No.

In the
Supreme Court of the United States

JANE DOE, individually and as Parent/Guardian of Baby Doe, BABY DOE,

Petitioners,

– v. –

MERCK & CO., INC., HEALTH AND HUMAN SERVICES, ALEX AZAR, in his official capacity as Secretary of Health and Human Services, NORMAN E. SHARPLESS, M.D. in his official capacity as Acting Commissioner of Food and Drug (a division of HHS), UNITED STATES OF AMERICA,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

On July 17, 2017, Petitioner *Jane Doe*, on behalf of her then minor, and disabled son, *Baby Doe,* filed this lawsuit in the Eastern District of New York under the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act"), *42 U.S.C. § 300aa-1, et. seq.,* seeking punitive damages against Merck under *§11(a)(2)(A),* and equitable relief against the Secretary of Health and Human Services [HHS] under *§31*, *Citizens Action*, alleging defendants are in violation of their respective licensing, product warning, labeling and reporting duties for the Food and Drug Administration's ["FDA's"] measles, mumps and rubeola ["MMR"] vaccine licensed to pharmaceutical defendant-respondent Merck & Co., Inc.

Petitioners present the following questions:

I. Should Courts extend the precedent of *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), for the legal requirement that a vaccine licensed through HHS, that is mandated, be *necessary, harm-avoidant, proportional and non-discriminatory,* requiring individualized exemptions for those eligible and not suitable for vaccinations?

II. Whether the Second Circuit erred finding plaintiff failed to exhaust remedies for a claim "*MMR causes autism*," overlooking petitioner had exhausted below on the "*MMR\TCV*[1] *causes autism*" and "*TCV causes autism*" theories, and

[1] Thimerosal is an organic compound that contains ethyl mercury and is found in Thimerosal Containing Vaccines "TCVs".

demonstrated the reliance necessary to prove fraud, and conspiracy to commit fraud, the Court found was lacking?

III. Whether the Second Circuit erred in declining primary jurisdiction over petitioner's Citizens Action against the Secretary, by creating an exhaustion requirement based on its policy view that FDA is better suited to adjudicate the §31 Citizens Action against the Secretary of HHS?

PARTIES TO THE PROCEEDING

The Petitioner in this matter is *Jane Doe*, individually, and as the parent and guardian of her son *Baby Doe*, a disabled adult, whose date of birth is November 10, 1998.

The Respondents are *Merck & Co., Inc., Health and Human Services, Alex Azar, in his official capacity as Secretary of Health and Human Services, Stephen Hahn, M.D., in his official capacity as Acting Commissioner of the U.S. Food and Drug Administration (a division of HHS), and substituted respondent United States of America.*

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PETITION FOR WRIT OF CERTIORARI

TO THE HONORABLE CHIEF JUSTICE AND ASSOCIATE JUSTICES OF THE SUPREME COURT OF THE UNITED STATES

Petitioner *Jane Doe* is the natural parent, and guardian of her disabled son *Baby Doe*, who respectfully petitions this Honorable Court for a writ of certiorari to review the judgment of the Second Circuit Court of Appeals in *Jane Doe, et al. v. Merck & Co., Inc., et al.* dated May 8, 2020, available on PACER.

OPINIONS BELOW

The decision of the Second Circuit Court of Appeals is an unpublished Summary Order cited as *Doe v. Merck & Co.,* 19-1052 (2d Cir. May 8, 2020) available on the Court's website, and is set out hereinafter as Appendix ("App.") A. The district court's judgment, App. B, is cited as *Doe v. Merck & Co*., No. 16-CV-04005 (FB) (RLM) (E.D.N.Y. Mar. 21, 2019) and is available on PACER.

STATEMENT OF JURISDICTION

The Judgment of the Court of Appeals was entered May 8, 2020. *App. A1.* Petitioner did not seek Rehearing, but came directly to this Court for a writ of certiorari. The Supreme Court has extended the time to file the petition due to covid.

SUPREME COURT PRECEDENT IMPLICATED

Jacobson v. Massachusetts, 197 US 11

In the 1905 landmark vaccine-refusal case *Jacobson vs. Massachusetts*, this Court in articulating a state's *police power* to mandate a compulsory vaccine in an emergency or epidemic, cautioned that if a compulsory vaccination is beyond all question, "a plain, palpable invasion of rights secured by the fundamental law, it is

the duty of the courts to so adjudge." *Id at 43.* Over 100 years ago in *Jacobson*, this Court anticipated a compulsory vaccination that could be "so arbitrary and oppressive . . . as to justify the interference of the courts to prevent wrong and oppression." Id at 44.

The Supreme Court expressly created a medical exemption for compulsory vaccinations in *Jacobson*, when a person was not a fit subject for vaccination, and it "would be cruel and inhuman in the last degree" to vaccinate him. *Id at 39.*

STATUTORY PROVISIONS INVOLVED

42 U.S.C. §300aa-1, et seq. National Childhood Vaccine Injury Act of 1986

(set out in fully in App. E)

§300aa–11. Petitions for compensation

(2)(A) No person may bring a civil action for damages in an amount greater than $1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, and no such court may award damages in an amount greater than $1,000 in a civil action for damages for such a vaccine-related injury or death, unless a petition has been filed, in accordance with section 300aa–16 of this title, for compensation under the Program for such injury or death and—

(i)(I) the United States Court of Federal Claims has issued a judgment under section 300aa–12 of this title on such petition, and (II) such person elects under section 300aa–21(a) of this title to file such an action, or

§300aa-31, Citizens Action

Except as provided in subsection (b), any person may commence in a district court of the United States a civil action on such person's own behalf against the Secretary where there is alleged a failure of the Secretary to perform any act or duty under this part.

STATEMENT OF THE CASE

A. Factual History

Petitioner *Jane Doe* is the natural parent and guardian of her son *Baby Doe* whose date of birth is November 10, 1998. *Baby Doe* was born perfectly healthy in a routine delivery at a Queens County, New York hospital. During his first 20 months of life, *Baby Doe* had frequent "well visits" with his pediatrician during which his mother was repeatedly assured of vaccine safety by her doctor. By nineteen months of age, *Baby Doe* had received approximately sixteen thimerosal (mercury) containing vaccines (TCVs), many of which are manufactured and licensed to Merck. Mercury is a highly toxic substance that petitioners allege causes brain injury, and other serious adverse health effects, in some children who are unable to metabolize the mercury in the thimerosal-containing vaccines. [2] *App. B-4.*

Included in the series of approximately 20 vaccinations *Baby Doe* received was a dose of Merck's trivalent live MMR vaccine administered on November 19, 1999 at his one year check-up. *App. A -2, B-4.* On July 10, 2000, *Baby Doe* received his final TCV-DTaP, and was never vaccinated again. *G-2, 6, 10.* These are the "relevant vaccines" in the series of vaccinations that allegedly injured *Baby Doe* as an infant for which he was denied compensation, and are causing him irreparable harm now.[3] *App. A-3.*

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[2] Thimerosal and Vaccines; https://www.cdc.gov/vaccinesafety/concerns/thimerosal/index.html

[3] *Recommended Child and Adolescent Immunization Schedule 2020;* https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf.

