

## Pesticides, Children's Health Policy, and Common Law Tort Claims

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## I. INTRODUCTION

Every year, hundreds of thousands of children are exposed to harmful pesticides, resulting in acute injury and even death, and contributing to longer-term chronic diseases and disabilities, which can include neurological disorders, reproductive problems, developmental delays, and cancer.<sup>1</sup> Until recently, however, the United States had nothing in its pesticide laws that addressed issues specific to children's health, and very little data was available regarding the unique impacts of pesticides on children. In 1996, Congress passed the Food Quality Protection Act of 1996 (FQPA),<sup>2</sup> which directs the Environmental Protection Agency (EPA) to apply a presumptive, additional tenfold margin of safety in setting pesticide residue tolerances on food to take into account toxicity and exposure of pesticides to infants and children. This law, arguably the first environmental law to require that issues specific to children's health be considered in setting environmental risk standards, resulted in a flurry of scholarly writing, ranging from hope to skepticism, as the scientific and regulatory aspects of the law were debated.<sup>3</sup>

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1. JOHN WARGO, OUR CHILDREN'S TOXIC LEGACY: HOW SCIENCE AND LAW FAIL TO PROTECT US FROM PESTICIDES 178 (1996) (stating that "[b]etween 1 and 3 million people, many of them children, are poisoned by pesticides in the world each year, and at least 168 different pesticide compounds are known to have caused significant human illness or death"); Bruce P. Lanphear, Charles V. Vorhees & David C. Bellinger, *Protecting Children from Environmental Toxins: Toxicity Testing of Pesticides and Industrial Chemicals Is a Crucial Step*, 2 PLOS MEDICINE 203, 203-04 (2005), available at [http://medicine.plosjournals.org/archive/1549-1676/2/3/pdf/10.1371\\_journal.pmed.0020061-L.pdf](http://medicine.plosjournals.org/archive/1549-1676/2/3/pdf/10.1371_journal.pmed.0020061-L.pdf).

2. Pub. L. No. 104-170, 110 Stat. 1489 (1996).

3. See, e.g., Frank B. Cross, *The Consequences of Consensus: Dangerous Compromises of the Food Quality Protection Act*, 75 WASH. U. L.Q. 1155 (1997) (arguing that FQPA continues overregulation of pesticide residues on food); Keith Cunningham-Parmeter, *A Poisoned Field: Farmworkers, Pesticide Exposure, and Tort Recovery in an Era of Regulatory Failure*, 28 N.Y.U. REV. L. & SOC. CHANGE 431 (2003) (analyzing the administrative state's failure to protect farmworkers from pesticides and how tort actions can catalyze improved field protections while compensating victims); Steven Geoffrey Gieseler, *On a Viable and Effective Future for the Food Quality Protection Act*, 9 ALB. L. ENVTL. OUTLOOK 345 (2004) (detailing history of FQPA and current scientific methodology under the law and providing suggestions to improve the law's implementation); Thomas O. McGarity, *Politics by Other Means: Law, Science, and Policy in EPA's Implementation of the Food Quality Protection Act*, 53 ADMIN. L. REV. 103 (2001) (discussing science and policy issues necessary to implement the FQPA's focus on risks to children and reasons why EPA has been unable to fulfill the law's mandates); Linda-Jo Schierow,

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Nearly ten years later, however, much of the law's promise remains unfulfilled as EPA has often failed to set pesticide tolerances with margins of safety that are sufficiently protective of children and failed to require manufacturers to conduct adequate tests to determine specific impacts of pesticides on children.<sup>4</sup> The purpose of this Article is to explore the extent to which state common law tort claims can act as a gap-filler to increase protection for children from harmful pesticides. Unlike a state or federal agency, which can delay action on a legal or technical issue for years as a result of scarce resources, limited data, alternate priorities, or political pressure, judges must decide the cases before them based on the available evidence within a discrete (and relatively short)

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*Pesticide Residue Regulation: Analysis of Food Quality Protection Act Implementation*, 10 RISK 281 (1999) (evaluating the status of FQPA implementation and concluding that EPA is making progress but contentious implementation issues remain unresolved); James Smart, *All the Stars in the Heavens Were in the Right Places: The Passage of the Food Quality Protection Act of 1996*, 17 STAN. ENVTL. L.J. 273 (1998) (detailing history of passage of FQPA); Valerie Watnick, *Risk Assessment: Obfuscation of Policy Decisions in Pesticide Regulation and the EPA's Dismantling of the Food Quality Protection Act's Safeguards for Children*, 31 ARIZ. ST. L.J. 1315 (1999) (arguing that EPA has failed to implement many of the FQPA's protections for children); Scott Douglas Bauer, Note, *The Food Quality Protection Act of 1996: Replacing Old Impracticalities with New Uncertainties in Pesticide Regulation*, 75 N.C. L. REV. 1369 (1997) (discussing uncertainties involved in assessing risk and benefits under FQPA); Andrew J. Miller, Note, *The Food Quality Protection Act of 1996: Science and Law at a Crossroads*, 7 DUKE ENVTL. L. & POL'Y F. 393 (1997) (describing difficult task for EPA in utilizing science to set new pesticide risk assessments); Jennifer C. Miner, Comment, *Do Environmental Laws Adequately Protect Children's Environmental Health? A Review of Existing Laws, Potential Legislation and Policy Considerations*, 78 OR. L. REV. 1101 (1999) (evaluating children's special environmental vulnerabilities and current and potential laws to address them); Michael Schon, Comment, *Susceptible Children: Why the EPA's New Risk Assessment Guidelines for Children Fail to Protect America's Future*, 36 ARIZ. ST. L.J. 701 (2004) (arguing that EPA's risk assessment guidelines do not sufficiently protect children).

4. See, e.g., DAVID WALLINGA, NATURAL RES. DEF. COUNCIL, PUTTING CHILDREN FIRST: MAKING PESTICIDE LEVELS IN FOOD SAFER FOR INFANTS AND CHILDREN 61-62 (1998) (discussing EPA failure to require data on neurotoxicity risks in pesticide registration process despite availability of validated testing protocols); Watnick, *supra* note 3, at 1341-43 (stating how EPA has failed to review the riskiest pesticide tolerances under the FQPA by the statutory deadline, has not routinely or consistently applied the tenfold safety factor to protect children in setting pesticide tolerances, and has not required pesticide registrants to test for a broad range of toxic effects in adults or children); Schon, *supra* note 3, at 720-23 (arguing that EPA guidelines for assessing cancer risks to children from pesticides do not fulfill the child protection mandates in the FQPA).

period of time. This Article concludes that the Supreme Court's 2005 decision in *Bates v. Dow Agrosciences LLC*,<sup>5</sup> which significantly limits the scope of federal preemption of common law tort claims against pesticide manufacturers, creates a significant opportunity for such claims to play an increasing role in pesticide policy with regard to children's health. Such claims can do so by spurring the collection and effective use of scientific data in this area.

