at 9-11. In *Dowhal*, the California Supreme Court held that because the FDA had demonstrated a clear and "sufficiently definite" federal policy through its letter, within a regulatory arena entrusted to it by Congress, the agency's policy preempted conflicting state law. *Ibid.*

In stark contrast, the Third Circuit declined to "afford preemptive effect" to any "less formal measures" than an agency's notice-and-comment rulemaking or adjudication. Pet. App. 12a. In taking a far more restrictive view of agency preemption, the lower court denied any preemptive force to the FDA's comprehensive and balanced approach to fish product labeling as expressed through (1) detailed consumer advisories

addressing the risks posed by mercury in fish, see Pet. 5-6, (2) the FDA's rejection – after public comment – of a petition that sought to require additional mercury-related warnings, see *id.* at 6-8, and (3) a letter written by the FDA Commissioner that explained how additional state-law warning requirements would "frustrate the carefully considered federal approach to advising consumers of both the benefits and possible risks of eating fish," *id.* at 12 (quoting FDA Commissioner's letter ("FDA Preemption Letter")); see also *id.* at 9-12. In the Third Circuit's view, these regulatory activities cannot, either singly or in combination, impliedly preempt state law claims that directly conflict with FDA's regulatory objectives.

The Third Circuit's view that agency action "less formal" than rulemaking and adjudication cannot preempt state law, Pet. App. 12a, contradicts decisions of the Second and Fourth Circuits holding that an agency's consent order is preemptive of conflicting state law. See *Feikema* v. *Texaco, Inc.*, 16 F.3d 1408, 1415-16 (4th Cir. 1994); *General Motors Corp.* v. *Abrams*, 897 F.2d 34, 39 (2d Cir. 1990). As *Feikema* suggests, where agency action conflicts with state law, courts have often focused on "whether the agency exceeded its statutory authority or acted arbitrarily" rather than on the degree of formality of the agency's action. 16 F.3d at 1416.

B. The Third Circuit's Restrictive View Of Preemptive Agency Action Is Inconsistent With Several Lines Of This Court's Decisions

In addition to conflicting with *Dowhal* and decisions of the Second and Fourth Circuits, the Third Circuit's decision is inconsistent with this Court's cases upholding preemption in a variety of circumstances in which agencies have taken regulatory action short of formal adjudication or rulemaking. In regulating

complex aspects of the national economy, administrative agencies often employ less cumbersome means of articulating and imposing federal requirements than the time-consuming, formal proceedings required of both notice-and-comment rulemaking and agency adjudication. See, *e.g.*, 21 C.F.R. § 10.40 (requiring, with limited exceptions, a 60-day comment period for proposed FDA rules and a 30-day delay before final rules become effective). This Court has repeatedly accorded preemptive effect to regulatory activity falling outside of such formal proceedings.

The Third Circuit's position is hard to square, for example, with the "century-old" line of this Court's cases applying the "filed rate" doctrine (a species of preemption). See *American Tel. & Tel. Co.* v. *Central Office Equipment, Inc.*, 524 U.S. 214, 222, 226 (1998). As this Court has repeatedly recognized, a federal agency's certification that a filed rate is "just and reasonable" – a certification made without the strictures of either rulemaking or adjudication – suffices to preempt a state's adjustment of that rate or award of damages that would contravene the filed rate. See, *e.g.*, *Arkansas Louisiana Gas Co.* v. *Hall*, 453 U.S. 571, 576-81 (1981).

The Third Circuit's reasoning is equally difficult to reconcile with this Court's decision just last Term in *Riegel* v. *Medtronic, Inc.*, 128 S. Ct. 999 (2008). In *Riegel*, the Court concluded that the FDA's premarket approval of a medical device preempted state-law tort claims that the approved device was unsafe or defective. Premarket approval is a "rigorous process" to be sure, *id.* at 1004 (internal quotation marks omitted), but it is no more formal rulemaking or agency adjudication than is the careful and considered process in *this* case through which the FDA rejected the Martek citizen petition (after public comment), formulated and issued consumer

advisories, and issued a letter to the California Attorney General. Through these various regulatory actions, the FDA has developed and articulated a balanced and nuanced policy on the proper mercury-related warnings for fish products.

