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VACCINE LIABILITY LAW CLARIFICATION PROTECTS LIVES AND RESOURCES

by

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The vaccine provision in the Homeland Security Act of 2002, Pub. L. No. 107-296, provided needed clarification of the law governing certain legal claims against vaccine manufacturers.[1] Specifically, the provision clarifies the original intent of Congress: claims involving vaccine ingredients are to be treated the same way as claims involving vaccines themselves. The provision closes a loophole that contingency fee personal injury lawyers have attempted to create. Closing this loophole will expedite payments to those who are truly injured by vaccine ingredients. Closing the loophole also will protect manufacturers from runaway legal liability. It will preserve their assets for research and development of new vaccines and pharmaceuticals, including those that may help fight bioterrorism.

Unfortunately, since the Act was signed into law in November, contingency fee personal injury lawyers and their supporters have been able to place their "spin message" about the Act throughout the media. Because the controversy will affect some lawsuits relating to thimerosal, a mercury-based vaccine preservative once manufactured by pharmaceutical companies, opponents have sought to smear the provision as politically motivated. Building on their media blitz, the vaccine provision's detractors in the Senate have pledged to repeal the provision as soon as the 108th Congress convenes. Some have even threatened to attach repealing language to every measure that comes to the Floor.

It is critical that members of the new Congress understand the true nature of the Act and appreciate the arguments for its preservation. Without the Act's protection, the companies that will be called on to develop the next generation of vaccines and vaccine ingredients to fight bioterrorism will have billions of dollars of litigation looming over them. They risk facing even more litigation in jurisdictions that have been termed "judicial hellholes," areas where the law is not fairly applied to out-of-state corporate defendants.

The Controversy Over Thimerosal. Thimerosal was first used in vaccines in the 1930s to prevent infections from fungus and bacteria. As a *Wall Street Journal* editorial stated, "the preservative … was so safe and uncontroversial that nobody even noticed it for 60 years." *The Truth About Thimerosal*, WALL ST. J., Dec. 5, 2002, A18. Its safety has been confirmed by studies released in 2002 by the World Health Organization's Global Advisory Committee on Vaccine Safety and the University of Rochester Medical Center.

By 1999, researchers realized the rise in childhood vaccinations overall meant that, theoretically, the thimerosal combined from all vaccinations could slightly exceed a very low EPA mercury guideline. While U.S. public health agencies knew in 1999 that thimerosal posed little risk to children, they were concerned that anti-vaccine groups would use this information to scare parents away from immunizations. *See id.* They

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recommended that manufacturers immediately remove the preservative. "We took it out precipitously, which made it look like thimerosal is harmful — when there is no evidence it is. I think we hurt the public trust," Paul Offit, a member of the Advisory Committee on Immunization Practices, told *The Wall Street Journal*. *See id*.

Fanned by the financial interests of personal injury lawyers and anti-vaccine groups, plaintiffs began charging that thimerosal in childhood vaccines caused autism and related problems. No credible scientific causal link has been established between thimerosal and autism or related adverse reactions in vaccines. But claiming injuries from a vaccine *ingredient* gives contingency fee personal injury lawyers a way to try to create a legal loophole to avoid the National Vaccine Compensation Injury Program ("VICP"). VICP sets forth the rules that govern claims for injuries that may arise from childhood vaccines.

The National Vaccine Injury Compensation Program. Led by Congressman Henry Waxman, Congress created childhood vaccine litigation management rules in the National Childhood Vaccine Injury Act of 1986, 42 U.S.C.A. §§ 300aa-10 *et seq*. ("Vaccine Act"). Congress recognized that excessive lawsuits were preventing truly injured persons from receiving a prompt and fair recovery for vaccine-related injuries. The lawsuits also discouraged companies from researching, developing and distributing new vaccines. Congressman Waxman, a noted health care expert and then chair of the Commerce Committee's Subcommittee on Health, worked to balance the interests of injured persons in gaining a timely and fair recovery with the need to create a stable vaccine market.

Any medical procedure, pharmaceutical product, or vaccine may have adverse health risks. Potential liability may occur if these risks manifest themselves. But of all pharmaceutical products, vaccines are easy targets for lawsuits. Vaccines are generally administered to healthy people. If a person is vaccinated and then develops a health problem of unknown cause, the illness almost always is blamed on the vaccine. Congress appreciated this liability nightmare. Through the Vaccine Act in 1986, Congress met two basic concerns: "the inadequacy — from both the perspective of vaccine-injured persons as well as vaccine manufacturers — of the current approach to compensating those who have been damaged by a vaccine; and … the instability and unpredictability of the childhood vaccine market." H.R. REP. NO. 99-908, at 7, *reprinted in* 1986 U.S.C.C.A.N. 6344, 6348. Lawmakers sought to create a system where awards could be made "quickly, easily, and with certainty and generosity." *Id.* at 3, *reprinted in* 1986 U.S.C.C.A.N. 6344, 6344.