In order to realize this opportunity, this Article proposes that courts apply a modified scientific evidence standard and then shift the burden of proof to pesticide manufacturer defendants in cases in which the plaintiff can establish that the defendant failed to conduct reasonably available testing to gather currently unavailable scientific evidence on the issue of causation. This Article posits that such a modification of current evidentiary standards under the common law can be justified not only on the precautionary principle inherent in the FQPA itself, but on the power of common law courts to shape tort law to reflect the complexities of risk in today's society.

Section II of this Article presents a brief summary of federal pesticide law and the enactment of the FQPA. Section III evaluates cases involving pesticides and children's health in the context of claims against EPA and other regulatory agencies, as well as claims against pesticide manufacturers and sprayers. Section IV explains why the Supreme Court's recent decision in *Bates* makes lawsuits against manufacturers based on negligent testing and negligent design theories an increasingly powerful tool in spurring manufacturers to gather scientific data and provide additional protections for children. Moreover, this Section proposes that courts look to the precautionary principle embodied in the FQPA, and rely on their inherent powers to shape tort law, to modify the evidentiary burden for plaintiffs in pesticide cases where scientific uncertainty reasonably attributable to manufacturers would otherwise pose a virtually insurmountable barrier to relief.

## II. PESTICIDE REGULATION FROM FIFRA TO FQPA

In 2000 and 2001, nearly five billion pounds of pesticides were used annually in the United States on homes, farms,

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5. 125 S. Ct. 1788 (2005).

gardens and for industrial applications.<sup>6</sup> Despite the widespread use of pesticides in nearly every sector of society, there is increasingly strong evidence that pesticides have had and continue to have adverse and pervasive effects on human health and the environment. Rachel Carson's 1962 book, *Silent Spring*,<sup>7</sup> along with targeted lawsuits to ban the pesticide DDT,<sup>8</sup> played a significant role<sup>9</sup> in prompting Congress to overhaul the existing federal pesticide law through the 1972 Amendments to the Federal Insecticide, Fungicide and

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6. TIMOTHY KIELY, DAVID DONALDSON & ARTHUR GRUBE, U.S. ENVTL. PROT. AGENCY, PESTICIDES INDUSTRY SALES AND USAGE: 2000 AND 2001 MARKET ESTIMATES 10 (2004).

7. RACHEL CARSON, *SILENT SPRING* (1962).

8. See Marshall Lee Miller, *Pesticides*, in ENVIRONMENTAL LAW HANDBOOK 645, 647 (Gov't Inst. 17th ed. 2003); see also Environmental Def. Fund v. Env'tl. Prot. Agency, 489 F.2d 1247 (D.C. Cir. 1973) (dismissing action challenging EPA's suspension of DDT use); Environmental Def. Fund v. Env'tl. Prot. Agency, 465 F.2d 528 (D.C. Cir. 1972) (remanding EPA decision not to suspend aldrin and dieldrin for consideration of additional scientific evidence); Environmental Def. Fund v. Ruckelshaus, 439 F.2d 584 (D.C. Cir. 1971) (requiring EPA Administrator to commence administrative proceedings to determine whether DDT registration should be canceled in the face of evidence concerning safety); Environmental Def. Fund v. Hardin, 428 F.2d 1093 (D.C. Cir. 1970) (holding environmental groups had standing to challenge Secretary of Agriculture's failure to take prompt action on request for DDT suspension); Environmental Def. Fund v. United States Dep't of Health, Educ. & Welfare, 428 F.2d 1083 (D.C. Cir. 1970) (holding action on petitioners' proposal to establish zero tolerance level for DDT residues on raw agricultural commodities did not have to await action by Department of Agriculture); THOMAS R. DUNLAP, DDT: SCIENTISTS, CITIZENS, AND PUBLIC POLICY 231-38 (1981) (discussing lawsuits); WARGO, *supra* note 1, at 87-88 (same); Andrew P. Morriss & Roger E. Meiners, *Property Rights, Pesticides, and Public Health: Explaining the Paradox of Modern Pesticide Policy*, 14 FORDHAM ENVTL. L.J. 1, 24-25 (2002) (detailing lawsuits against the Department of Agriculture and EPA).

9. See CHRISTOPHER J. BOSSO, PESTICIDES AND POLITICS: THE LIFE CYCLE OF A PUBLIC ISSUE 154-58 (1987) (recounting litigation and policy battles over DDT); DUNLAP, *supra* note 8, at 129-245 (same); Angus A. MacIntyre, *Why Pesticides Received Extensive Use in America: A Political Economy of Agricultural Pest Management to 1970*, 27 NAT. RESOURCES J. 533, 572-73 (1987) (detailing political, social, and legal activities leading up to the banning of DDT); *Toward a Noisier Spring: D.C. Circuit Upholds Cancellation of DDT Registrations*, 4 Env'tl. L. Rep. (Env'tl. Law Inst.) 10,013 (1974) (detailing litigation and political fight leading up to decision by the D.C. Circuit Court of Appeals affirming EPA's cancellation of DDT). By the late 1960s, estimates were that one billion pounds of DDT were circulating throughout the world's air and water; traces of DDT were found in birds and wildlife from Antarctica to the mid-Pacific Ocean, as well as in the body tissues and food supply of humans throughout the world. 3 WILLIAM H. RODGERS, JR., ENVIRONMENTAL LAW: PESTICIDES AND TOXIC SUBSTANCES § 5.1, at 12 (1988).

Rodenticide Act (FIFRA).<sup>10</sup>

#### A. FIFRA AND COST-BENEFIT ANALYSIS

FIFRA's primary provisions create and administer a federal, uniform system of registering pesticides. A pesticide cannot be distributed, sold, or used until it is registered and approved by EPA.<sup>11</sup> The EPA Administrator approves the registration based on its composition, labeling, and whether "it will perform its intended function without unreasonable adverse effects on the environment."<sup>12</sup> FIFRA defines "unreasonable adverse effects on the environment" as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."<sup>13</sup>

Thus, EPA's major policy function under FIFRA is to balance the pesticide's risks to human health and the environment against the potential benefits flowing from its use.<sup>14</sup> As a result, cost-benefit analysis is a central part of FIFRA's regulatory framework.<sup>15</sup> Although FIFRA provides for civil and criminal penalties for violation of the law's requirements,<sup>16</sup> it does not contain a private right of action.<sup>17</sup>

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10. Pub. L. No. 92-516, 86 Stat. 973 (1972) (codified at 7 U.S.C. §§ 136-136y (2000)). For judicial treatment of FIFRA's evolution, see, for example, *Wisconsin Pub. Intervenor v. Mortier*, 501 U.S. 597, 601-02 (1991); and *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 992 (1984).