On July 19, 2016, after exhausting below, *Doe* filed this case in the District Court. *App. B. Doe's* claims in this case are predicated upon evidence she newly learned about in 2014, showing that Merck, and the Secretary of HHS knew, or should have known, as early as June 7-8, 2000, about credible CDC evidence of vaccine harm for the TCVs, that to date has never been disclosed by the Secretary of HHS to Congress, or disclosed by Merck in its warning labels or packaging inserts. *App. B-7.* Petitioners alleged the non-disclosure of evidence of vaccine harm is a violation of respondents' respective licensing and reporting duties causing petitioners' injuries and irreparable harm. *42 U.S.C. §300aa-22(d)(2), §27(b)(c).*

Doe's evidence shows that instead of disclosing the credible evidence of vaccine-induced brain injury in children, fully briefed by a CDC autism researcher at a June 7-8, 2000 "emergency meeting," at a place called *Simpsonwoods*, Merck and other government-pharmaceutical scientists in attendance, decided to conceal the CDC information at the close of the meeting, and agreed to keep it "out of let's say less responsible hands." *Compl. at D.E. 39 at pg. 39-40; D.E. 1-10*; *App. B-7. Doe's* Complaint alleged if that information of vaccine-induced brain injury allegedly known by Merck and CDC, had been disclosed to the medical community and the public in June of 2000, as required by the disclosure duties of Act, when first uncovered by CDC and Merck, *Doe* never would have revaccinated her son again in July of 2000, with the final TCV, that when combined in the series of vaccinations with the live MMR vaccine, pushed her son over the edge causing his brain injury and autism. *Id.*

The non-disclosure of the above-described evidence of vaccine harm, allegedly known to Merck executives, and the Secretary, at the time while *Baby Doe* was still being vaccinated as an infant, proximately caused his MMR\TCV injuries as a baby; the denial of vaccine injury compensation to his parents in the administrative hearings in 2011 (packaging inserts, warnings and disclosures are admissible evidence); and is causing him irreparable harm from risk of imminent re-injury from a booster MMR vaccine for *Baby Doe,* he now needs to reside in an adult care facility for care his parents can no longer provide to him. *App. A-4, B-2,9.* Each of these three (3) claims accrued after first "alleged fraudulent act occurred in June of 2000" at *Simpsonwoods*, with the disclosure to Merck of CDC evidence of TCV harm, that has not been reported in Merck's product warning labels or packaging inserts required under the Act. §300aa-23(d)(2) & 31. *App. A-3, B-2, 7, 8,*

In short, if *Baby Doe* were now twenty years later to be injured again by the MMR booster vaccine he needs to reside in an adult group home (without the possibility of a medical exemption), his mother *Doe* would be precluded from vaccine injury compensation or a death benefit pursuant to §22(d) of the Act, and the District Court's dismissal of this case with prejudice that is reversible error. *42 USC §300aa-22(d).*

B. Proceedings in Vaccine Court

In May of 2003, *Doe's* claims first originated under *§300aa-11* in the United States Court of Federal Claims Office of Special Masters, in what is commonly known as "Vaccine Court." *Doe's* petition for no-fault injury compensation alleged the Merck

vaccines *Baby Doe* received in the first 20 months of his life (MMR\TCVs) caused his brain injuries and autism. *App. A-2.* Merck holds 12 out of 17 FDA licenses for school required vaccinations that *Baby Doe* received as an infant. Merck is the exclusive license holder for the MMR vaccine distributed in the United States. *App. at B 4-6.*

Merck is shielded from most tort liability for any injury from an "unavoidably unsafe" vaccine that is presumed to be accompanied by proper warning labels and instructions. *§300aa–22(b)(2).* Federal law provides almost complete immunity from liability to vaccine manufacturers on the ground that vaccines are "unavoidably unsafe," even if properly prepared and manufactured in compliance with FDA standards. *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 243 (2011) ("we hold that the National Childhood Vaccine Injury Act preempts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects").

At issue in this case are the exceptions to Merck's no-fault liability protections, and petitioners' claims of vaccine injury and irreparable harm due to Merck's improper warnings, labeling and use instructions for the FDA MMR-TCV licensed vaccines. *App. E-2, 20, 22.*

Section 23(d)(1)(2) provides:

> (d) Punitive damages
>
> (2) …the manufacturer shall not be held liable for punitive damages unless the manufacturer engaged in—
>
> (A) fraud or intentional and wrongful withholding of information from the Secretary during any phase of a proceeding for approval of the vaccine under section 262 of this title,

> (B) intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine after its approval, or
>
> (C) other criminal or illegal activity relating to the safety and effectiveness of vaccines, which activity related to the vaccine-related injury or death for which the civil action was brought.

Between 2000 and 2008, about 5400 vaccine injury petitions were filed in Vaccine Court alleging the childhood vaccinations were causing autism in children. *App. B-4.* An Omnibus Autism Proceeding (OAP) was formed to consolidate the similitude of cases alleging vaccine-induced autism in formerly-healthy, normally-developing children. *App. G-4.* Autism is estimated to affect more than 3 million individuals in the U.S. [4] *Baby Doe*'s diagnosis is autism. *App. A-2, B-5.*

In 2003, *Doe* had filed a *Short Form Autism Petition* to be included in the OAP seeking no-fault liability compensation from HHS for her son's alleged vaccine induced autism. *App. G-11.* The parties ultimately agreed there would be two(s) theories involving six (6) OAP test cases; three (3) per each theory of causation, *i.e.*, whether it was the MMR\TCV vaccines combined, or the TCVs administered alone, causes autism. *App. B-4, G-2.* Although an "*MMR only*" causes autism theory was considered it was never prosecuted. Indeed, there never was an *MMR only* theory of causation considered by the Special Masters in Vaccine Court from which *Doe* could have failed to exhaust her remedies, and this finding is clear error and grounds for reversal. *App. B-5.*

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[4] Vaccines and Autism https://www.cdc.gov/vaccinesafety/concerns/autism.html

More important, the lower Courts never considered any of petitioners' other evidence that was beyond a perceived November 1999 MMR vaccine administration deadline because of the lower Court's error in misunderstanding the claims prosecuted in the OAP. This is reversible error because *Doe's* claims in the OAP were covered under both test theories because her son had received both MMR and TCVs, in the series that ended July 10, 2000, with the administration of the last TCV vaccine, one month after the first alleged fraudulent act occurred in June of 2000 at Simpsonwoods. *App. A-2, B-4, G-2, G-6, G-10.* The lower courts in error miscalculated the timeline of vaccinations that ended in July of 2000, with the last TCV in the MMR\TCV series, and misapprehended the claims below in the OAP, that never included an MMR only theory of causation before the Special Masters. Id.

In 2006, shortly before the OAP hearings were to begin, Baby Doe was selected to replace a previously selected OAP test case petitioner *Child Doe\77* on a "TCV only" theory test case because of the seriousness of his injuries, and weight of his credible evidence demonstrating severe vaccine injury. App. B-5. *Baby Doe's* "MMR\TCV" claim remained covered under the other three (3) test cases that were alleging MMR, when combined with mercury in the TCVs, causes autism. The MMR\TCV combined theory was never abandoned by Doe although she as a TCV only test case, and thus, *Doe* fully exhausted under both theories. Id.