The Vaccine Act created VICP, a no-fault administrative program to give people injured by childhood vaccines a way to obtain prompt and fair compensation without the delay and expense of the traditional tort system. Under VICP, most claims for injuries from childhood vaccines must be filed with the U.S. Court of Federal Claims to be adjudicated by a special master. The government is the defendant, not the vaccine manufacturers. Damages are paid from a fund created by a tax on all vaccines. Claimants can recover unlimited medical expenses, reasonable attorney's fees, and up to $250,000 for pain and suffering. Punitive damages are not allowed. Last year, the average award from VICP exceeded $1 million.

Requiring claimants to first file their claims in VICP does not deprive them of their right to a civil suit. Claimants unhappy with their VICP recovery can reject the award and then proceed in state or federal court — and attempt to recover punitive damages. Fifteen years of experience reveals that most claimants are satisfied with their recoveries and do not choose to proceed to a lawsuit. For that reason, it is understandable that contingency fee personal injury lawyers have tried to circumvent VICP. They prefer to share in a large punitive damages award or punitive damages-driven settlement that may be available through the tort system.

Plaintiffs' lawyers have tried to avoid VICP by arguing the Vaccine Act's language creates a legal loophole. The Act defines "vaccine-related injury" subject to VICP as "an illness, injury condition or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine." Neither the statute nor its legislative history expressly defines "adulterant," "contaminant," or "vaccine." Plaintiffs' lawyers argue the thimerosal preservative was an "adulterant" or "contaminant" and that claims alleging harm from thimerosal are excluded specifically by the Vaccine Act's definition of "vaccine-related injury." This argument has flopped in every court that has considered it. As one court said, "every

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federal court to have ruled on the issue has held that injuries resulting from Thimerosal contained in vaccines are vaccine-related under the meaning of the Act." *Bertrand v. Aventis Pasteur, Lbs., Inc.*, 226 F. Supp. 2d 1206, 1213 (D. Ariz. 2002).

Still, the four manufacturers of children's vaccines, as well as pediatricians and other health care providers, are facing more than 190 individual and class action lawsuits with millions of plaintiffs alleging potential thimerosal-related injuries. *See* Letter from Elizabeth J. Noyes, Chair of the Advisory Commission on Childhood Vaccines, to Tommy G. Thompson, Secretary of the U.S. Department of Health and Human Services (Dec. 6, 2002). The lawsuits allege the preservative causes such health disorders as autism, attention deficit disorders, and learning disorders. There is no credible scientific evidence to support these allegations, but experts can always be paid to proffer an opinion. While most judges reject such "junk science" testimony, these experts sometimes find a welcome home in so-called "judicial hellhole" jurisdictions. In these jurisdictions, the rule of law may not be equally applied to out-of-state corporate defendants. *See* American Tort Reform Association, *Bringing Justice to Judicial Hellholes* (2002). If the vaccine ingredient provision is removed from the Act, forum-shopping of thimerosal lawsuits in these jurisdictions will increase and the potential for high defense costs, liability and huge punitive damages awards will increase with it.

The potential liability exposure and defense costs in these cases can crush the companies that made thimerosal. These companies must remain viable to continue making products that help Americans stay healthy. *See* Government Accounting Office, *Childhood Vaccines: Ensuring an Adequate Supply Poses Continuing Challenges* (Sept. 2002) (identifying liability concerns and defense costs as one factor leading to vaccine shortages and the need to improve vaccine stockpiles to protect against future shortages). To help protect our country's resources, especially if there are bioterrorism attacks perpetrated against the Nation, Congress recognized that the Homeland Security Act of 2002 should clarify the original intent of Congress in 1986: to prevent excessive liability in thimerosal cases from destroying segments of the pharmaceutical industry.

The Vaccine Ingredient Clarification. The vaccine ingredient provision provides that lawsuits against manufacturers of vaccine ingredients are first required to go through VICP, just like any childhood vaccine claim. The provision clarifies the Vaccine Act's definitions of "vaccine manufacturer" and "vaccine-related injury," and adds the definition of a "vaccine." *See* Pub. L. No. 107-206, §§ 1714-1716. Claimants still can choose to file suit later if they are displeased with their administrative recovery, as long as a statute of limitations problem is addressed.[2]

The Act's clarification of congressional intent is supported by the Advisory Commission on Childhood Vaccines ("ACCV"), which is authorized to advise the HHS Secretary on the implementation of the vaccine program. In a December 6 letter to HHS Secretary Thompson, ACCV said the panel had reviewed the "vaccine ingredient" clarification as enacted, and had "renewed its support." Describing the thimerosal lawsuits as a "disturbing new trend in civil litigation" that will "result[] in unneeded and expensive litigation costs and plac[e] the stability of the childhood immunization program at risk,"the letter said: "Thimerosal, as you know, is approved for use by the Food and Drug Administration and is part of the vaccine formulation when licensed; hence clarification is needed to direct these claims to the VICP before civil action can be pursued." The American Association of Pediatrics also supported clarifying that vaccine ingredient claims belong under VICP. *See* Letter from Louis Z. Cooper, President, American Academy of Pediatrics, to Sen. Bill Frist (July 19, 2002).

