No. 10-1524

IN THE

Supreme Court of the United States

APRIL TERM 2010

DAN COOKS, *et al*.,

Petitioners,

-versus-

CAROLINA LABORATORIES, Inc.,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Thirteenth Circuit

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BRIEF FOR RESPONDENT

Counsel for Respondent
Team 11

Questions Presented

I. Whether the National Childhood Vaccine Injury Act of 1986 preempts state products liability suits for design defects when Congress' intent is plainly expressed in the text of the Act and evident throughout the legislative history.

II. Whether the appellate court properly applied the Twombly pleading rules when it dismissed Petitioners' Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) for failing to establish a plausible entitlement to relief.

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Statement of Facts

Carolina Laboratories manufactures a Diptheria and Tetanus Toxoids and Pertussis ("DTP")-Haemophilus influenzae type b ("Hib") combination vaccine. (R. at 1.) Carolina Laboratories combination DTP-Hib product is a vaccine included within the National Childhood Vaccine Injury Act ("Vaccine Act"). (R. at 1 n.2.) The vaccine contains Thimerosal, an organic preservative containing approximately fifty percent ethylmercury by weight. (R. at 1.) Ethylmercury is known to have neurotoxic properties in certain dosage levels. (R. at 4.) Between March 1996 and October 1998, Petitioners received three doses of Carolina Laboratories' combination DTP-Hib vaccine. (R. at 1.)

Petitioners believe the vaccine manufactured by Carolina Laboratories caused Petitioners' injuries. (R. at 1.) Petitioners sought compensation by filing a petition with the Vaccine Court. (R. at 1-2.) Congress created the Vaccine Court to provide compensation for vaccine related injuries. (R. at 5.) Initially, Petitioners filed a petition in the Vaccine Court because the Vaccine Act section 300aa-22 imposes limitations on filing civil claims. (R. at 5.) Section 300aa-22 conveys Congress' intent to supersede, or preempt, state tort law standards and create legal protections that apply in any civil action brought against a vaccine manufacturer. (R. at 5.) Congress modeled section 300aa-22(b)(1) after the principle of "unavoidably unsafe" products found in comment k of section 402A of the Restatement (Second) of Torts. (R. at 10-11.)

After seeking compensation in the Vaccine Court pursuant to the Vaccine Act, Petitioners filed a notice of withdrawal with the Vaccine Court and filed a civil action election. (R. at 1-2.) Petitioners filed a civil Complaint in the State of Grace against Carolina Laboratories alleging

negligent and strict liability design defect claims. (R. at 2.) Specifically, the Complaint alleges Carolina Laboratories breached a duty by negligently failing to conduct adequate safety tests to determine whether Thimerosal was safe and nontoxic to humans in the doses administered and Carolina Laboratories is strictly liable for defectively designing their vaccine because a safer alternative existed. (R. at 2.) According to the Complaint, safety tests were deficient because Carolina Laboratories did not determine whether the dosage was safe with each individual injection, each single day administration of multiple shots, or with the cumulative administration of multiple shots for children two years and younger and pregnant women. (R. at 4.) However, Petitioners concede Carolina Laboratories properly manufactured their DTP-Hib vaccine in accordance with the intended design and provided adequate warnings with the vaccine. (R. at 2 n.5.) Petitioners' Complaint alleges as a result of the exposure to mercury, Petitioners' daughter began exhibiting developmental and social delays, as well as learning disabilities, impaired fine motor skills, gastrointestinal illness, and an immune system dysfunction sometime between October 1998 and September 2001. (R. at 1 n.1, 4 n.7.) Additionally, the Complaint alleges the Petitioners' injuries are symptoms of mercury poisoning. (R. at 4 n.7.)

The State of Grace recognizes three types of products liability claims: (1) defective design, (2) defective manufacture, and (3) inadequate warning or failure to warn. (R. at 3.) Furthermore, Grace's products liability jurisprudence applies the risk-utility analysis, balancing the risks inherent in product design against the utility of the product. (R. at 4.) In applying the risk-utility test, Grace courts consider factors such as the gravity and severity of danger caused by the design, the avoidability of the danger, and the ability to eliminate the danger without

impairing the product's usefulness. (R. at 4.) The jury ultimately weighs each of these factors in the application of the risk-utility test. (R. at 4.)

The district court dismissed Petitioners' Complaint with prejudice because, although the design defect claims were sufficiently plead, negligent and strict liability design defect claims are preempted by the Vaccine Act. (R. at 4, 8.) On appeal, the United States Court of Appeals for the Thirteenth Circuit affirmed the district court's decision, and found the Vaccine Act does not preempt state court design defect claims, but Petitioners failed to sufficiently plead their design defect claims. (R. at 11, 13.)

Summary of the Argument

In 1986 Congress created the Vaccine Act in order to stem the tide of excessive litigation directed at vaccine manufacturers. This wave of litigation threatened to cause a national health crisis and, therefore, required decisive congressional action.

Prior to the development of vaccines children were dying from diseases which, if vaccinated against, could have been prevented. Due to this public health concern, vaccine manufacturers and the federal government invested in scientific research to develop life-saving vaccines. Consequently, millions of school-aged children are able to receive life-saving vaccinations deterring diseases such as polio, whooping cough, rubella, diptheria, and tetanus. Unfortunately, a small but significant number of children who receive vaccinations in hopes of guarding against disease suffer from adverse, occasionally grave side effects. However, these unfortunate circumstances have allowed manufacturers to develop even safer vaccinations.