Similar to *Doe*, Child *Doe*\77's case was alleging brain injuries and autism from a series of nine (9) vaccinations, also administered in July of 2000 to *Child\Doe 77*, that included the MMR and at least one TCV, about the same time *Baby Doe*

received his final TCV-DTaP vaccine in the series of relevant vaccinations on July 10, 2000, and developed autism. App. F-1. Both *Baby Doe* and *Child Doe\77* are severely autistic, non-verbal and require full-time care and expensive medical treatments. *App. G, Child Doe\77 v HHS.*

In an August 27, 2010, OAP published decision of Special Master Campbell-Smith, Child Doe\77 v. Secretary of Health and Human Service, MMR Vaccine; Thimerosal-Containing Vaccines, Autism Spectrum Disorder; Finding of Entitlement; Damages Decision Based on Proffer; the Court explained that respondent Secretary of HHS had conceded that Child Doe\77's injuries were vaccine induced. Child Doe\77's case was compensated based on a presumptive MMR Table Injury of encephalopathy (brain injury), which had manifested with "features of autism spectrum disorder," related to the vaccines child petitioner received in July 2000. App. at F-2.

Under a July 3, 2002 Autism General Order #1, In Re: Claims for Vaccine Injuries Resulting Autism Spectrum Disorder or A Similar Neurodevelopmental Disorder, Various Petitioners v. Secretary of Health and Human Services, all evidence from any OAP case was to be shared with other "interested persons" including OAP test case litigants in prosecuting their claims, but because *Child*

Doe\77's case was confidentially settled, the evidence was not placed in the General File or disclosed during the OAP to *Doe*.[5] *App. G-3.*

Petitioners' evidence submitted in this case demonstrated that *Child Doe\77's* case had established, more likely than not, the series of vaccinations administered to her in July of 2000 had caused her brain injury and vaccine-induced autism. However, the District Court never considered Child Doe\77s evidence in support of Doe's claim because of the error made with the timeline of vaccinations, and misapprehension of the claims raised below in the OAP that is reversible error. App. B-8.

By 2010, all the 5400 other test cases were eventually dismissed by the Special Masters, and appeals exhausted in 2011, finding no causal link between MMR\TCVs combined, or TCVs alone, with autism, except for the one notable exception above in *Child Doe\77's* case that was originally a *"TCV only*" theory case (prior to Doe's substitution), but later confidentially settled by HHS, as an MMR encephalopathy Table injury Id. The expert testimony and evidence later obtained by *Doe* from *Child Doe\77's*, after *Doe's* OAP case had been dismissed, established the MMR\TCV vaccine-induced causation. However, the expert report and evidence relied upon in *Child\ Doe 77's* in support of the settlement was never

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[5] "*The court will, as proposed, establish an "Autism Master File" with respect to the general causation issues involved in these cases. That file will be open to inspection by any interested persons, and will constitute an evidentiary record with respect to the general causation issues. All evidence relevant to the general causation issues, including transcripts of any evidentiary hearings, will be placed into that file." See July 3, 2002, Autism General Order #1, App. H.*

disclosed to *Doe* during the OAP or placed in the Autism General File. App. B-6 fn 5.

By 2010, all the 5400 other test cases were eventually dismissed by the Special Masters, and appeals exhausted in 2011, finding no causal link between MMR\TCVs combined, or TCVs alone, cause autism, except for the one notable exception above in Child *Doe/77's* case that was a former TCV theory case, but confidentially settled as an MMR encephalopathy Table injury, and the expert testimony and evidence proving causation from that settlement was never disclosed to *Doe. App. B-6 fn 5.*

Parents of vaccine-injured children in Vaccine Court can face significant hurdles like this in proving their claims, opposing Secretary of HHS, without the ability to obtain civil discovery from the manufacturer to prove their injuries. A petitioner relies on the government's and manufacturers' disclosure duties in proving their claims in Vaccine Court. §300aa-22(d)(2). The Department of Justice records indicate that 99.8% of successful Compensation Program claimants have accepted their awards, foregoing any tort remedies against vaccine manufacturers"); S. Plotkin, W. Orenstein, & P. Offit, Vaccines 1673 (5th ed.2008).

"[A] petitioner to whom the Vaccine Court gives nothing may see no point in trying to overcome tort law's yet more serious obstacles to recovery." See Schafer v. American Cyanamid Co., 20 F. 3d 1, 5 (CA1 1994). This is likely because few tort firms, that would be equipped to handle this type of case against Merck, are willing to do so because of the sweeping no-fault liability protections afforded to the

licensee for vaccines. This peculiar effect eliminates the specter of damages that ordinarily provides strong incentives to manufacturers to improve drug safety and efficacy.

C. Proceedings in the District Court, EDNY

In July of 2016, petitioners timely filed this case under *§11(2)(A)* in the District Court alleging licensing fraud, and conspiracy to commit licensing fraud, in the withholding of evidence of vaccine harm against Merck, that is information required to be disclosed by Merck in its product warnings and packaging inserts under *§22 Standards of Responsibility* of the Act, and under §27 *Mandate for Safer Vaccines* that specifically enumerates the Secretary's licensing duties. *App. B. Doe's* claims were supported by *prima facie* proof showing Merck, and the Secretary both know, or should know, about evidence of MMR\TCV harm and vaccine-induced autism that has not been disclosed in accordance with the terms of Merck's purchase contract and licensing duties specified in the Act. *App. B-6,7.*

On May 14, 2018, Merck moved to dismiss pursuant to Rule 12 (b)(6). On May 24, 2018, HHS, the Secretary of HHS, FDA, the acting Commissioner of FDA, and the United States of America (substituted plaintiff for Julie Gerberding, M.D., former CDC Director during the OAP 2000-2009, and now Merck executive since 2010 in charge of Global Vaccines) [hereinafter "Federal Defendants"] filed their Motion to Dismiss pursuant to Rule 12 (b)(6), or in the alternative, Motion for Summary Judgment pursuant to Rule 56, supported by a Memorandum of Law, Rule 56.1 statement, and declaration of an FDA scientist William R. Mac Kenzie

(acknowledging FDA is aware of Dr. Thompson' whistleblower evidence). On May 31, 2018, Plaintiffs filed their combined opposition papers including a Rule 56.1 Counterstatement, Memorandum of Law in Opposition to both Merck and the Federal Defendants' Motions to Dismiss\Summary Judgment motions.

On March 21, 2019, the Hon. Frederic Block granted defendants' motions, and dismissed the lawsuit against Merck with prejudice. In dismissing the case, the District Court held that Doe failed to state a claim for relief, and the claim that vaccines cause autism was meritless. App. B-3. Doe's claims against the Secretary under §31 of the Vaccine Act were also dismissed. The Court declined to exercise jurisdiction over the Secretary's licensing duties enumerated in §27, Mandate for Safer Vaccines deferring to the FDA's regulatory authority over the MMR licensing. App. B-9.

Judgment was entered on March 25, 2019, and Plaintiffs timely filed their Notice of Appeal on April 19, 2019. *App. B*.