11. See 7 U.S.C. § 136a(a) (2000). For a more detailed description of federal pesticide regulation, see Alexandra B. Klass, *Bees, Trees, Preemption and Nuisance: A New Path to Resolving Pesticide Land Use Disputes*, 32 *ECOLOGY L.Q.* (forthcoming 2005).

12. 7 U.S.C. § 136a(c)(5).

13. 7 U.S.C. § 136(bb) (2000).

14. See *Miller*, *supra* note 8, at 653.

15. See, e.g., *Washington Toxics Coal. v. Env'tl. Prot. Agency*, 413 F.3d 1024, 1032 (9th Cir. 2005) (stating that "FIFRA's objective is to protect human health and prevent environmental harm from pesticides through a cost-benefit analysis of the pesticides"); *Headwaters, Inc. v. Talent Irrigation Dist.*, 243 F.3d 526, 532 (9th Cir. 2001) (stating that "FIFRA registration is a cost-benefit analysis that no unreasonable risk exists to man or the environment" weighing the economic, social, and environmental costs and benefits of the pesticide use (citing *Save Our Ecosystems v. Clark*, 747 F.2d 1240, 1248 (9th Cir. 1984))); see also DANIEL A. FARBER, *ECO-PRAGMATISM: MAKING SENSIBLE ENVIRONMENTAL DECISIONS IN AN UNCERTAIN WORLD* 103 & n.16 (1999) (describing FIFRA as one of the only federal environmental statutes that provides for open-ended cost-benefit analysis as opposed to the vast majority of other environmental statutes that establish a "pro-environmental baseline").

16. See 7 U.S.C. § 136l(a), (b) (2000).

17. See, e.g., *Bates v. Dow Agrosciences, LLC*, 125 S. Ct. 1788, 1801 (2005)

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This omission compromises optimal enforcement of federal pesticide law through private attorney general suits and limits the law's ability to provide compensation for damages and deter improper pesticide registration and use.

While FIFRA allows states to regulate the sale or use of any federally registered pesticide,<sup>18</sup> it prohibits state involvement in pesticide labeling. In a section entitled "Uniformity," FIFRA provides that a state "shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter."<sup>19</sup> The question of which state actions (whether actions by state agencies, jury verdicts, or judicial decisions) are (or should be) subject to federal preemption under this provision is significant in creating the boundaries within which litigants may use the courts to spur policy changes and data gathering through common law claims for damages arising from pesticides.

#### B. THE FQPA AND THE PRECAUTIONARY PRINCIPLE

The FQPA of 1996 represents the most recent iteration of Congress's efforts to reconcile regulation of pesticides and control of pesticide residues on food. In doing so, the FQPA also created one of the first environmental laws that specifically addressed the needs of children. Before turning to the child-specific provisions of the law, the history leading up to the enactment of the FQPA helps place the law in its appropriate context.

As detailed above, all pesticides are registered and regulated under FIFRA as administered by the EPA. However, EPA regulates allowable levels of pesticide residues on food under a separate law—the Federal Food, Drug, and Cosmetic

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(noting that FIFRA does not provide a federal remedy for persons injured as a result of a manufacturer's violation of FIFRA's labeling requirements); *No Spray Coalition, Inc. v. City of New York*, 351 F.3d 602, 605 (2d Cir. 2003) (discussing absence of private right of action in FIFRA).

18. 7 U.S.C. § 136v(a) (2000).

19. 7 U.S.C. § 136v(b). By contrast, states may impose additional requirements relating to the sale or use of pesticides. *See, e.g.*, *National Bank of Commerce v. Dow Chem. Co.*, 165 F.3d 602, 608 (8th Cir. 1999) (stating that FIFRA strikes a balance between state and federal control and "leaves ample room" for state regulation (citing *Wisconsin Pub. Intervenor v. Mortier*, 501 U.S. 597, 613 (1991))); *Lowe v. Sporicidin Int'l*, 47 F.3d 124, 128 (4th Cir. 1995) (holding that while FIFRA preempts a state's imposition of additional labeling requirements, "it does not preempt a state's authority to monitor compliance with labeling or other requirements imposed by FIFRA").

Act (FFDCA).<sup>20</sup> Under the FFDCA, EPA is responsible for setting the maximum allowable safe levels of a substance in or on a food (called a “tolerance”) while the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) are responsible for enforcing those tolerances.<sup>21</sup> Under FIFRA, EPA will not register a pesticide until the applicant has obtained the necessary tolerances or exemptions in accordance with the FFDCA.<sup>22</sup>

The Food Quality Protection Act of 1996 came about in large part as a compromise to address the so-called “Delaney Paradox,” created by the Delaney Amendment to the FFDCA, which set a zero tolerance for carcinogenic pesticides in processed foods.<sup>23</sup> The “paradox” resulted because in effect the law prohibited any carcinogenic substance in processed foods, even if it posed only a *de minimis* risk, while allowing the same substance to be present in raw foods.<sup>24</sup>

The FQPA repealed the Delaney clause and contains, for the first time, provisions specifically designed to protect the health of infants and children.<sup>25</sup> This new focus on the impacts of pesticides on infants and children was more than justified and deserves attention.

In 1993, after several years of study, the National Academy of Sciences (NAS) released a report entitled *Pesticides in the Diets of Infants and Children*,<sup>26</sup> on the subject of whether pesticides posed special risks to children because of heavier exposure and greater susceptibility to the toxic effects of such

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20. 21 U.S.C. §§ 301-395 (2000).

21. See Miller, *supra* note 8, at 697-98.

22. See 40 C.F.R. § 152.112(g) (2004); Linda J. Fisher et al., *A Practitioner’s Guide to the Federal Insecticide, Fungicide, and Rodenticide Act: Part III*, 24 *Envtl. L. Rep. (Envtl. Law Inst.)* 10,629, 10,646 (1994). The EPA Administrator has authority under section 408 of the FFDCA to issue “exemptions” for pesticides for which a tolerance is unnecessary to protect public health. See Miller, *supra* note 8, at 697-98.