Finally, the Third Circuit's inflexible and formalistic requirement that agency action take the form of a regulation or adjudicatory decision in order to preempt state law is also at odds with this Court's recognition that an agency's decision to *forgo* regulation, at least when it implies an authoritative determination that a given area is best left unregulated, has the same preemptive effect as a decision *to* regulate. *Sprietsma* v. *Mercury Marine*, 537 U.S. 51, 66 (2002); see also *Arkansas Elec. Coop. Corp.* v. *Arkansas Public Serv. Comm'n*, 461 U.S. 375, 384 (1983). This Court has never suggested that in order to carry out a preemptive deregulatory decision, an agency must announce its decision to forgo regulation in a formal regulation. Here again, the *substance* rather than the *form* of the agency's policy is what ought to be determinative.

The approach taken by the Third Circuit also warrants review because it puts regulated entities to the untenable choice between obeying a federal agency's clear and authoritative directives under the regulatory scheme Congress entrusted to it, and obeying the contradictory requirements that a state jury may impose pursuant to state law. In this case, the FDA Commissioner has made clear that additional warning requirements imposed under state law would "frustrate the carefully considered federal approach to advising consumers of both the benefits and possible risks of eating fish and shellfish." FDA Preemption Letter. Moreover, the Commissioner has warned (see *ibid.*) that if petitioner and other tuna manufacturers obey those

conflicting state requirements, they will have misbranded their product under the Food, Drug, and Cosmetic Act, 21 U.S.C. § 343. It is inconceivable that any reasonable manufacturer, under these circumstances, would ignore such a clear and direct admonition; a violation of the federal misbranding provision, after all, would trigger potential fines, imprisonment, and product seizure. See 21 U.S.C. §§ 333(a)(1), 334.

By ignoring these practical implications, the Third Circuit's analysis blinkers reality. The predictability of legal duties and obligations is critical in heavily regulated industries. This Court should provide clarity for businesses that, like the petitioner here, face state laws that directly conflict with the requirements federal agencies have clearly imposed through regulatory actions less formal than rulemaking and adjudication.

C. The Court Granted Review Of This Issue But Did Not Resolve It In *Altria* v. *Good*

In *Altria Group, Inc.* v. *Good*, 129 S. Ct. 538 (2008), this Court granted review of the First Circuit's conclusion that any FTC policy governing tar and nicotine testing and advertising could not preempt conflicting state law because the agency had "never issued a formal rule." *Good* v. *Altria Group, Inc.*, 501 F.3d 29, 51 (1st Cir. 2007). The petitioner in *Good* presented this issue for review, and cited many of the cases discussed above, including *Dowhal*, to demonstrate that the First Circuit's conclusion was contrary to the treatment of informal agency action by other courts. No. 07-562 Pet. 23.

This Court granted review in *Good*, and the parties' briefs addressed whether the agency's action was too "informal" to preempt conflicting state law. No. 07-562 Pet. Br. 51-54; No. 07-562 Resp. Br. 53-54. In the end, however, the Court's rejection of implied preemption in

Good rested on narrower grounds and left that important question unresolved. In contrast to the FDA's longstanding position in this case, the United States took the view in *Good* that the FTC had not – either formally *or* informally – authorized manufacturers to base representations that cigarette products were "light" or "low tar" on the results of FTC-required testing methods. See *Good*, 129 S. Ct. at 549 ("The Government itself disavows any policy authorizing the use of 'light' and 'low tar' descriptors."). This Court agreed that the FTC had "no longstanding policy" with which state law could conflict. *Id.* at 550. Given that conclusion, this Court had no occasion to decide whether such a policy, if it had existed, would have been drained of preemptive effect because it happened to be expressed only in "informal" agency action. See *id.* at 549.

This case presents an excellent vehicle for resolving the question left unanswered in *Good*. There can be no serious doubt that the FDA has a "longstanding policy" governing the labeling of fish products; it expressed that policy unambiguously in its Preemption Letter, in consumer advisories, and in its denial of the Martek petition. See Pet. 4-11. Indeed, the agency could hardly be clearer that the use of any warning labels that are inconsistent with the FDA's policy – including any labeling requirements imposed by state law – would "caus[e] tuna products with such warnings to be misbranded under federal law." FDA Preemption Letter. All that remains is for this Court to resolve whether such a policy, expressed in something other than a formal regulation, is capable of preempting conflicting state law. A clear resolution of that question will provide much-needed clarity for regulated entities that face the Pushme-Pullyou of unambiguous directives by federal agencies made outside of rulemaking and

adjudication that directly conflict with obligations imposed under state law.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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MARCH 2009

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