D. Proceedings in the Court of Appeals

On April 19, 2019, a Notice of Civil Appeal was filed by *Doe* in the United States Court of Appeals for the Second Circuit (2nd Cir. 2019); *App. A*. A panel of the Second Circuit affirmed the district court's decision to dismiss Count One claims against both Merck and the Federal Defendants with prejudice. In dismissing Count two against Merck, the Court found the "relevant vaccines" in the series were given to *Baby Doe* before the first "allegedly fraudulent act took place" in June of 2000, and affirmed

petitioner could not demonstrate reliance to prove fraud, and conspiracy to commit fraud. *App. A-3.* The Second Circuit however overlooked for a second time the final TCV in the MMR\TCV series was administered in July of 2000, a month after the June 2000 first, allegedly "fraudulent act" occurred at Simpsonwoods, and was the final vaccine in the MMR\TCV series that injured *Baby Doe. Id. Compl. [D.E. 39, pgs. 24-25].*

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112. At the November 22, 1999 Baby Doe's medical records show he received a PPD skin test for tuberculosis that came back negative, and he received Merck's Multi-dose live virus MMR vaccination.

113. On March 1, 2000, Baby Doe was seen again by his pediatrician and received another Merck vaccination, the Varicella vaccine and another Hib titer.

114. On July 10, 2000, about a month after Simpsonwoods, Baby Doe was then 20 months of age, he was seen at his pediatrician's office and was noted to have limited speech, approximately 3-5 words. Baby Doe was referred to speech therapy at this time.

115. During the July 10, 2000 doctor's examination, Baby Doe was administered another dose of the Dtap and IPV vaccinations.

*Dtap and HibTITER are TCVs.

As to Count Three, the panel found plaintiffs below may sue the Secretary pursuant to 42 U.S.C. *§ 300aa-31*, but not the FDA, then declined primary jurisdiction over petitioners §31 claim, deferring to the FDA's regulatory authority. App. A-3. The Second Circuit found the claims against the Secretary contained no factual allegations articulating which duties were violated or how they were violated by the Secretary, overlooking plaintiffs below cited directly from *§27* in the Complaint, that listed each of the enumerated duties of the Secretary in sections 1 & 2, underlining and highlighting the Secretary's "licensing" duties to assure safer vaccines:

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> ***In the administration of this part and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall—***
> *(1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and*
> *(2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the* ***licensing****, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.*

Further, at all relevant times, any knowledge of the CDC\FDA scientists about evidence of vaccine harm that was allegedly concealed, sanitized or altered, prior to being and admitted into evidence by the Secretary of HHS, as respondent in the OAP, opposing Doe's injury claim, is an alleged dereliction of the Secretary's licensing duties actionable in this Complaint under §31.

E. Why this case should be heard.

In counsel's judgment, the panel's decision involves (1) questions of exceptional legal importance; (2) departs from well-established precedents of the Supreme Court in *Jacobson v Massachusetts*, 197 US 11, and (3) the Second and Third Circuit Court of Appeals are in disagreement regarding Merck's disclosure duties, which petitioners, respectfully, assert are specific licensing duties under the Act consistent with the Third Circuit in *Mazur v Merck* that held:

> "[Merck's] responsibility is continuous, and it must therefore apprise the CDC [Secretary] of any risks it later discovers, or in the exercise of reasonable care, should have discovered." "[Merck's] responsibility is continuous, and it must therefore apprise the CDC [Secretary] of any risks it later discovers, or in the exercise of reasonable care, should have discovered." *Mazur v. Merck*, 964 F.2d 1348,1365-66 (3d Cir. 1992). It is also a condition of purchase. See *Mazur v. Merck*, 767 F. Supp. 697, 703 (E.D. Pa. 1991) (describing history of Merck/CDC negotiations over MMR vaccine purchase contract).

The District Court dismissed with prejudice holding:

> "Nor is it relevant that the government once employed an individual who now works for Merck, even if said individual knew then or knows now about a causal link between MMR vaccines and autism…every alleged statement or omission made by a Merck employee occurred after *Doe* received the vaccine in 1999. Thus, *Doe* cannot prove reliance, which is fatal to his fraud claim. See *Schlaifer Nance & Co. v. Estate of Warhol*, 119 F.3d 91, 98 (2d Cir. 1997). *App. B-8.*

In granting defendants' motion(s) to dismiss, the District Court's findings were clear error because the District Court misapprehended the timeline of relevant vaccines that ended in July of 2000, with the last TCV in the MMR\TCV series, and the District Court misunderstood the administrative claims in the OAP, in that there was never an "*MMR only"* theory prosecuted in Vaccine Court from which *Doe* could

have failed to exhaust her remedies. The only two theories considered in the OAP were "MMR\TCV" *in seriatim*, or "TCV only" causes autism, and *Doe* was covered under both test theory cases because her son had received both MMR\TCV vaccines between November of 1998 and July of 2000. *App. B-6.*

As a result of the error below, the lower Courts never considered any of Doe's other prima facie evidence from events that occurred after the November 1999 MMR vaccination, proffered with the Complaint as exhibits, sufficient to establish the fraud, and conspiracy to commit fraud needed to recover punitive damages against Merck §22(d)(2). Notable in this this regard was the evidence from a 2014 CDC Whistleblower who was alleging CDC had altered study results from a 2002 Atlanta Metropolitan Area Autism Study, that had been published by CDC in the Journal of Pediatrics in 2004 in DeStefano, et al., that had falsely concluded CDC had found no correlation in the Atlanta study between the FDA-MMR licensed vaccine and autism when, according to the whistleblower, the opposite was true. App. B-6.

In August of 2014, Dr. William Thompson, a CDC vaccine-autism researcher and whistleblower, one of DeStefano's et al., study co-authors, reported to Rep. William Posey, (Fla), that CDC had actually found the opposite result from the Atlanta study than what had been published in DeStefano, et. al., and the researchers had intentionally destroyed evidence. Compl. D.E. 39, par. 134-148, Exhs. 1-10. This same DeStefano, et al., study published by CDC in 2004 was later in 2006 admitted into evidence by Secretary of HHS, appearing as respondent, opposing petitioners' claims for vaccine injury compensation where Doe had been denied vaccine injury

compensation. App. at B-6. 42 U.S.C. §300aa-11(A)(1); Compl. D.E. 39 at 8, 21, 53, 73.

According to Dr. Thompson's evidence sometime in the fall of 2002, CDC had again uncovered more evidence of a statistically-significant correlation of brain injury and vaccinations, this time directly linking the "MMR only" (without mercury) with autism in children, and for a second time CDC concealed the evidence. Id. This evidence was never considered by the District Court, even though Doe did exhaust below on the MMR\TCV theory before filing this case. 42 USC 300aa-11.

According to Dr. Thompson's statements to Congressman Posey, the findings CDC published in DeStefano, et. al. had been sanitized by the study authors to remove data sets that were race related, and were showing a positive correlation between the MMR alone, and autism in some children under age 3. The removal of specific race related data violated the CDC's pre-determined research protocols for the study. Dr. Thompson alleged this was intentionally done by DeStefano et al.'s, authors to alter the final solution to show there was no correlation between FDA-MMR licensed vaccine and autism in children of any race. Compl. at D.E. 1-11.