Despite the tremendous advances in vaccine manufacturing, the vaccine market was severely burdened by litigation and the unpredictability of tort liability. This unpredictability forced many vaccine manufacturers to abandon the vaccine market to stave off bankruptcy. The consequent threat of vaccine shortages caused a preventable health crisis and forced Congress to act. Congress recognized the necessity of a steady and safe supply of vaccines and enacted the Vaccine Act. Congress intended the Vaccine Act to limit vaccine manufacturers' liability while also providing a no-fault compensation system for children injured by vaccines. After filing a claim in the Vaccine Court, injured plaintiffs may elect to file a claim in a state tort system unless the plaintiffs injury is "unavoidable."

Accordingly, the Vaccine Act expressly and impliedly preempts state court vaccine design defect claims. Congress' intent to expressly preempt state law is derived from the plain language of the statute as well as the factual and policy justifications for enacting the Vaccine Act outlined in the committee reports. Congress passed the Vaccine Act to limit a vaccine manufacturer's liability for vaccine design defect claims and explained the scope of the Vaccine Act's preemption, stating that a plaintiff should only seek compensation in a state tort system if the plaintiff can establish a manufacturing defect, inadequate warnings, or improper directions.

Vaccine design defect claims are also barred in state court due to field preemption and implied conflict preemption. The federal government occupies and controls the entire field regulating the vaccine market in regard to vaccine design. The Food and Drug Administration ("FDA") conducts research and clinical trials before approving a vaccine for the market and regulates the resulting product after it enters the market. Furthermore, the federal government provides a no-fault remedy to those injured by a vaccine in the Court of Federal Claims that provides compensation, even where a state court would not, due to a significantly lower standard of proof. Finally, allowing vaccine design defect claims against vaccine manufacturers in state court would severely frustrate the purposes and objectives of the Vaccine Act. The Vaccine Act was intended to provide stability to the vaccine market by removing the unpredictability of tort claims. Additionally, the Vaccine Act was intended to provide a simple, no-fault federal claims court that guarantees compensation to the majority of injured parties. Allowing state court vaccine design defect claims would upset the balance of the already volatile vaccine market. Manufacturers would be forced out of the market by unpredictability, injured children would go

uncompensated in the tort system, and yet other children would not receive life-saving vaccinations because of vaccine shortages.

Congress stated a plaintiff should only seek compensation in a state tort system if it can be established a manufacturing defect, inadequate warnings, or improper directions. Therefore, design defect claims are expressly and impliedly preempted by the Vaccine Act.

The appellate court properly applied the Twombly pleading rules when it dismissed Petitioners' Complaint for negligent and strict products liability design defect pursuant to Federal Rule of Civil Procedure 12(b)(6). Petitioners' Complaint does not establish a plausible entitlement to relief and therefore, was properly dismissed. Petitioners' Complaint makes conclusory allegations and threadbare recitals of the elements of negligent and strict liability design defect claims without providing any factual allegations to support the conclusions. Petitioners' Complaint lacks factual support for the allegations that Respondent negligently designed the vaccine and a safer alternative design exists. Additionally, Petitioners' Complaint fails to allege any facts that would allow a court to draw a reasonable inference that Respondent defectively designed the vaccine and is liable for Petitioners' alleged injuries.

Furthermore, Petitioners' claim presents a complex issue because the allegations in the Complaint do not necessarily indicate wrongdoing. Several explanations exist for Petitioners' alleged injuries and thus, Petitioners' Complaint fails to provide enough factual allegations to "nudge" the entitlement to relief from speculative to plausible. Additionally, Petitioners' Complaint lacks adequate factual specificity to raise a reasonable expectation discovery will reveal evidence that Respondent either negligently designed the vaccine or a safer alternative

design existed. Therefore, in light of the potential cost and burden of discovery on both the court and Respondent, Petitioners' complaint was properly dismissed.

Standard of Review

The determination of whether a federal law preempts state law is reviewed de novo. Hesling v. CSX Transp., Inc., 396 F.3d. 632, 636 (5th Cir. 2005) (citing Branson v. Greyhound Lines, Inc., 126 F.3d 747, 750 (5th Cir. 1980)). A court of appeal reviews de novo a court's decision to grant a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). Morrison v. Marsh & McLennan Cos., 439 F.3d 295, 299 (6th Cir. 2006).

Argument

I. The National Childhood Vaccine Injury Act of 1986 expressly and impliedly preempts state products liability design defect suits because the plain language of the Act, the pervasive federal scheme regulating vaccines, and the impediments posed by state tort claims to the purposes and goals of the Act all require preemption.

A state law that conflicts, either expressly or impliedly, with a federal law is always subordinate to the federal law. The Supremacy Clause requires the "Constitution and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made under the Authority of the United States, shall be the Supreme Law of the Land." U.S. Const. art. IV, cl. 2. Under the Supremacy Clause, any state law that conflicts with federal law must yield to the federal law, even when the state law is within the state's acknowledged power. Gade v. Nat'l Solid Waste Mgmt. Ass'n, 505 U.S. 88, 108 (1992). State laws may be preempted by either federal regulations or federal statutes. Hillsborough County, Fla. v. Automated Med. Labs., Inc., 471 U.S. 707, 713 (1985). The Vaccine Act is a federal statute that specifically expresses which state civil actions are barred in certain situations. Therefore, the Supremacy Clause mandates that the Vaccine Act preempt any state civil actions that conflict with its purpose.