23. Compare 21 U.S.C. § 348(c)(3)(A) (1994) (setting “zero tolerance” standard for carcinogenic pesticides in processed foods), and 21 U.S.C. § 346a(b)(2)(A)(ii) (2000) (defining “safe” with respect to a tolerance for a pesticide chemical residue), with Fisher et al., *supra* note 22, at 10,648-49, Miller, *supra* note 8, at 693-95, and RODGERS, *supra* note 9, § 5.22, at 282-88.

24. See Watnick, *supra* note 3, at 1324-26.

25. See *id.* at 1329-31.

26. COMMITTEE ON PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN, NAT’L RESEARCH COUNCIL, *PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN* (1993).



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chemicals.<sup>27</sup> The NAS study, along with subsequent research, supports the conclusion that infants and children are indeed more vulnerable to health damage from pesticides. This is because the dietary diversity of children is extremely low and they are more vulnerable to the effects of toxic chemicals as their cells and organs develop. Also, pound for pound, children breathe, eat, and drink more than adults, and engage in activities closer to the ground where pesticide residues in air, dirt, and on floors are often the greatest.<sup>28</sup>

However, the NAS study concluded that insufficient data on children's food consumption and pesticide toxicity prevented them from determining a precise level of increased risk to children posed by pesticides.<sup>29</sup> The NAS study's authors recommended that an additional child-specific uncertainty factor be used routinely in setting pesticide tolerances whenever toxicity data was incomplete to account for potential vulnerability in children.<sup>30</sup> It was these and other findings that led to several key provisions of the FQPA.<sup>31</sup>

The FQPA requires EPA to quantitatively assess the risks of a pesticide residue and the potential for aggregate exposure and use an additional tenfold margin of safety when setting pesticide tolerances unless reliable data suggests some other margin will be safe for infants and children.<sup>32</sup> As EPA

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27. See *id.* at 267-363; WARGO, *supra* note 1, at 10-11.

28. See NATURAL RES. DEF. COUNCIL, TROUBLE ON THE FARM: GROWING UP WITH PESTICIDES IN AGRICULTURAL COMMUNITIES, ch. 2 (1998), <http://www.nrdc.org/health/kids/farm/farminx.asp>; WALLINGA, *supra* note 4, at 1; WARGO, *supra* note 1, at 10-13; Denise Koch et al., *Temporal Association of Children's Pesticide Exposure and Agricultural Spraying: Report of a Longitudinal Biological Monitoring Study*, 110 ENVTL. HEALTH PERSP. 829, 829 (2002) (stating that children may be more susceptible to the effects of pesticides than adults and finding that pesticide spraying in agricultural regions can increase children's exposure in the absence of parental work contact with pesticides or residential proximity to pesticide-treated farmland), available at <http://ehp.niehs.nih.gov/members/2002/110p829-833koch/EHP110p829PDF.PDF>; Lanphear, *supra* note 1, at 203-04.

29. See COMMITTEE ON PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN, *supra* note 26, at 360-63; WARGO, *supra* note 1, at 12.

30. COMMITTEE ON PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN, *supra* note 26, at 361.

31. See Watnick, *supra* note 3, at 1324-32 (detailing legislative history of FQPA).

32. See 21 U.S.C. § 346a(b)(vi) (2000); Watnick, *supra* note 3, at 1342 (citing OFFICE OF PREVENTION, EPA, 10X SAFETY FACTOR SHEET, PESTICIDES AND TOXIC SUBSTANCES 1 (1999)); U.S. ENVTL. PROT. AGENCY, FACT SHEET: PROTECTING CHILDREN FROM PESTICIDES (Jan. 2002), <http://www.epa.gov/pesticides/factsheets/kidpesticide.htm> (discussing FQPA's

generally uses a hundred-fold margin of safety, this results in potentially multiplying that margin by an additional factor of ten when there is evidence of developmental toxicity or when exposure data is incomplete.<sup>33</sup> Moreover, in assessing the risk of the pesticide chemical residue, the FQPA directs EPA to consider: (1) information about consumption patterns of infants and children that are likely to result in disproportionately high consumption of foods containing pesticide residues in comparison to the general population, (2) special susceptibility of infants and children to pesticide residues, (3) information concerning cumulative effects on infants and children of substances that have a common mechanism of toxicity, (4) information to ensure a reasonable certainty of no harm to infants and children from aggregate exposure to pesticide residues, and (5) other relevant factors relating to data, toxicity, dietary consumption patterns, and information “concerning the variability of the sensitivities of major identifiable subgroups of consumers.”<sup>34</sup>

If nothing else, the FQPA is significant in that it is one of the only examples of environmental legislation that contains specific provisions for the protection of infants and children.<sup>35</sup>

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requirement of an additional safety factor for children in setting pesticide residue standards).

33. See Watnick, *supra* note 3, at 1339. For a discussion of the tenfold safety factors, see OFFICE OF PESTICIDE PROGRAMS, U.S. ENVTL. PROT. AGENCY, DETERMINATION OF THE APPROPRIATE FQPA SAFETY FACTOR(S) IN TOLERANCE ASSESSMENT A-3 (Feb. 2002). Some argue that EPA policy documents and practice have reversed the burden of proof in some instances and failed to impose one or more of the safety factors in the face of data uncertainty. See Natural Res. Def. Council, Re: Draft Science Policy Document, “Consideration of the FQPA Safety Factor and Other Uncertainty Factors in Cumulative Risk Assessment of Chemicals Sharing a Common Mechanism of Toxicity,” Docket No. OPP-00759 (April 29, 2002) at 3-4 [hereinafter NRDC Comments]; see also OFFICE OF PESTICIDE PROGRAMS, U.S. ENVTL. PROT. AGENCY, CONSIDERATION OF THE FQPA SAFETY FACTOR AND OTHER UNCERTAINTY FACTORS IN CUMULATIVE RISK ASSESSMENT OF CHEMICALS SHARING A COMMON MECHANISM OF TOXICITY 10 (Draft, Feb. 28, 2002) (stating that the absence of data on common mechanism toxicity does not automatically warrant the application of an uncertainty or safety factor, but that risk assessors should evaluate the overall value of the missing study); WALLINGA, *supra* note 4, at 42 (stating that EPA typically has not imposed the FQPA safety factor in setting pesticide tolerances and questioning what the EPA considers “reliable data” to justify departure from the presumptive safety factor).