Dr. Thompson's evidence submitted with the Complaint demonstrated the former CDC Director in 2002, who is now a senior scientist and executive at Merck since 2010, allegedly knew the DeStefano, et. al, findings were intentionally falsified concealing the evidence of vaccine-induced autism that had been uncovered by CDC from the Atlanta study findings. Compl. at D.E. 1-15. Under the Vaccine Act, any Merck executive now, with any knowledge of vaccine harm caused by the FDA-MMR

vaccine is required to disclose that information in the MMR warning labels and packaging inserts, as a condition of Merck's licensing agreement, and in exchange for no-fault liability under the Act. §300aa-22(b).

Under the Vaccine Act's strict disclosure duties, it does indeed matter very much what knowledge a former CDC employee has, if any, about the alleged, illegal destruction and alteration of vaccine safety data by CDC admitted into evidence in the OAP. This Complaint involves allegedly falsified information embedded within the DeStefano, et al., study findings by CDC, that were submitted as evidence by Secretary of HHS in Vaccine Court, opposing Doe's injury claim. No doubt this information was directly imputed from the CDC employee(s) to the Secretary at the time during the OAP, and is evidence of a dereliction of the Secretary's duties alleged in Counts One and Three of the Complaint against the Secretary. App. A-3.

This same knowledge today, if any, known to the former Director of CDC during the OAP, would have been later imputed to Merck, the licensee, upon the hiring of that person as Merck's Director of Global Vaccines in 2010 as alleged in Count Two. This is evidence of alleged fraud, and conspiracy to commit fraud, between former CDC employee and Merck, and was more than sufficient to survive a motion to dismiss. The immunity from liability for injury does not apply if the plaintiff establishes by clear and convincing evidence that the manufacturer was negligent, or was guilty of fraud, intentional and wrongful withholding of information, or other unlawful activity. See §§300aa– 22(b)(2), 300aa– 23(d)(2).

REASONS FOR GRANTING THE PETITION

A. THE SECOND CIRCUIT'S INTERPRETATION OF THE VACCINE ACT CONFLICTS WITH JACOBSON'S PRECEDENT REQUIRING THIS COURT EXERCISE ITS SUPERVISORY POWERS AND INTERVENE

The Second Circuit has misinterpreted Petitioners' constitutional and statutory rights under the Vaccine Act.

In the 1905 landmark vaccine-refusal case, the Supreme Court articulated a state's *police power* to mandate vaccinations. This is well understood, but *Jacobson* also required that if a vaccination is compulsory, and could cause injury and death, then courts must "interfere for the protection" of those affected. *Id.* at 28. *Jacobson* foresaw over 100 years ago that there might be compulsory vaccinations that are a violation of "rights secured by the fundamental law," and in such cases, the Supreme Court considered it "the duty of the courts to so adjudge." *Id.* at 31. *Jacobson* does not offer no-fault liability vaccine makers *carte blanche*. *Jacobson* required the District Court to assess the constitutionality of Merck's FDA licensed vaccines individually, as the Supreme Court did for the sole smallpox vaccine in *Jacobson*.

This case has not occurred in a vacuum. Foremost on the minds of the American people today is the increasing number of compulsory vaccines, and the shrinking ability to obtain a medical or religious exemption for those not suitable to be vaccinated. As it is now, children in New York State already receive an estimated

53 plus vaccinations by age 18 to attend school.[6] *See Apps. C & F.* In 2015, the Second Circuit in *Phillips v. City of New York*, 775 F.3d 538, 543 (2d Cir. 2015) dismissed an earlier due process challenge to NY PHL § 2164, holding the statute "goes beyond what the Constitution requires" which at the time, included robust religious and medical exemptions comporting with *Jacobson's* legal requirements. In the multitude of recent New York cases filed in the last year, unsuccessfully challenging the repeal of the religious exemption in New York State in June of 2019, *Jacobson* is often erroneously cited by the Courts for the proposition *police power* is without restraint.

Five years later New York's regulations are dramatically different than what the Second Circuit considered in *Phillips* in 2015. *Id.* The statute no longer provides a religious exemption, and offers a medical exemption that is barely obtainable for anyone, relying on the CDC guidelines to determine eligibility, that is very often in conflict with the physician's learned medical opinion to waive vaccinations for the patient. State law is well established in this regard with respect to other biological drugs, and leaves safety and efficacy of any drug up to the treating physician as the learned intermediary to consider the individual's medical history, genetic predispositions and disabilities, and is the recognized authority to do so for his patient. This is why the issue of drug safety in New York, as articulated by the decision in *Marcus v. Specific Pharmaceuticals, Inc.*, 77 N.Y.S.2d 508 (App. Div. 1948)., "is left up to the physician under the learned intermediary rule," and PHL 2164 (8).

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[6] https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf

In New York State, individuals who are eligible for medical exemptions are not automatically exempt from vaccinations. A contraindication for a medical exemption under state law has to be a side effect either 1) disclosed by Merck in its product warning labels and packaging inserts; or 2) recognized by CDC as an acceptable ground for obtaining the medical waiver. *10 NYCRR 66.1-10*. Currently Merck's product warning labels and CDC guidelines do not include vaccine-induced autism as a side effect for any vaccination. It is for precisely this reason that if the licensing information is so deficient, and goes "so far beyond what was reasonably required for the safety of the public, as to authorize or compel the courts to interfere." *Jacobson* at 28.

In that context, Congress has also authorized the Institutes of Medicine (IOM) to report on vaccine adverse reactions. The IOM has produced a series of adverse reaction reports in striking contrast to the CDC guidelines, repeatedly finding that the schedule for school required vaccinations lacks adequate safety data. A scholarly review of those reports shows significant additional grounds for legitimate medical exemptions, beyond the limited grounds permitted by the CDC. See: *United States Institutes of Medicine (IOM) Reviews of Pediatric Vaccine Safety and Schedules Repeatedly Cite Lack of Scientific Basis for Positive Claims*, Journal of the Institute for Health Research.[7]

Fortunately, over the years an evolving body of science and law has developed to protect public health, and has placed clear restraints upon Merck, as the licensee,

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[7]http://www.inhere.org/wp-content/uploads/2019/12/JSHO-IOM-vaccine-safety-paper.2019.pdf

that further *Jacobson's* precedents under the Vaccine Act. The Act created clear, enumerated duties imposed upon the Secretary of HHS to *Mandate Safer Vaccines §27,* that did not exist in 1905, substituting commonly held beliefs about vaccination safety and efficacy under the discretion of Secretary of HHS' licensing duties clearly specified by Congress in §27 of the Act. These duties require full disclosure of evidence of vaccine harm in exchange for no-fault liability afforded to the manufacturer for vaccine injury liability caused by any "unavoidably unsafe" vaccination mandated on infants and children. *Id.*

Today, the vaccine science is no longer based on "common knowledge" of the legislature this Court relied upon in *Jacobson*. Vaccinology has evolved into a financially lucrative, complicated, overly-burdened, technical regulatory process that is heavily influenced by no-fault liability pharmaceutical companies, and is nearly impossible for a parent to comprehend.[8] However, in 1986, with the passage of the Vaccine Act, the safety and efficacy of compulsory vaccinations was placed under the responsibility of the Secretary of HHS, which permits a citizen like *Doe* to challenge the Secretary's duties under §31, when there has been an alleged dereliction of those specific duties in §27, *Mandates for Safer Vaccines*, of which caused *Baby Doe's* injuries and irreparable harm.