A. Sections 300aa-22(a) and (e) of the Vaccine Act expressly preempt state court design defect claims because the plain language bars state civil suits where the injury or death resulted from unavoidable side effects.

The Vaccine Act's plain language expressly preempts state vaccine design defect claims. A court must start with the statute's language when interpreting the congressional intent. Knight v. Comm'r of Internal Revenue, 552 U.S. 181, 187 (2008). Additionally, statutes should be read as a whole rather than as a series of unrelated and isolated provisions. Gonzales v. Oregon, 546 U.S. 243, 274 (2006). Courts have a variety of tools to aid in interpreting Congress' purpose.

Medtronic, Inc. v. Lohr, 518 U.S. 470, 486 (1996). For example, one interpretive tool is the structure and purpose of the statute as a whole, as revealed in the text and the way Congress intended the statute and its regulatory scheme to affect business, consumers, and the law. Lohr, 518 U.S. at 486. Additionally, when interpreting a statute this Court considers the factors that served as the "catalyst for the passage" of the statute. Cipollone v. Liggett Group, Inc., 505 U.S. 504, 519 (1992). A state law is preempted when a federal enactment contains language requiring express preemption of the law. Bruesewitz v. Wyeth, 561 F.3d 233, 239 (3d Cir. 2009) (citing Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 541 (2001)). The Vaccine Act includes a clause entitled "preemption" and provides, "[s]tate law shall apply to a civil action brought for damages for a vaccine-related injury or death." 42 U.S.C. § 300aa-22(a); 42 U.S.C. § 300aa-22(e) (2006). The Vaccine Act further provides that vaccine manufacturers are not liable for "unavoidable" side effects when a vaccine is properly prepared and accompanied by proper directions and warnings. 42 U.S.C. § 300aa-22(b)(1). A defect is considered "unavoidable," and therefore barring a tort claim, unless a claimant's injury results from a manufacturing defect or improper directions or warnings. Blackmon v. Am. Home Prods. Corp., 328 F. Supp. 2d 659, 664 (S.D. Tex. 2004). Congress created the National Vaccine Injury Compensation Program to provide a remedy for those injured by a vaccine as a result of an unavoidable side effect. 42 U.S.C. § 300aa-11.

In Bates v. Dow Agrosciences, LLC, this Court held common law actions preempted by a provision in the Federal Insecticide, Fungicide, and Rodenticide Act. Bates v. Dow Agrosciences, LLC, 544 U.S. 431, 443 (2005). The provision prohibited states from imposing or continuing "any requirements" in addition to or distinct from those required by the statute. Id.

This Court found state common law actions preempted because there is "no distinction between positive enactments and common law." Id. Jury determinations are a type of additional state requirement because such determinations impose state tort duty. Cipollone, 505 U.S. at 524.

The language of the Vaccine Act in sections 22(b)-(c) explicitly precludes state tort claims when a vaccine causes injury due to unavoidable side effects. Congress excluded design defects from state civil liability by explicitly stating when state tort claims may be pursued and required all other claims to be pursued through the Vaccine Court. The Vaccine Act enumerates two situations where a plaintiff may recover via a state tort claim: manufacturing defects and inadequate labeling or warnings. The two state court claims permitted by the Vaccine Act correspond with two areas of Grace's recognized areas of tort products liability. The Vaccine Act's "properly prepared" language aligns with manufacturing defects recognized by Grace law, while "proper directions and warnings" equate to the state's inadequate warning civil tort claim. Although Grace's defective design claim is not explicitly mentioned in the Act, its exclusion is striking considering Congress specifically enumerated the situations where a plaintiff may recover for a vaccine-related injury via a state tort claim.

B. The Vaccine Act impliedly preempts state court design defect claims because Congress established a pervasive regulatory scheme occupying the field of vaccines and allowing design defect claims in state court will impede the purposes and goals of the Vaccine Act.

This Court will eviscerate the purposes of the Vaccine Act by allowing state court vaccine design defect claims. Preemption may be implied where the wording of the statute or its legislative history evinces Congress' intent to occupy a field, thereby excluding state law. Wood v. Gen. Motors Corp., 865 F.2d 395, 401 (1st Cir. 1988). Therefore, Petitioners' design defect claim is preempted because Congress intended to occupy the entire vaccine field by establishing

a pervasive regulatory scheme and undermining this intent will lead to vaccine shortages and a lack of vaccine development.

1. **The Vaccine Act establishes a pervasive regulatory scheme controlling the design of vaccines by dictating which vaccines are placed on the market, providing a remedy for those injured by approved vaccines, and federal regulations provide for the continued supervision and scientific research of vaccines.**

Although a statute's language offers a starting point, courts are often called upon to identify the domain expressly preempted by the statutory language. Bruesewitz, 561 F.3d at 239 (citing Lohr, 518 U.S. at 484). Identifying the scope of the domain preempted requires determining Congress' purpose, which is the ultimate touchstone in every preemption case. Lohr, 518 U.S. at 485. The authoritative source for understanding congressional intent is the committee reports which represent the "considered and collective understanding" of the Legislators involved in drafting the legislation. Garcia v. United States, 469 U.S. 70, 76 (1984). Additionally, it is possible to infer congressional intent to preempt solely from a statutory or regulatory scheme's effects. Taylor v. Gen. Motors Corp., 875 F.2d 816, 826 (11th Cir. 1989). Congressional intent to preempt state law may be inferred when a scheme of regulation is so pervasive that it leaves no room for the states to supplement it. Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 152 (1982).