34. See 21 U.S.C. § 346a(b)(2)(C)-(D) (2000).

35. See David E. Adelman, *The False Promise of the Genomics Revolution for Environmental Law*, 29 HARV. ENVTL. L. REV. 117, 138 (2005) (noting that “[t]he FQPA is arguably the first environmental statute that addresses

Moreover, the law's provisions relating to children rely much more heavily on the "precautionary principle" than cost-benefit analysis. The precautionary principle is an approach to regulation, used widely today in European nations, which states that if an activity might threaten human health or the environment, precautionary measures should be taken even if some of the cause-and-effect relationships are not fully established scientifically.<sup>36</sup>

By contrast, under a cost-benefit analysis, the potential risks of an activity are merely weighed against the potential benefits, and as long as the latter are greater than the former, the activity should be allowed. While cost-benefit analysis is central to the determination of whether to register a pesticide under FIFRA, the FQPA creates an overlay requiring increased margins of safety in order to protect children's health, even in the absence of data showing a causal relationship between the pesticide and harm to children's health.<sup>37</sup> As a result, the FQPA, based on the findings of the NAS study, promotes the precautionary principle over traditional cost-benefit analysis used to register pesticides generally under FIFRA.<sup>38</sup>

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population-wide variation in toxic susceptibilities" in its focus on infants and children).

36. See CASS R. SUNSTEIN, LAWS OF FEAR: BEYOND THE PRECAUTIONARY PRINCIPLE 13-20 (2005) (describing the precautionary principle and arguing that it is incoherent and can lead to paralysis, but that applying a refined version of the precautionary principle in cases where the risk of catastrophic damage exists makes sense); see also FARBER, *supra* note 15, at 6-7, 170-71; CASS R. SUNSTEIN, THE COST-BENEFIT STATE: THE FUTURE OF REGULATORY PROTECTION 6-10, 23-24 (2002); Frank Ackerman & Lisa Heinzerling, *Pricing the Priceless: Cost-Benefit Analysis of Environmental Protection*, 150 U. PA. L. REV. 1553, 1553-84 (2002). The European Union recently proposed a draft regulation on chemicals known as REACH (Registration, Evaluation and Authorisation of Chemicals) that expressly adopts the precautionary principle in restricting the use of a wide range of chemicals used in everything from medicine to farming. Under the proposed regulations, REACH "reverses the burden of proof" by forcing industry to provide evidence on the safe use of their products before they can be marketed rather than forcing government authorities to prove the products are dangerous in order to restrict them. See EUROPEAN TRADE UNION CONFEDERATION, EU CHEMICAL SAFETY PROPOSAL – REACH, June 28, 2005 [hereinafter REACH], available at <http://www.etuc.org/a/496>; see also KEN GEISER & JOEL TICKNER, LOWELL CENTER FOR SUSTAINABLE PRODUCTION, NEW DIRECTIONS IN EUROPEAN CHEMICALS POLICY: DRIVERS, SCOPE, AND STATUS 7 (2003) (discussing history of development and use of the precautionary principle in Europe).

37. See NRDC Comments, *supra* note 33, at 3-4 (arguing that the EPA policy applies a lesser safety factor or no safety factor at all for children in the absence of data justifying the need for the tenfold factor).

38. Other provisions of the FQPA require EPA to reassess the more than

EPA's implementation of the FQPA has been subject to significant criticism, ranging from its failure to review the approximately 10,000 existing pesticide tolerances by 2006 under the new provisions,<sup>39</sup> failure to presumptively apply the tenfold safety factor to protect children,<sup>40</sup> and failure to require manufacturers to test for the broader range of toxic effects in adults and children set forth in the law.<sup>41</sup> Some of these criticisms have led to lawsuits against the Agency discussed later in this Article. A review of these criticisms leads to the conclusion that EPA so far has failed to create an adequate regulatory structure under the FQPA to effectively protect children's health to the full extent available under the law.<sup>42</sup>

However, despite EPA's failure to fully implement the law's precautionary principle with regard to children's health and pesticides, the fact remains that the FQPA on its face rejects a cost-benefit analysis when it comes to pesticide tolerances and their impact on children. While EPA's shortcomings to date do not mean the agency will never use the FQPA to its full potential, this Article explores whether

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9,000 pesticide tolerances and exemptions in existence at the time the new law was enacted to determine whether those tolerances meet the more stringent FQPA standards. *See* 21 U.S.C. § 346a(q) (2000); *American Farm Bureau v. Evtl. Prot. Agency*, 121 F. Supp. 2d 84, 89 (D.D.C. 2000). As amended, the FFDCA sets forth a three-tiered schedule for reassessing existing tolerances and exemptions, and requires that thirty-three percent be reassessed by August 1999, sixty-six percent by August 2002, and 100 percent by August 2006. *See* 21 U.S.C. § 346a(q)(1). EPA is to give priority in the reassessment to those tolerances and exemptions that "appear to pose the greatest risk to public health." 21 U.S.C. § 346a(q)(2). As of February 15, 2005, EPA had reassessed over 7,140 of the 9,728 tolerances for pesticides in existence on August 2, 1996. *See* *Natural Res. Def. Council v. Whitman*, No. C 99-03701 WHA, 2001 WL 1221774, at \*1 (N.D. Cal. Sept. 24, 2001); *Environmental Prot. Agency: Alachlor, Carbaryl, Diazinon, Disulfoton, Pirimiphos-methyl, and Vinclozolin; Proposed Tolerance Revocations*, 70 Fed. Reg. 14,618, 14,621 (Mar. 23, 2005) (to be codified at 40 C.F.R. pt. 180) (stating that EPA had reassessed over 7,140 tolerances as of February 14, 2005). Finally, the law requires EPA to promulgate regulations governing the establishment of tolerances for pesticide uses exempted under FIFRA's emergency provisions within 365 days after enactment of the FQPA. *See* 21 U.S.C. § 346a(l)(6); 7 U.S.C. § 136p (2000).

39. *See* *Whitman*, No. C 99-03701 WHA, 2001 WL 1221774 (N.D. Cal. Sept. 24, 2001).

40. *See* NRDC Comments, *supra* note 33, at 4-5; WALLINGA, *supra* note 4, at 42-43 (criticizing EPA for its failure to routinely use the FQPA tenfold safety factor in setting tolerances).

41. *See, e.g.,* WALLINGA, *supra* note 4, at 47-50; Watnick, *supra* note 3, at 1341-43.

common law claims, particularly claims against pesticide manufacturers that emphasize the policy goals of the FQPA, can act as a gap-filler to spur the creation and effective use of scientific data in this area.

Section III of this Article thus evaluates case law involving children's health and pesticides in both an administrative law and common law context. That Section concludes that while direct challenges to EPA regulatory policy under the FQPA have been less than successful so far, common law claims against manufacturers may hold more promise to encourage the collection of valuable scientific data that can be used to protect children's health.