The sweeping assertion that petitioners' claim of vaccine-induced autism is meritless, discounting petitioners' *prima facie* evidence as "hazy insinuations" has a profound and tragic legacy. *App. B-4.* Courts are "fundamentally unsuited to

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[8] https://www.cdc.gov/vaccines/schedules/index.html (last accessed 10.2.2020).

undertake," and in fact are not permitted to undertake, "credibility assessments" at the Rule 12(b)(6) stage. *Turkmen v. Hasty*, 789 F.3d 218, 226 n.6 (2d Cir. 2015); accord *Wood v. Moss*, 134 S. Ct. 2056, 2065 n.5 (2014) ("In ruling on a motion to dismiss, we have instructed, courts 'must take all of the factual allegations in the complaint as true.'") Petitioners' evidence included video statements, relevant documentary evidence, expert evidence, and three separate transcripts sufficient to establish her claim, but the Court never considered the evidence, in error, miscalculating the timeline of vaccinations, and misapprehending the claims in the OAP, which the Court held were determinations "fatal to *Doe*'s claim." App. B-8.

In a cursory assessment of the petitioners' evidence the District Court tied much of its decision to the credibility of a June 2000 CDC transcript from the *Simpsonwoods* emergency meeting, obtained by petitioners through Freedom of Information Law, that speaks for itself. The June 2000 CDC transcript demonstrates both respondent Merck, and the Secretary (imputed from the CDC\FDA researchers) knew about a statistically, significant correlation between childhood vaccinations and brain damage, a month before Baby Doe was injected with another mercury vaccine in July of 2000, severely injuring Baby Doe. Compl. D.E. 39 at 114, 115; D.E. 1-10,11,15. The Court never reached petitioners' additional evidence after the November 1999 MMR administration, because of the erroneous finding *Doe* failed to exhaust an MMR only theory case in the OAP, when there was no MMR only theory prosecuted in Vaccine Court. App B-6.

The June 7-8, 2000, CDC transcript proffered by *Doe* shows an agreement by Merck, and other government-industry scientists in attendance at the CDC "emergency meeting," to keep evidence of vaccine harm disclosed by CDC to Merck, correlating mercury in the TCVs with a dramatic increase in brain injury in children, from out of "let's say, less responsible hands.". This blatant violation the Act's disclosure duties occurred one month before *Baby Doe* and *Child Doe\77* received their last TCVs in the MMR\TCV series in July of 2000. Id. The District Court clearly misunderstood the claims below, and miscalculated the timeline of vaccinations showing the last TCV vaccine in the series with the MMR, that Baby Doe received as an infant, was administered in July of 2000, one month after the first "alleged fraudulent act occurred" in June of 2000 demonstrating reliance. App A-3.

It was precisely this unfortunate judicial outlook that led the Supreme Court in 1927 to affirm the constitutionality of Virginia's compulsory eugenic sterilization law in *Buck v. Bell*. 274 U.S. 200 (1927). Oliver Wendell Holmes, writing for the majority, stated that "the principle that sustains compulsory vaccination is broad enough to cover cutting the Fallopian tubes. Three generations of imbeciles are enough." *Id*. at 207. This misguided eugenic decision led directly to the compulsory sterilization of tens of thousands of poor, minority and working class Americans being between the 1920's and mid-1970's. Today, forced sterilization is considered a war crime, yet the Supreme Court sustained its constitutionality through its over-broad

interpretation of *Jacobson*. Rome Statute of the International Criminal Court Art. 8(2)(b)(xxii) (1998).

The Supreme Court majority has clearly annunciated a commitment to the more contemporary view that truly voluntary informed consent is the prerequisite for any medical intervention, including vaccination. Without full disclosure of evidence of vaccine harm by the manufacturer there can be no informed consent. In a case about taking blood from the body without consent (surely less invasive than injecting "unavoidably unsafe" vaccines), the Supreme Court held:

> Even a "…diminished expectation of privacy does not diminish the… privacy interest in preventing a government agent from piercing the… skin. And though a blood test conducted in a medical setting by trained personnel is less intrusive than other bodily invasions, this Court has never retreated from its recognition that any compelled intrusion into the human body implicates significant, constitutionally protected privacy interests…" *Missouri vs McNeely*, 569 US 141 at 15 (2013)

Some of these rights are rooted not only in the legal and ethical traditions of this country but are also internationally recognized as fundamental human rights. The rights of informed consent and the related right to refuse unwanted medical interventions, for example, are not only deeply rooted in myriad ethical, philosophical and legal foundations of this nation, but are the pivotal principles articulated by the Nuremberg Declaration and form the basis for internationally recognized fundamental human rights protections. See, e.g., TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNAL COUNCIL LAW No. 10, at 181-82 (1997) [hereinafter TRIALS OF WAR CRIMINALS].

In 1905, *Jacobson* upheld a smallpox vaccination mandate for the adult population based on the then common belief that the vaccine prevented the disease, and because it was perceived as a potentially fatal epidemic. The FDA-MMR licensed vaccine is dramatically different from the sole (discontinued) smallpox vaccine of more than a century ago, and of questionable necessity, proportionality and harm avoidance particularly in the absence of a true epidemic. *Jacobson* requires that a compulsory vaccination be made possible only in highly circumscribed situations: when there is "an emergency," "imminent danger," when "an epidemic of disease…threatens the safety of [society's] members" and when the epidemic "imperil[s] an entire population." *Id.* at 29, 27, 29, 31.

In April of 2019 in New York, at the epicenter of last year's prequel epidemic, a State Supreme Court found the number of measles cases in Rockland County was insufficient to rise to the level of epidemic, and overturned an Executive Order that excluded children who were not vaccinated from public places. The Court defined epidemic, and then concluded an epidemic did not exist. *Jane Doe v Ed Day*, Index No. 031784/2019, Hon. Rolf Thorsen, SCJ, April 5, 2019, County of Rockland, State of New York. "In a population of roughly 330,000 people, 166 cases is equal to .05% of the population, which does not appear, on the record before the Court, to rise to the level of an "epidemic" as included in the definition of "disaster" under Executive Law §24." *Id.*

The *Jacobson* Court did not recognize or condone unlimited authority for the constitutionality of all vaccinations licensed by FDA that exist today. In *Jacobson*,

the case before the Supreme Court involved a statute that imposed a $5 fine on the plaintiff for refusing to submit to a compulsory vaccination during a perceived epidemic. No other penalty was at issue, and the plaintiff was never at risk of being forced vaccinated.

Here, the District Court below rejected petitioners' reliance on *Jacobson* for the proposition that courts are required to:

> " 'assess the constitutionality of each vaccination mandate individually,' *Doe* Br. at 25, and that such mandates may only be allowed in 'highly circumscribed situations,' such as emergencies, epidemics, and the like,' id. at 26. In *Jacobson*, the Court held that a Massachusetts mandate requiring smallpox vaccinations did not violate the Constitution. *Doe*'s quotations are taken entirely out of context. See *Jacobson*, 197 U.S. at 38 (establishing what amounts to a rational basis test for vaccination mandates)."

However, according to this Court's precedents in *Jacobson*, a public health initiative to control disease is constitutionally permissible only if the powers exercised conform with principles of fairness and necessity, and *Doe* quoted directly from the text of *Jacobson* in her Complaint in support of the legal requirements set by this Court. Id.