The FDA controls the vaccine market through its extensive approval process. Centers for Disease Control and Prevention, History of Vaccine Safety, http://www.cdc.gov/vaccinesafety/Vaccine_Monitoring/history.html. The FDA approval process for vaccines requires manufacturers to provide information regarding the safety and efficacy of the vaccine, its method of manufacture, and quality control tests. Id. Additionally, the FDA performs its own research as well as a multi-phase clinical trial for every vaccine. Id. As a result of this extensive research,

the typical vaccine approval process takes an average of ten years from the time a manufacturer submits a vaccine for review to the time the vaccine is available to the public. Id. After approval, manufacturers are required to keep the FDA informed of developments with regard to a vaccine's safety and efficacy, submit vaccine lots to the FDA for testing, and report adverse effects through the Vaccine Adverse Event Reporting System. Id. When a defendant complies with federal regulations that have a preemptive effect on claims under state law, the defendant is entitled to summary judgment or dismissal of the state claims. Pokorny v. Ford Motor Co., 902 F.2d 1116, 1122 (3rd Cir. 1990). Congress explained that a claimant may recover in the state tort system only when a vaccine is either "improperly prepared" or is accompanied by "improper directions" or "inadequate warnings." H.R. Rep. No. 99-908, pt. B, at 26 (1986). Congress intended the principle of unavoidably unsafe products established in Comment k of the Restatement (Second) of Torts to apply to the vaccines covered in the Vaccine Act. Militrano v. Lederle Labs., 810 N.Y.S.2d 506, 508 (N.Y. App. Div. 2d 2006); Restatement (Second) of Torts § 402A, cmt. k (2009). Congress defined "unavoidably unsafe products" as those which cannot be made safe through present human skill and knowledge. Militrano, 810 N.Y.S.2d at 508. The language "resulting from unavoidable side effects," in isolation, appears to leave open the possibility that design defect claims could be brought in state court. Id. However, considering the committee report in its entirety demonstrates Congress' intent to bar design defect claims. Id.

At the time the DTP-Hib vaccine received FDA approval and became available to the public, a safer alternative did not exist. The safety of a vaccine is measured at the time of its approval because manufacturers cannot bring a safer vaccine to market as soon as one exists due to the FDA's lengthy approval process. In addition to the extensive approval process, the FDA

continues to monitor vaccines through the Vaccine Adverse Effect Reporting System. Finally, the Vaccine Act provides a no-fault federal remedy to injured children. This pervasive system of regulation and monitoring demonstrates Congress' intent to ensure the safest vaccines possible for the greatest number of people and to supersede state court design defect claims.

2. Allowing design defect claims in state court will severely frustrate the purposes and goals of the Vaccine Act, destabilizing the vaccine market, causing devastating vaccine shortages, and leaving those injured by vaccines uncompensated.

This Court, by allowing state court vaccine design defect claims, will destabilize the vaccine market, causing vaccine shortages and freezing the development of new vaccines. Congress intended the Vaccine Act to secure the availability of current vaccines and to ensure manufacturers are able to provide new vaccines to protect against both known and unknown diseases. If new, life-saving vaccines are not developed, the unfortunate, but relatively few, injuries seen today would become much more prevalent and cause unnecessary suffering to many more individuals.

a. Allowing design defect claims against vaccine manufacturers in state courts will impede the Vaccine Act's purpose because it will force vaccine manufacturers out of the market, creating a destabilized market and a devastating vaccine shortage.

Allowing state design defect claims will conflict with the goals of the Vaccine Act. Implied conflict preemption arises when state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. Hines v. Davidowitz, 312 U.S. 52, 67 (1941). Implied conflict preemption is still possible, even if there exists an express preemption provision. Geier v. Am. Honda Motor Co., 529 U.S. 861, 869 (2000). A court must use its discretion to determine whether a state law stands as an obstacle to a federal objective.

Bruesewitz, 561 F.3d at 239-40. Additionally, a court must examine the federal statute in its entirety to determine its purpose and intended effects as well as the policies underlying the statute. Id. At the time the Vaccine Act was passed, hundreds of design defect cases were being filed each year. Geoffrey Evans, Update on Vaccine Liability in the United States, 42 Clinical Infectious Diseases S131 (2002). The costs of defending against these cases proved to be prohibitive and ever-increasing. See H.R. Rep. No. 99-908, pt. B, at 6. In 1984, one major vaccine manufacturer estimated its potential liability from DTP vaccine lawsuits was 200 times its annual sales for the vaccine. Childhood immunizations, Subcomm. on Health & the Env't, Comm. on Energy & Commerce, 99th Cong. (1986). This influx in lawsuits forced many manufacturers out of the vaccine market creating an unstable and constricted vaccine supply. Id. In response to this, the Vaccine Act substantially reduced the number of cases litigated each year by preempting certain tort claims and by providing a no-fault compensation program. Press Release, HRSA Press Office, HRSA Awards Contract to Study Adverse Events in Childhood Vaccines (Oct. 23, 2008), available at http://archive.hrsa.gov/newsroom/releases/2008/vaccinestudy.htm. No manufacturers have left the vaccine market since the Vaccine Act passed, creating a more stabilized market. Compare H.R. Rep. No. 99-908, pt. B, at 7 with Thimerosal in Vaccines, http://www.fda.gov/CBER/vaccine/thimerosal.htm. However, the number of manufacturers in the market is still limited, there is still only one manufacturer for the polio vaccine, one for the measles, mumps and rubella vaccine, and two for the DTP vaccine. Id. Therefore, the loss of just one vaccine manufacturer to the fear of litigation expense could lead to a grave "public health hazard." H.R. Rep. No. 99-908, pt. B, at 7.