### III. PESTICIDES AND CHILDREN'S HEALTH IN THE COURTS

This Section analyzes judicial decisions involving children's health and pesticides. There are countless cases involving claims by children and their parents against pesticide manufacturers for pesticide-related damages and numerous other suits involving general challenges to EPA and other agencies regarding pesticide-related rulemaking. However, the cases discussed below are limited to those cases in which the courts have wrestled specifically with evidentiary or policy matters specific to children.

As a result, these cases provide some indication of the availability or lack thereof of data and other studies specific to children and pesticides as well as how the courts are dealing with that evidence or lack of evidence. This Section starts with an evaluation of claims against EPA and other regulatory agencies. These cases tend to show that while claims against EPA under the FQPA have not obtained major results, administrative law cases in other contexts provide a roadmap for how courts can invoke statutory precautionary principles to place data-gathering incentives on pesticide manufacturers to avoid risks to children. This Section then reviews common law tort claims by children and their parents against pesticide manufacturers and users. This evaluation establishes that in light of the Supreme Court's recent decision in *Bates*,<sup>43</sup> common law tort claims based on negligent testing and negligent design principles can act as a catalyst to spur manufacturers to collect and evaluate data not currently required by EPA. Courts can

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43. 125 S. Ct. 1788 (2005).

look to the precautionary principle embodied in the FQPA to do so.

#### A. AGENCY CASES BEFORE THE FQPA

Not surprisingly, even before the enactment of the FQPA, state and federal courts were called upon to consider the impacts of pesticides on children's health in an administrative law context. A review of these early cases provides some valuable historic lessons about the ability of the judiciary to promote sound policy regarding children's health and pesticides.

One notable case involving children's health and pesticides in an administrative law context is *National Association of Farmworkers Organizations v. Marshall*.<sup>44</sup> In that case, private nonprofit organizations representing farmworker families sued the Secretary of the U.S. Department of Labor over regulations governing employment of children younger than twelve years of age for harvesting crops. In general, federal law prohibited the employment of children under twelve years of age, but a 1977 amendment to the law allowed employers to apply to the Secretary for a waiver of the child labor laws in order to employ ten- and eleven-year-old children for harvesting short-season crops.<sup>45</sup> Such waivers could be granted only if, among other things, the levels and types of pesticides and chemicals used "would not have an adverse effect on the health or well-being of the individuals to whom the waiver would apply."<sup>46</sup> Such findings by the Secretary to grant a waiver had to be "based on objective data submitted by the applicant."<sup>47</sup>

In attempting to enact regulations under the 1977 amendments, the Department of Labor was faced with a problem in setting uniform standards with little or no data regarding the impact of pesticides on children. Indeed, when the first set of regulations were proposed, representatives of EPA, other agencies, and the public commented that epidemiologic information for pesticide effects on children was essentially nonexistent,<sup>48</sup> that children are more vulnerable to

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44. 628 F.2d 604 (D.C. Cir. 1980).

45. See *id.* at 606-07; see also 29 U.S.C. § 213(c) (2000).

46. Marshall, 628 F.2d at 607 (citing 29 U.S.C. § 213(c)(4)(A) (1979)).

47. *Id.*

48. See Bernard D. Goldstein & Mary Sue Henifin, *Reference Guide on Toxicology*, in FEDERAL JUDICIAL CENTER, REFERENCE MANUAL ON

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harmful effects of pesticides than adults, and that there was no basis on which to set standards to protect children from the adverse effects of pesticide exposure.<sup>49</sup>

Despite this lack of data, the Department approved numerous pesticides for use with "preharvest intervals" before children could enter the field. It granted these approvals even though EPA argued that the available data was insufficient to make a decision on the safety of children exposed to the pesticides, several of which were either known carcinogens or found to be dangerous in the commissioned study.<sup>50</sup>

In response to a challenge to the approvals, the D.C. Circuit Court of Appeals, in an opinion by Judge Bazelon, began by framing the issue as "[h]ow can an administrator set safety standards in the absence of adequate scientific evidence?"<sup>51</sup> In answering that question, the court acknowledged that assuring safety in pesticide exposure "may be beyond the range of scientific certainty at present."<sup>52</sup> However, the court rejected the argument that the Secretary could not delay the issuance of waivers until he received assurances that certain pesticides were absolutely safe or presented zero risk because the state of scientific knowledge could not soon, or ever, provide such assurances.<sup>53</sup> The court focused on the fact that the statute required a finding based on "objective data" submitted by the applicant that the pesticides would not have an effect on the health or well-being of the individuals to whom the waiver would apply, but the Secretary had no data that even tended to point in that direction.<sup>54</sup> The court took issue with the district court's conclusion that the state of scientific knowledge could not in the near future or ever provide sufficient assurances for safety. The court held that the study the Department had commissioned indicated that data could be generated "time permitting," but that the Department did not seek any such studies before issuing its

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SCIENTIFIC EVIDENCE 401, 413 (2d ed. 2000) (defining epidemiology as "the study of the incidence and distribution of disease in human populations"); see also 40 C.F.R. § 158.340 (2004) (regarding toxicology data requirements for pesticide registration).

49. See *Marshall*, 628 F.2d at 607-08.

50. See *id.* at 609-10.

51. *Id.* at 606.

52. *Id.* at 617 (citing NATIONAL ACAD. OF SCIENCES, SCIENCE AND TECHNOLOGY: A FIVE-YEAR OUTLOOK 462 (1979)).

53. See *id.* at 617.

54. See *id.* at 617-18.

lists of pesticides.<sup>55</sup> Significantly, the court rejected the premise that in the absence of good evidence, the Secretary was justified in relying on the “best available evidence” in light of the express statutory language requiring “objective data” to support a waiver.<sup>56</sup>

The *Marshall* opinion is significant for several reasons. First, throughout the opinion, the court cites extensively to studies, data, and reports on the impact of pesticides on children’s health and the lack of data available to establish safety standards. Second, the opinion is an example of the adoption of the precautionary principle over the more often-used cost-benefit analysis in making decisions that impact economic values on the one hand and public health and environmental values on the other.<sup>57</sup>

Thus, helped along by the “objective data” standard in the statute at issue, the court was able to place the protection of children above any economic concerns. As a result, the court put the burden on the defendants to create “objective data” to justify continued use of pesticides in the presence of workers under twelve years of age. In doing so, the court was able to use its authority to promote gathering data and information that could be used in further studies and legal proceedings.<sup>58</sup>

While there are certainly many other examples of courts refusing to place such an information-gathering burden on manufacturers to justify use of a pesticide, those cases generally arise in the FIFRA regulatory context, where cost-benefit analysis is expressly built into the statute. For instance, in a pre-FQPA case, *Love v. Thomas*,<sup>59</sup> the Ninth Circuit Court of Appeals rejected the use of the precautionary principle over cost-benefit analysis in the context of pesticide risks to children. In *Love*, farmers and food processors sought a preliminary injunction against an EPA emergency suspension order under FIFRA preventing further sale, distribution, or use of pesticide products containing dinoseb.<sup>60</sup> EPA had issued the

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55. *Marshall*, 628 F.2d at 618-19.