Under *Jacobson*'s legacy, the legitimacy of the licensed vaccination may not go "beyond what was reasonably required for the safety of the public." *Jacobson,* 197 U.S. at 28. There must exist a reasonable relationship between the public health intervention and the achievement of a legitimate public health objective. *Id.* at 26. Even though the objective of the Secretary of HHS may be valid, the licensing methods and procedures for the FDA vaccines must conform with provisions of the

Act, and have a "real or substantial relation" to protect the public health and cannot be "a plain, palpable invasion of rights"; *Id.* at 31.

Justice Harlan writing for the majority stated in circumstances where the "regulations [are] so arbitrary and oppressive in particular cases… justify the interference of the courts to prevent wrong and oppression." *Jacobson,* 197 U.S. at 38-39. Thus, a licensed vaccination may be unconstitutional if the licensing disclosures are gratuitously onerous or unfair. Where it was reasonably likely that a person was "not a fit subject of vaccination or that vaccination, by reason of his then condition, would seriously impair his health", licensing vaccinations without exemptions would be "cruel and inhuman in the last degree." *Id.* 38-39.

This case squarely addresses the type of overreach against which the *Jacobson* Court expressly forbid. Moreover, to force *Doe*, who has suffered so much already, to play Russian Roulette and risk re-injury, without the possibility of any compensation, would be "cruel and inhuman to the last degree," and violates the Act. The challenged actions of the respondent Secretary fails every aspect of the *Jacobson* test.

B. PETITIONERS MET THEIR PLEADING REQUIREMENTS WITH *PRIMA FACIE* PROOF DEMONSTRATING THE LICENSEE IS VIOLATING THE ACT IN ITS PRODUCT WARNING LABELS AND PACKAGING INSERTS FOR THE FDA-MMR VACCINE.

It was clear judicial error misapprehending petitioners' claims raised in the OAP, which never considered an "*MMR only"* theory of causation from which *Doe* could have failed to exhaust remedies. *App. B-6.* There was no basis to determine an MMR only theory of autism was prosecuted in Vaccine Court, or that Doe was not covered under the MMR\TCV test cases. *App. B-5.* Baby Doe had received both types

of vaccinations and was covered under both test case theories. Moreover, *Child Doe \ 77's* case was settled as an MMR table injury although she was the original TCV test case, prior to *Baby Doe's* substitution, and both children received MMR and TCVs alleged to have caused their autism. *App. B-6, G-4.* Courts of appeal draw an important distinction between the review of factual issues and the review of legal issues. Findings of fact are upheld unless clearly erroneous. *Media Services Group v. Bay Cities Communications, Inc., 237 F.3d 1326, 1329 (11th Cir. 2001).*

Doe did not need to prove vaccines cause autism based on the pleadings alone to overcome a motion to dismiss. In dismissing the case, the District Court improperly resolved factual issues against *Doe* misapplying the *Iqbal-Twombly* pleading standard. On a motion to dismiss, the Court accepts all factual allegations as true to determine whether they "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The District Court improperly drew inferences against *Doe* relying, in part, on the Special Masters decisions in the OAP that are inadmissible in this case. §22(e). *App. B-11.*

"In *Doe*'s OAP petition, Special Master Vowell lamented that:

> '[u]nfortunately, the [*Does*] (and uncounted other parents of children with ASD) have relied upon practitioners and researchers who peddled hope, not opinions grounded in science and medicine...' 2010 WL 892250, at *201. The Court must do likewise and dismisses the TAC with prejudice." *Id.*

Simply put, the district court disbelieved that vaccines cause autism, and so dismissed the case with prejudice. This is error because the District Court was

required to accept the factual allegations as true, and to draw reasonable inferences in *Doe's* favor, see, e.g., *Barrows v. Burwell*, 777 F.3d 106, 114-15 & n.47 (2d Cir. 2015). Instead the District Court improperly acted as a fact finder, and erroneously decided issues of fact without scientific or medical evidence, and assessed the credibility of the *Doe's* proffer adverse to petitioner. See *Althen v. Sec's of Health & Human Serves.*, 418 F.3d 1274 (Fed. Cir.2005) (Medical science is "a field bereft of complete and direct proof of how vaccines affect the human body.") Yet the Complaint set forth a plausible claim that surely entitled *Doe* to move forward with her suit and obtain discovery to prove her claim.

The Complaint contained more than "cryptic" allegations from "backroom deals" but instead provided well-pleaded factual allegations with extraordinary detail, supported by *prima facie* proof, of which "the court must "assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Pension Ben. Guar. Corp. ex rel. St. Vincent Catholic Med. Ctrs. Ret. Plan v. Morgan Stanley Inv. Mgmt. Inc., 712 F.3d 705, 717 (2d Cir. 2013) (quoting Ashcroft v. Iqbal,* 556 U.S. 662, 678-79 (2009)). [9] *App. B-7.*

As the Supreme Court recently reiterated, plaintiffs are "required to do no more to stave off threshold dismissal for want of an adequate statement of their claim" than "simply, concisely, and directly" set out the facts and events "that, they

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[9] The two arguments the District Court claimed were raised for the first time in the opposition memorandum of law [D.E., 71], constituting the impermissible amendments were the Dr. Bustyn evidence that was originally pleaded in the complaint, and the state action argument that was first raised by Merck in the motion to dismiss, to which petitioners replied, and thus not an impermissible amendment to the Complaint. *App. B-6.*

allege[ ], entitle[ ] them to damages." *Johnson v. City of Shelby*, 135 S. Ct. 346, 347 (2014). The Second Circuit's reliance on District Court's findings without meaningful review, or performing any *de novo* analysis of the particular facts and circumstances of this case, represents such a departure from the proper course of judicial proceedings, on a topic of such great public importance, *no-fault, compulsory vaccinations*, warranting the exercise of this Court's supervisory powers to intervene.

The Second Circuit did not review for error, and adopted the District Court's clear error in the timeline of vaccinations, again misapprehending the OAP theories in Vaccine Court, and affirming an exhaustion requirement that is not contemplated in the Act under §31, dismissing against the Secretary with prejudice. *App. A.* An abuse of discretion may consist of an error of law, an error of fact, or an error in the substance or form of the trial court's order. For example, the trial judge may have an erroneous view of the law which controls the pending suit — a statute, standard or line of cases may be misapprehended — or the judge may have misapplied the rules governing the issuance of injunctive relief. The Supreme Court has viewed an error of law as an abuse of a trial court's discretion. See *United States v. Corrick*, 298 U.S. 435, 438, 56 S.Ct. 829, 830, 80 L.Ed. 1263 (1936).

The Second Circuit reasoned "uniformity would be more appropriately reached through application to one administrative agency rather than the various courts. *App. A-3.* The Second Circuit in *Doe's* case has created a new procedure for adjudicating licensing violations not contemplated in the Act, directing petitioners to the FDA on the issue of safety and efficacy when this case is about the alleged withholding and

destruction of credible evidence of vaccine harm by both CDC\FDA and Merck that caused the injuries and irreparable harm. *Id.*

The decisions below is reversible error because any knowledge of vaccine harm by CDC\FDA researchers alleged in the Complaint is imputed to the Secretary, and thus actionable under §31.