Conflict preemption was illustrated in Geier, where this Court held that compliance with federal safety standards under the act in question exempted manufacturers from liability under common law. Geier, 529 U.S. at 866. In Geier, the petitioner was seriously injured in an automobile accident and brought suit against American Honda claiming negligent and defective design because his car lacked a driver's side airbag. Id. at 865. This Court reasoned that it would, as it had in the past, decline to give broad effect to saving clauses so as to not upset careful regulatory schemes established by federal law. Id. at 870 (citing United States v. Locke, 529 U.S. 89 (2000)). Additionally, despite the savings clause, the preemption provision itself reflected a desire to subject the industry to a uniform set of federal safety standards in order to avoid the conflict, uncertainty, cost, and risk associated with multiple safety standards. Geier, 529 U.S. at 871. The preference for uniformity and consistency favors preemption of state tort suits because the varying rules of law created by judges and applied by juries create undesired and unpredictable outcomes. Id. Moreover, conflict arises when juries in different states reach contrasting conclusions based on similar facts. Id. Because the conflicts that arise from state tort suits interfere with important federal objectives, state tort suits were intended to be preempted. Id. at 881 (citing Int'l Paper Co. v. Ouellette, 479 U.S. 481, 493 (1987); de la Cuesta, 458 U.S. at 156; Hines, 312 U.S. at 67)).

Congress intended to preempt defective design claims for vaccines brought in state court. The Vaccine Court was intended to provide a more secure alternative of compensation for plaintiffs injured by a vaccine and to relieve manufacturers of the potential burdens of litigation. Furthermore, Congress did not intend the Vaccine Act to serve as merely a checkpoint for plaintiffs on their way to civil court. For the same reasons this Court found it was necessary for

the Department of Transportation to implement a federal system of regulation for vehicular safety in Geier, in the present case, Congress found that such costs would force vaccine manufacturers out of the market causing a grave public health hazard and directly conflict with the Vaccine Act's purpose. Congress' purpose is still being served today because to reach the stage in litigation where a discredited causation hypothesis can be challenged, a vaccine manufacturer would have to first face an expensive discovery process—potentially thousands of times over. Therefore, allowing state design defect claims would frustrate the purpose of the Vaccine Act and the issues that moved Congress to act in 1986 would reemerge.

b. Allowing design defect claims against vaccine manufacturers in state court will impede the purposes and goals of the Vaccine Act because the development of new life-saving vaccines will be stalled.

Congress' intent to facilitate the development of new vaccines will be eroded if plaintiffs are permitted to bring state design defect claims. Determining congressional purpose is the ultimate touchstone in every preemption case. Wyeth v. Levine, 129 S. Ct. 1187, 1194 (2009). Committee reports represent the definitive source for understanding congressional purpose because these reports reflect the common understanding of the Legislators involved in drafting the legislation. Zuber v. Allen, 396 U.S. 168, 186 (1969). The cost of developing new vaccines is prohibitive, and investment in such development could equal as much as thirty percent of the entire industry's annual sales. Childhood immunizations, Subcomm. on Health & the Env't, Comm. on Energy & Commerce, 99th Cong. (1986). Furthermore, potential tort liability for vaccine-related injury claims could easily force a drug manufacturer out of the market. Id. Congress understood that efforts to develop a safe and stable supply of vaccines would fail unless there was close collaboration between the agencies and the industry. See H.R. Rep. No.

99-908, pt. B, at 11. For this reason, Congress established a system whereby several federal agencies supplement the vaccine research being carried out by the industry. Id. at 11. As a result of the collective effort of these agencies and the industry, seven new vaccines have been developed and are now considered part of a child's routine immunization schedule: hepatitis B; varicella; pneumococcal disease; influenza; hepatitis A; meningococcal disease; and rotavirus. Compare Recommended Immunization Schedules for Active Immunization of Normal Infants and Children, http://www.cdc.gov/mmwr/preview/mmwrhtml/00000805.htm with Recommended Immunization Schedules for Persons Aged 0-18 Years—United States 2008, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5701a8.htm.

Despite these accomplishments, there is still necessary research and development to be done, such as adapting current influenza and pneumococcal vaccines to combat new strains of the diseases. See Laura Beil, Worrisome Infection Eludes a Leading Children's Vaccine, N.Y. Times, Oct. 14, 2008, at D1. In addition to the diseases already known to afflict our population, public health authorities must guard against foreign invaders. For example, similar to the Severe Acute Respiratory Syndrome ("SARS") epidemic that spread from China to thirty-seven countries in only a matter of weeks, a single vacationer visiting our shores carrying a foreign disease could lead to an epidemic. See Richard D. Smith, Responding to Global Infectious Disease Outbreaks: Lessons from SARS on the Role of Risk Perception, Communication and Management, 63 Soc. Sci. & Med. 3113 (2006).