Most courts already refer thimerosal cases to VICP.[3] These courts often look to the "plain meaning" and intent of the statute or the ordinary definitions of the terms "adulterant" and "contaminant." As the U.S. Court of Federal Claims recently explained, "a preservative is not an intentionally added ingredient of the vaccine meant to make impure, inferior, or contaminated the vaccine end product. Rather, a preservative is the antithesis of these descriptions, as it actually prevents corruption of the vaccine." *Leroy v. Sec'y of Health and Human Servs.*, 2002 WL 31730680, *5 (Fed. Ct. Cl. Oct. 11, 2002). The thimerosal cases are in accord with other cases involving claims of injury from a vaccine component.[4]

The Vaccine Clarification Provision Serves Homeland Security. Some of the provision's detractors in the Senate argued it had nothing to do with homeland security. This assertion is unfounded.

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The provision is critical to homeland security. In the floor debate, newly elected Senate Majority Leader Dr. Bill Frist, the only practicing doctor in the Senate, explained the use of bioterrorism as a weapon of mass destruction is new to the American people. Twelve countries have offensive biological weapons programs. Vaccines are "absolutely important" as a front line of defense to bioterrorism and must be addressed in measures to protect homeland security. While government organizations such as the National Institutes of Health are conducting research, as Sen. Frist said, "unless we have manufacturers in the field manufacturing vaccines, we can have the greatest research in the world and know how to do it, but unless we can produce it and produce it quickly, the know-how does not do us any good." 148 Cong. Rec. S11169-01, S11177 (Nov. 15, 2002).

Clarifying that VICP covers the pharmaceutical companies that manufacture vaccine ingredients will help reduce their excessive liability exposure and their legal costs, and help preserve their ability to manufacture vaccines needed to protect against bioterrorism. Otherwise, contingency fee personal injury lawyers who desire to proceed outside VICP will keep seeking judicial forums where they can successfully sue the manufacturers of vaccine components. If they are successful, it will cumulate in the disappearance of vaccine manufacturers. As Sen. Frist said, "Then who is going to make the vaccine for the Ebola virus, which our Federal Government, through intelligence, has identified as one of the six agents of which we are at risk? … The threat of liability should not become a barrier to the protection of the American people." *Id.* at S11178, S11176.

Conclusion. The vaccine ingredient provision should remain in the law. It will allow a quick no-fault recovery for persons who have a disease caused by vaccines. It will also combat excessive, unwarranted litigation that diverts companies' resources away from the development of vaccines and other products that help preserve the health and safety of Americans in both peacetime and when preparing defenses against bioterrorist attacks. The controversy generated by the provision's political opponents is a smokescreen to hide their pecuniary interests — that their personal injury lawyer allies and supporters will lose opportunities for windfall fees if this provision remains good law. Logic, public policy and common sense all support the vaccine ingredient provision.

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1. The Kansas City, Mo., office of Shook, Hardy & Bacon L.L.P. has been retained to represent Eli Lilly & Co. in the thimerosal litigation. The authors of this article have not worked on or participated in this litigation. Neither the authors nor Shook, Hardy & Bacon were part of any lobbying effort to have the vaccine ingredient provision placed in the Homeland Security Act of 2002.

2. VICP has a three-year period to bring vaccine claims; some plaintiffs are worried that if they cannot pursue their lawsuits they will be too late to file a claim with VICP. Congressional leaders already have said they plan to fix the limitations problem in the next Congress.

3. Even before the vaccine ingredient provision was signed into law, courts granted motions to dismiss by thimerosal manufacturers in other vaccine-related injury cases. *See e.g.*, *Collins v. Am. Home Prods. Corp.*, No. 3:01CD979LM (S.D. Miss. Aug. 2, 2002); *Holder v. Abbott Labs., Inc.*, No. 4:02CV148LN (S.D. Miss. Oct. 15, 2002); *Wax v. Aventis Pasteur, Inc.*, CV 02-2018 (JBW) (E.D.N.Y. Dec. 16, 2002); *Radulovic v. Am. Home Prods. Corp.*, No. 02-05033 (Fla. Cir. Ct. Nov. 19, 2002); *Liu v. Aventis Pasteur*, 219 F. Supp. 2d 762 (W.D. Tex. Aug. 23, 2002); *Russak v. Aventis Pasteur,* No. A-02-CA-480-SS (W.D. Tex. Sept. 9, 2002); *Carabine v. Aventis Pasteur*, No. A-02-501-SS (W.D. Tex. Oct. 8, 2002).

4. *See*, *e.g.*, *Grant v. Sec'y of Health and Human Servs.*, 956 F.2d 1144, 1149-50 (Fed. Cir.1992). The Department of Health and Human Services says that plaintiffs in thimerosal-related cases "must first file the claim with the VICP before pursuing any other civil litigation." *Commonly Asked Questions About The National Vaccine Injury Compensation Program*, *available at* http://www.hrsa.gov/osp/vicp/qanda.htm.

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