> "The law charges HHS with responsibility for overseeing vaccine production and safety. It is "likely to have a thorough understanding" of the complicated and technical subject matter of immunization policy, and it is comparatively more "qualified to comprehend the likely impact of state requirements." *Geir v. American Honda Motor Co.*, 29 U. S. 861, 883 (2000) (internal quotation marks omitted).

The Second Circuit in affirming the dismissal is imposing its own bare policy preference over the considered judgment of Congress regarding the §31 claim. While under the abuse of discretion standard, "an appellate court will "uphold any district court determination that falls within a permissible range of permissible conclusions." *Cooter & Gell v. Hartmarx Corp.,*496 U.S. 384, 400 (1990)." Here the findings of facts and conclusions of law were clearly erroneous and far outside a permissible range of permissible conclusions.

The Second Circuit in affirming added it failed to appreciate how the FDA-MMR license effects New York State's MMR regulations, but petitioners' claim was not a Fourteenth Amendment challenge to the state's mandate. App. A-4. This case is a challenge to respondents' failed licensing and disclosure duties, permissible under the Act, and not a challenge to the state police power to mandate the MMR vaccine in the absence of a measles epidemic. To view FDA-MMR's licensed vaccine solely through the lens of the police power to mandate vaccination, as the Second

Circuit seems to do, without considering rights of petitioners, and duties of the respondents under the Vaccine Act, is to look at one side of a two-faced coin. Petitioners' claim for equitable relief is correctly directed to the Secretary, and not the State of New York, as permitted by the §31 waiver of sovereign immunity. Id.

In 2012, the Second Circuit expressed its view in an earlier due process challenge to state mandates holding it is "well within the State's police power, and thus its constitutionality is too well established to require discussion." Caviezel v. Great Neck Pub. Sch., 500 F. App'x 16 (2d Cir. 2012), citing Mc Cartney v. Austin, 31 A.D.2d 370 (3d Dep't 1969). This decision fails to comport with Jacobson's due process requirements which identified fundamental liberty interests in avoiding compulsory vaccinations that are medically unsafe. Surely courts today should apply Jacobson's due process criteria with scrutiny and diligence, especially to the licensing duties of the Secretary under the Act, because the alleged violations of are impinging upon petitioners' fundamental liberty interests causing irreparable harm.

C. THE COURT WAS REQUIRED BY THE ACT TO EXERCISE PRIMARY JURISDICTION OVER THE §31 CITIZENS ACTION AGAINST THE SECRETARY OF HHS.

The United States Supreme Court in Price v. United States 174 U.S. 373 (1899) observed: "It is an axiom of our jurisprudence. The government is not liable to suit unless it consents thereto, and its liability in suit cannot be extended beyond the plain language of the statute authorizing it." Under the Act, Congress specified a waiver of sovereign immunity in §31, providing that an aggrieved citizen may pursue an

action in the District Court against the Secretary, not the FDA. The only prerequisite or exhaustion requirement to bring the §31 Action against the Secretary was to file a Notice of Intent to Sue which petitioners did do prior to filing this lawsuit, and after fully exhausting for nearly a decade in Vaccine Court. No other exhaustion to FDA is required in §31.

§31 does not limit petitioners' remedies against the Secretary in any way. Doe's Complaint called upon the Court to invoke its broad equitable powers in granting the relief against the Secretary, consistent with Jacobson's precedents to avoid injury or possible death to her son, that requires intermediate or strict scrutiny be applied to the §31 claims. In Jacobson, the Supreme Court's standard of review was only rational basis. Today petitioners' equitable relief sought under the Act against the Secretary requires at least intermediate scrutiny, if not strict scrutiny, because the government's actions are imposing on petitioners' fundamental liberty interests. City of Cleburne Texas v. Cleburne Living Center, 473 U.S. 432 (1985). Since the 1960's, the Supreme Court set limits on state interference with medical autonomy in three landmark cases: Cruzan v. Dir., Mo. Dept. of Health, 497 U.S. 261 (1990), Washington v. Harper, 494 U.S. 210 (1990) and Washington v. Glucksberg, 521 U.S. 702 (1997).

While these cases do not discuss vaccination, their reasoning on bodily integrity and medical decision making locate a constitutionally protected, fundamental liberty interest in the medical exemption required by this Court's reasoning in Jacobson. Cruzan found that the "freedom from unwanted medical

attention is unquestionably among those principles 'so rooted in the traditions and conscience of our people as to be ranked as fundamental'". Cruzan at 305 (quoting Snyder v. Mass., 291 U.S. 97, 105 (1934)).

Doe has had no opportunity to further investigate Dr. Thompson's whistleblower evidence to challenge the DeStefano et al., study admitted into evidence in the OAP. CDC and FDA are component divisions of HHS, under the auspices of the Secretary. Pursuant to 45 C.F.R. Part 2, HHS employees do not participate, give deposition or trial testimony in their official capacities in private litigation in which the United States is not a party. In United States ex rel. Touhy v. Reagan, 340 U.S. 462 (1951), the Court recognized the authority of federal agencies to limit their employees' involvement in such actions. In this case however, the United States is a party, and thus, Touhy is not a bar to deposing Dr. Thompson (as a representative of the Secretary) to prove her claim for punitive damages against Merck. Id.

Under the Vaccine Act, it does indeed matter very much what knowledge a former CDC employee has, if any, about the alleged, illegal destruction and alteration of vaccine safety data by CDC. App.B-8. This Complaint involves allegations of falsified information embedded within the DeStefano, et al., study findings by CDC, that were submitted as evidence by Secretary of HHS in Vaccine Court, opposing Doe's injury claims in the OAP. No doubt this information was directly imputed from the CDC employee(s) to the Secretary at the time during the OAP, and is evidence of an alleged dereliction of the Secretary's duties actionable in this case now.

This same knowledge today, if any, known to the former Director of CDC during the OAP, would have been later imputed to Merck, the licensee, upon the hiring of that person as Merck's Director of Global Vaccines in 2010. This is evidence of an alleged conspiracy to commit fraud between former CDC employee and Merck, sufficient to overcome a motion to dismiss. To obtain punitive damages available to Doe under the Act, she would need discovery to prove the former Director of CDC, who now works for Merck as the Director of Global Vaccines, knew about the destruction of evidence in 2002 from the CDC Atlanta autism study in DeStefano, et al., admitted into evidence in the OAP, and is knowingly concealing a correlation between MMR and vaccine-induced autism in Merck's product warning labels and packaging inserts now, that is needed by Doe to prove liability under the Act.

And lastly, if that same person today who now works for Merck, knows about evidence of MMR\TCV harm that has not yet been disclosed by Merck, it must be disclosed now, immediately, in exchange for Merck's no-fault liability and FDA licenses being mandated upon Baby Doe. The disclosure, of course, of vaccine-induced autism as a side effect of the MMR would enable Doe to obtain a medical exemption for MMR induced autism for her son to reside in a group home, and for the care he needs now she can no longer provide to him warranting reversal and remand to the District Court for the discovery necessary to prove Doe's claim.

CONCLUSION

For the reasons set forth hereinabove, petitioners respectfully request that this Honorable Court grant the petition and issue a writ of certiorari to the Second Circuit to review the issues raised herein.

Respectfully submitted,
/s/ Patricia Finn
Patricia Finn (Counsel of Record)