To guard against foreign invaders like SARS, manufacturers must be able to invest in research. The best defense against epidemics and other newly discovered diseases requires a robust research program that constantly explores new vaccines. Allowing defective design

claims would seriously hamper the effort to defend against diseases because manufacturers will be forced into litigation that will constrain expenditures into the research and development. Considering the high costs associated with developing new vaccines, the potential liability from the state tort systems will make future development costs prohibitive to manufacturers. Forcing manufacturers out of the market in this manner would slow the development of new vaccines to a trickle, resulting in epidemics against which society has no protection. While it is unfortunate when anyone suffers adverse effects from a vaccine, such suffering would be unnecessarily multiplied in the event of a preventable outbreak.

II. The appellate court properly applied the Twombly pleading rules when dismissing Petitioners' Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) because Petitioners' Complaint does not establish a plausible entitlement to relief on its face or plead sufficient factual allegations, in light of the complex nature of the claim, to establish a reasonable expectation that discovery will reveal evidence of Petitioners' claim.

The Twombly decision is based on the interpretation and application of Rule 8 of the Federal Rules of Civil Procedure. Ashcroft v. Iqbal, 129 S. Ct. 1937, 1953 (2009). Rule 8 applies to all civil actions. Fed. R. Civ. P. 1. Even prior to Iqbal, the federal courts of appeals concluded that the broad language in Twombly meant that its standard applies in all types of cases, not merely antitrust cases. See Phillips v. County of Allegheny, 515 F.3d 224, 234 (3d Cir. 2008); Wilkerson v. New Media Tech. Charter Sch., 522 F.3d 315, 322 (3d Cir. 2008); In re Elevator Antitrust Litig., 502 F.3d 47, 50 n.3 (2d Cir. 2007). Therefore, the Twombly plausibility standard applies in the instant case.

A. Petitioners' Complaint does not establish an entitlement to relief that is plausible on its face because Petitioners' Complaint contains conclusory allegations and threadbare recitals of the elements of the claim which are unsupported by sufficient factual allegations to allow the Court to draw a reasonable inference that Respondent is liable for Petitioners' alleged harm.

Petitioners' Complaint fails the Twombly test because it contains allegations that are conclusory and factually insufficient. Before Twombly, a claimant could allege the basic elements of an action and proceed to discovery. However, in response to frivolous claims, the Twombly Court modified the liberal pleading rules by requiring that a complaint contain sufficient facts to be "plausible" in order to survive a Federal Rule of Civil Procedure 12(b)(6) motion to dismiss.

1. Petitioners' Complaint contains conclusory allegations and threadbare recitals of the elements of a design defect claim unsupported by factual allegations.

Federal Rules of Civil Procedure require all pleadings to include "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Therefore, Rule 8(a) requires a complaint to "show" an entitlement to relief rather than just a blanket assertion which merely creates a possibility for relief. Swierkiewicz v. Sorema N.A., 534 U.S. 506, 508 n.1 (2002). While a court must accept as true all factual allegations within a complaint, a court is not required to accept as true conclusory allegations wholly unsupported by facts. Iqbal, 129 S. Ct. at 1949. An allegation without factual support of the defendant's deficiencies is conclusory and insufficient to establish a plausible claim of relief. McFadden v. City of Yukon, No. CIV-09-0839-HE, 2010 WL 125444, at *3 (W.D. Okla. Jan. 7, 2010). An allegation that an injury is vaccine-related based on nothing more than a temporal association between a vaccination and an injury is conclusory and insufficient to establish a claim of relief under the Vaccination Compensation Program. Bailey v. Sec'y of Dept. of Health & Human

Servs., No. 06-464V2008, 2008 WL 482359, at *7 (U.S. Fed. Cl. Feb. 12, 2008). In order to establish a plausible entitlement to relief in products liability claims, a plaintiff must allege sufficient facts to permit a court to conclude there is either a defect in the design, formulation, or manufacture of the product, and the defect was the proximate cause of the plaintiff's alleged injuries. Frey v. Novartis Pharms. Corp., 642 F. Supp. 2d 787, 795 (S.D. Ohio 2009).

In Lewis v. Abbott Laboratories, a plaintiff alleging a medicinal drug was not reasonably safe because it caused dangerous side effects and that she suffered injuries as a result did not sufficiently state a claim for relief. Lewis v. Abbott Labs., No. 08 Civ. 7480(SCR)(GAY), 2009 WL 2231701, at *2-3 (S.D.N.Y. July 24, 2009). The court reasoned the allegations were conclusory because the plaintiff failed to allege it was feasible for the defendant to design the drug in a safer manner. Id. at *4.

In the instant case, Petitioners' Complaint alleges Respondent failed to conduct adequate safety tests to determine whether each of the elements of the vaccines were "safe and nontoxic to humans in the doses administered to pregnant women, infants or small children." However, similar to the complaint in Lewis, Petitioners' products liability claim is devoid of any facts surrounding Respondent's safety tests, such as allegations that the research and preparation of the vaccine in accordance with the regulations of the Vaccine Act are deficient. Additionally, Petitioners do not allege what tests Respondent performed, could have performed, or did not perform that were necessary to create a safer vaccine. Furthermore, Petitioners allege a belief that Respondent's vaccine caused the injuries complained of, but only provide a temporal association between the inoculation and the alleged injuries. Petitioners do not allege any facts

to show a safer design existed, therefore Petitioners' allegations are conclusory and insufficient to establish plausible claim of relief.