56. *Id.* at 619 & n.73 (comparing other statutes that require safety standards based on “best available evidence”).

57. *See supra* note 36 and accompanying text.

58. *See also* *Chemical Specialties Mfrs. Ass’n v. Jorling*, 85 N.Y.2d 382 (1995) (upholding state agency ban on pesticide products with high concentrations of DEET based on evidence of risk to human health and particularly children’s health).

59. 858 F.2d 1347 (9th Cir. 1988).

60. *See id.* at 1350-51.



order based on preliminary studies showing that dinoseb may cause serious health risks to persons exposed to it, including sterility in men and birth defects in the unborn children of pregnant women.<sup>61</sup>

The Ninth Circuit held that EPA had acted in an arbitrary and capricious manner in failing to consider the economic benefits of dinoseb in issuing its order. The court concluded that EPA had failed to adequately study the economic impact on the plaintiffs and their crops and thus failed to conduct the necessary balancing required by the statute.<sup>62</sup> Indeed, the court used strong language in stating that “[w]ith all due respect to the EPA and its overworked staff, such insensitivity to the local economic problems caused by its decision is unbecoming and inappropriate.”<sup>63</sup> In reaching its decision, the court spent little time discussing EPA’s data on the pesticide’s potential harm to unborn children and significant time discussing EPA’s failure to consider data regarding the economic benefits of the pesticide. As a result, the court placed the information-gathering burden squarely on EPA, rather than those wishing to manufacture and use the pesticide.

In many ways, the *Love* case is the mirror image of the *Marshall* case. In *Marshall*, the lack of evidence quantifying the pesticide’s risks meant that the pesticide could not be used. In *Love*, the lack of evidence quantifying the pesticide’s benefits meant that the restrictions on the pesticide were improper despite potential harm to unborn children. This difference in result is due, for the most part, to the very different provisions of the two statutes at issue. While the labor law in *Marshall* required “objective data” to allow a pesticide to be used with child workers under twelve years of age, the key provisions of FIFRA at issue in *Love* expressly incorporated a cost-benefit analysis in determining whether a pesticide should be suspended.<sup>64</sup>

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61. *See id.* at 1350.

62. *See id.* at 1357-62.

63. *Id.* at 1362. The court went on to reverse the district court’s injunction imposing conditions on the use of dinoseb on the grounds that the district court’s authority was limited to stay the EPA order or leave it in place. *See id.* at 1364 (citing 7 U.S.C. § 136d(c)(4)). The court thus remanded the case to the lower court to consider whether it would have been willing to allow the unrestricted use of dinoseb. *See Love*, 858 F.2d at 1364.

64. *See* 7 U.S.C. § 136a(c)(5)(D) (2000) (stating that a pesticide shall be registered if, among other things, it will not cause “unreasonable adverse effects on the environment” when used in accordance with widespread and

What one can take away from these cases is that the courts can exercise their authority to encourage manufacturers to obtain new data to justify use of their pesticides in the presence of a statutory precautionary principle. While the *Marshall* case illustrates this in an administrative law context, such principles can apply equally to tort claims against pesticide manufacturers.

#### B. MORE AGENCY CASES: THE FQPA

It did not take long after the enactment of the FQPA for the lawsuits to begin. However, a review of these cases shows that at least so far, direct challenges to EPA action under the FQPA have been less than effective, and the courts have rarely reached the merits of any dispute. Thus, in the short term, it may be wise to look beyond administrative law challenges to the potential of tort law to spur greater protection for children's health.

The first lawsuit, *American Farm Bureau v. United States Environmental Protection Agency*,<sup>65</sup> was brought by pesticide manufacturers and farm groups against EPA alleging that the agency had failed to: (1) set tolerances for emergency exemptions under FIFRA, (2) promulgate data requirements for establishing and continuing tolerances, (3) update data requirements for registering pesticides under FIFRA, (4) comply with various data collection requirements to complete tolerance assessments, and (5) follow appropriate rulemaking procedures in implementing a FQPA infant and child safety factor policy.<sup>66</sup>

The District Court for the District of Columbia dismissed most of the claims for lack of standing. Of most interest for purposes of this Article is the plaintiffs' argument that they had suffered economic injury "as a result of the uncertainty about pesticide safety created by the EPA's alleged failure to meet its tolerance reassessment schedule."<sup>67</sup> Plaintiffs further

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commonly recognized practice); 7 U.S.C. § 136(bb) (2000) (defining "unreasonable adverse effects on the environment" as taking into account the "economic, social, and environmental costs and benefits of the use of any pesticide").

65. 121 F. Supp. 2d 84 (D.D.C. 2000).

66. *See id.* at 89-90. This last argument involved the EPA's alleged failure to apply the presumptive tenfold safety factor for infants and children required by the FQPA in the absence of "reliable data" showing a different margin of safety should be used. *See* 21 U.S.C. § 346a(b)(2)(C) (2000).