2. Petitioners' Complaint does not contain sufficient factual allegations to allow the Court to draw a reasonable inference that Respondent is liable for the alleged harm.

A court must determine whether a complaint states a plausible claim for relief considering only well-pleaded factual allegations. Iqbal, 129 S. Ct. at 1949-50. Determining a complaint's plausibility is a "context-specific task" which requires a reviewing court to draw on its "judicial experience and common sense." Id. at 1941. In ruling on a motion to dismiss, the court will assume all factual allegations are true, however, legal conclusions couched as factual allegations within the complaint will not receive the same treatment. Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007). A well-pleaded complaint may proceed even when it appears that recovery is very remote and unlikely. Id. at 556 (quoting Scheuer v. Rhodes, 416 U.S. 232, 236 (1974)). A judge's disbelief of a complaint's factual allegations will not be considered in a Rule 12(b)(6) motion to dismiss. Neitzke v. Williams, 490 U.S. 319, 327 (1989). To survive a motion to dismiss, a complaint must provide enough factual matter to allow a court to draw a reasonable inference that the defendant is liable for the alleged misconduct. Twombly, 550 U.S. at 556. In other words, the plausibility standard requires a complaint to set out more than a mere possibility the defendant acted unlawfully—the complaint must be facially plausible. Id. at 556.

In the present case, assuming all the allegations are true, the Complaint still lacks the requisite factual specificity to show Petitioners are entitled to relief through the state tort system. Petitioners' Complaint lacks support for their assertion that Respondent knew, at the time the vaccine was designed, ethylmercury had neurotoxic properties that caused adverse effects in the

doses administered to toddlers and infants. Additionally, the Complaint lacks any factual support Respondent failed to test the vaccine to ensure it could be safely administered to pregnant women, infants or small children, either when done so in a single-day administration or over the course of the first twenty-four months of a child's life. Further, Petitioners failed to allege any facts linking the vaccine to Petitioners' claimed injuries. The only statement Petitioners make linking the vaccine to Petitioners' injury is that the vaccine was a "substantial contributing cause."

Even where there is a strong possibility that a single entity could make a mistake leading to a design defect, such a possibility decreases considerably when a group of entities work together to create the safest possible vaccine. Here, Respondent worked in conjunction with the FDA to create the safest vaccine. Petitioners did not allege facts establishing how these two groups collectively failed to conduct adequate safety tests. Rather, Petitioners asserted a legal conclusion as fact when alleging Respondent did not conduct adequate safety tests. Furthermore, Petitioners did not enumerate either the safety tests performed by Respondent or which standard safety tests were not performed by Respondent. Finally, Petitioners do not provide a basis for a court to determine whether the products described were actually "unreasonably dangerous and defective." As a result, without the requisite factual specificity, Petitioners' allegations are mere legal conclusions that do not establish that either Petitioners are entitled to relief or draw a reasonable inference that Respondent is liable for the alleged misconduct.

B. In light of the complex nature of the claim, Petitioners failed to sufficiently plead factual allegations to establish a plausible claim to relief or subject Respondent to discovery.

Petitioners must convince this Court that their Complaint has a sufficient factual support to warrant proceeding to the discovery phase of litigation. Requiring Petitioners to plead sufficient facts is especially important in the present case because of the potential economic burden on the Court and Respondent as well as the complex nature of Petitioners' claim. Therefore, Petitioners do not establish a plausible claim to relief because they do not allege sufficient factual support for their claim.

1. Petitioners' claim is complex requiring more factual allegations to show an entitlement to relief because the allegations do not necessarily indicate wrong doing and the allegations can be explained by several different explanations.

The amount of factual detail required to state a claim of relief that is plausible on its face depends on the context of the claim being asserted. Limestone Dev. Corp. v. Vill. of Lemont, 520 F.3d 797, 803 (7th Cir. 2008). Where the context presents a complex issue, more facts are required to be plead to establish a plausible claim of relief. Phillips, 515 F.3d at 232. For instance, a simple negligence claim involving a car accident may require relatively few factual allegations because car accidents are commonly the result of wrongdoing. Robbins v. Oklahoma, 519 F.3d 1242, 1246 (10th Cir. 2008). However, more factual allegations are required in complex cases where wrongdoing is neither patently obvious nor the only likely explanation. Id. Complaints in complex cases are not "nudged" from speculative to plausible where the allegations are so general that lawful explanations exist to explain the alleged wrong. Id. at 1247.

For example, in Twombly, the Court was presented with a complex anti-trust case where plaintiffs alleged that the defendant-companies were conspiring to set prices. Twombly, 550 U.S.

at 548. This Court reasoned that plaintiffs' complaint required more factual allegations because lawful competitive behavior could be just as likely an explanation for the alleged harm. Id. at 554. Due to the complex nature of the claim, the plaintiff's complaint established only a speculative entitlement to relief. Id. at 556.

As in Twombly, Petitioners' claim is complex because the allegations in the Complaint could be explained by either lawful or unlawful behavior. First, the alleged injuries could have resulted from the genetic predisposition of Petitioners' daughter rendering coincidental the alleged association between the vaccine and Petitioners' injuries. Second, Respondent's vaccine could be the cause of the alleged injuries, but because the vaccine's benefits to society outweigh the potential risk of injuries from side effects, Respondent is not liable. Applying the same rationale from Twombly, the complexity of Petitioners' claim requires Petitioners to allege more facts to render plausible an entitlement to relief because alternative explanations for the alleged harm exist. Therefore, the complaint establishes only a speculative entitlement to relief and should be dismissed.

Moreover, a design defect claim is particularly complex because of the requirements imposed by the Vaccine Act. For example, every vaccine must go through the FDA testing and approval process. The Centers for Disease Control and Prevention estimates the typical approval process takes ten years. Centers for Disease Control and Prevention, History of Vaccine Safety, http://www.cdc.gov/vaccinesafety/Vaccine_Monitoring/history.html. In addition to the complex and lengthy approval process, the harmfulness of the preservative Thimerosal is questionable. Thimerosal is an organic mercury compound that is metabolized to ethylmercury and thiosalicylate. Immunization Safety Review Committee, Immunization Safety Review:

Thimerosal-Containing Vaccines and Neurodevelopment Disorders 1 (Kathleen Stratton et. al. eds., Nat. Acad. Pres. 2001). Thimerosal has been used since the 1930s as a preservative in vaccines and pharmaceutical products to prevent bacterial and fungal contamination. Id. While mercury is known as a neurotoxin in high doses, it has not been established that the low doses of ethylmercury contained in Thimerosal are dangerous. Id. at 27. Low-dose Thimerosal exposure in humans has not been demonstrated to be associated with effects on the nervous system. Id. at 3. The claim that Thimerosal causes neurodevelopmental disorders is unsupported by either clinical or experimental evidence. Id. at 13. There is limited toxicological information regarding ethylmercury administered in low doses. Id. at 4. Further, Thimerosal exposure from vaccines has not been proven to result in the levels of mercury associated with toxic responses. Id.

2. The potential cost and burden of discovery on Respondent requires Petitioners to plead sufficient factual allegations establishing a reasonable expectation that discovery will reveal evidence of the claim.

In complex cases, such as the Sherman Antitrust Act or the Racketeer Influenced and Corrupt Organizations Act cases, defendants should not be forced to endure the costly discovery process unless the plaintiff has set out enough factual or argumentative detail in the complaint to show that the plaintiff has a substantial case. Twombly, 550 U.S. at 559 (quoting Dura Pharms., Inc. v. Broudo, 544 U.S. 336, 347 (2005)). A plaintiff must plead sufficient factual allegations to raise a reasonable expectation that discovery will reveal evidence of the plaintiff's claim to proceed to the inevitably costly and extensive discovery phases. Twombly, 550 U.S. at 545. Courts should dismiss a complaint where no reasonable likelihood exists that a plaintiff can state a claim from the facts alleged in the complaint. Id. The deficiency of a complaint should be exposed at the point of minimum expenditure of time and money by the parties and the court. Id.

Allowing a plaintiff's conclusory allegations to proceed will expose the defendant to extensive discovery before a motion for summary judgment may be filed. McZeal v. Sprint Nextel Corp., 501 F.3d 1354, 1362 (Fed. Cir. 2007). A case that requires massive expenses due to extensive discovery and potential liability costs has an *in terrorem* effect on the defendant, forcing the defendant to settle without regard to the merits of the plaintiff's claim. Limestone Dev. Corp., 520 F.3d at 803. Furthermore, defendants cannot rely on a court's careful case management to protect defendants from the expenses of discovery due to the relatively low success rate of "judicial supervision in checking discovery abuse." Id. at 559.

In Twombly, this Court required further factual amplification of the plaintiff's allegations because of the time and cost of tracking down unspecified instances of unlawful conduct in an enormous company over a long period of time. Twombly, 550 U.S. at 559. This Court further stated that the only way to avoid the potentially enormous expense of discovery in cases, with no reasonably founded hope that the discovery process will reveal relevant evidence, is to require allegations in a complaint establish a plausible entitlement to relief and a reasonable expectation that discovery will reveal evidence of the alleged harm. Id. at 560.

The purpose of requiring plausibility at the pleading stage, as articulated in both Twombly and Iqbal, is to avoid the cost and burden of discovery. These decisions provide district courts with more leeway to dismiss actions at the pleading stage before reaching the more costly discovery stage of litigation. The instant case is analogous to Twombly in several ways, one of which is the potentially expansive cost of discovery in a case where the allegations contained in the pleading lack the requisite factual specificity. Taken at face value (and not considering that the allegations themselves are merely legal conclusions as discussed above),

Petitioners' allegation that Respondent "knew or should have known" its vaccine caused the side effects complained of would result in an incredibly costly discovery process. Yet the allegations do not make a link between the vaccine and the injuries complained of. The allegation ethylmercury causes undesired side effects in this application is not a forgone conclusion, and Petitioners failed to allege facts to establish a causal link. Therefore, simply alleging that Respondent "knew or should have known" the alleged side effects does not meet the standard required to proceed to discovery, especially when there is little evidence to this effect within the scientific community.

Conclusion

Therefore, Respondent respectfully requests this Court to reverse the appellate court's decision as to the Vaccine Act and affirm with respect to the Twombly pleading rules. This Court should hold that the Vaccine Act preempts state products liability design defect claims and that Petitioners' complaint fails to satisfy the Twombly plausibility standard.

Respectfully submitted,

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