67. *American Farm Bureau*, 121 F. Supp. 2d at 99.

alleged that they would have to expend funds on “public education and outreach” to combat “misinformation about crop protection and other chemical products” and would suffer from “product deselection by consumers, growers, and pesticide manufacturers.”<sup>68</sup> In rejecting the plaintiffs’ claim of economic injury, the court held that the alleged injuries were not concrete and particularized, and moreover, the plaintiffs failed to demonstrate a causal connection between the alleged harm and EPA’s alleged inaction.<sup>69</sup>

The *American Farm Bureau* case was quickly followed by a challenge from the other side. The Natural Resources Defense Council (NRDC) and other environmental groups sued EPA for inadequate regulation of pesticides under the FQPA in *Natural Resources Defense Council v. Whitman*.<sup>70</sup> Initially, the plaintiffs alleged that EPA had failed to meet the tolerance-reassessment deadlines and priorities in the FQPA. Most of the original parties reached a settlement, but the settlement was later challenged by the American Farm Bureau and other farming and pesticide manufacturing interests. In dismissing the challenge to the settlement, the court rejected the argument that the consent decree would have “devastating economic consequences” on the manufacturing and farming community, noting that the law does not require EPA to assess the economic consequences of performing reevaluations.<sup>71</sup> The court did note, however, that “[t]o the extent EPA fails to properly account for the economic benefits of a given pesticide in any final rule, judicial review will be available.”<sup>72</sup>

The next case involving the FQPA, *Croplife America v. Environmental Protection Agency*,<sup>73</sup> was a challenge by pesticide manufacturers and trade associations to an EPA directive that it would no longer accept third-party human studies in regulatory decisionmaking. The petitioners alleged that the directive was a binding regulation rather than a policy statement and required formal notice and comments prior to enactment. The petitioners further alleged they were injured because the new policy precluded EPA’s consideration of studies petitioners had previously used to verify the safety of

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68. *Id.*

69. *See id.*

70. No. C 99-03701 WHA, 2001 WL 1221774 (N.D. Cal. Sept. 24, 2001).

71. *See id.* at \*20.

72. *Id.*

73. 329 F.3d 876 (D.C. Cir. 2003).

their products.<sup>74</sup> In this 2003 opinion, the D.C. Circuit Court of Appeals held that EPA's broad moratorium on the use of third-party human test data (which had been allowed on a case-by-case basis in the past) was a binding regulation enforceable against the petitioners and subject to notice and comment requirements.<sup>75</sup> Once again, the case did not allow the court to reach the merits of data requirements or other issues at the heart of the FQPA.

Finally, in 2004, in *New York v. United States Environmental Protection Agency*,<sup>76</sup> states and nonprofit groups sued EPA for failure to apply the presumptive tenfold margin of safety for children in reassessing certain pesticide tolerances. The plaintiffs argued that by "leaving certain existing tolerances in place for these pesticides without applying the tenfold margin of safety, the EPA failed to take into account scientific data demonstrating serious safety risks."<sup>77</sup> The plaintiffs also alleged that EPA's failure to designate farmworkers' children as a "major identifiable subgroup" violated the FQPA because of their heightened vulnerability to pesticide exposures.<sup>78</sup> Although the allegations in this case went to the heart of the FQPA requirements relating to children, the District Court for the Southern District of New York dismissed the case for lack of subject matter jurisdiction. The court reasoned that section 408(h)(1) of the FQPA vested jurisdiction in the federal courts of appeals and that the plaintiffs had not exhausted their administrative remedies.<sup>79</sup> Thus, once again, efforts to reach the merits of the suit were derailed.

Efforts to force EPA to fulfill its mandate under the FQPA continue. In June 2005, NRDC and other groups filed suit against EPA in the Northern District of California for failure to designate children of farmworkers as a "major identifiable subgroup" subject to special protection under the FQPA.<sup>80</sup> In support of their claims, the plaintiffs detailed the fact that

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74. *See id.* at 884.

75. *Id.* at 881.

76. 350 F. Supp. 2d 429 (S.D.N.Y. 2004).

77. *Id.* at 432.

78. *See id.* at 433.

79. *See id.* at 438 (citing 21 U.S.C. § 346a(h)(1), (g)(2)(C) (2000)).

80. *See* Complaint for Declaratory and Injunctive Relief and Petition for Writ of Mandamus at 10, Pesticide Action Network North America v. United States Env'tl. Prot. Agency, No. 4:05CV02312, (N.D. Cal. June 7, 2005); *see also* 21 U.S.C. § 346a(b)(2)(D) (2000).

more than one million children of farmworkers and farmers live in this country, and more than 300,000 children under the age of six live on farms. The plaintiffs cited studies showing that children are at heightened risk of harm from pesticides and that children on farms, because of their proximity to direct application of pesticides, are at even greater risk.<sup>81</sup>

The plaintiffs alleged that EPA had failed to respond to an October 1998 petition by NRDC and other groups requesting the agency to identify children living on or near farms as a "major identifiable subgroup." The plaintiffs sought a declaratory judgment that EPA's failure to respond to the petition violated the Administrative Procedure Act<sup>82</sup> and asked the court to compel the agency to respond to the petition in ninety days.<sup>83</sup> In August 2005, the plaintiffs voluntarily dismissed that action without prejudice when EPA acted on the NRDC's original petition through its issuance of an "Order Denying Objections to Issuance of Tolerances" on August 10, 2005.<sup>84</sup>

NRDC and other nonprofits followed the dismissal of this suit with a set of new lawsuits that are being consolidated in the Ninth Circuit Court of Appeals. These lawsuits challenge directly EPA's August 10, 2005 Order, its refusal to treat farm children as a major identifiable subgroup under the FQPA, EPA's refusal to apply a tenfold safety factor on certain pesticides in the absence of developmental neurotoxicity testing (DNT) data establishing that the pesticides at issue are not neurotoxic, and EPA's action on other pesticide tolerance issues under the FQPA.<sup>85</sup> What the court will do with this most

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81. See Complaint for Declaratory and Injunctive Relief and Petition for Writ of Mandamus, *supra* note 80, at 4-10 (citing NATURAL RES. DEF. COUNCIL, *supra* note 28; NATURAL RES. DEF. COUNCIL, HIDDEN DANGER: ENVIRONMENTAL HEALTH THREATS IN THE LATINO COMMUNITY (2004); and COMMITTEE ON PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN, *supra* note 26).

82. See 5 U.S.C. §§ 553(e), 555(b) (2000).

83. See Complaint for Declaratory and Injunctive Relief and Petition for Writ of Mandamus, *supra* note 80, at 11.

84. See Notice of Voluntary Dismissal Without Prejudice Under Fed. R. Civ. P. 41(a)(1), Pesticide Action North America v. United States Env'tl. Prot. Agency, No. 05-02312-CW (N.D. Cal. Oct. 4, 2005); see also Order Denying Objections to Issuance of Tolerances, 70 Fed. Reg. 46,706 (Aug. 10, 2005).

85. See Northwest Coalition for Alternatives to Pesticides v. United States Env'tl. Prot. Agency, No. 05-75255 (9th Cir., Sept. 1, 2005) (appealing EPA Order); Notice of Selection of Venue by MDL Panel, Croplife America v. United States Env'tl. Prot. Agency, No. 05-1343 (D.C. Cir. Oct. 12, 2005) (consolidating

recent suit remains to be seen. However, the cases so far show that FQPA administrative litigation is in its early stages where decisions on the merits can force EPA and/or pesticide manufacturers to adequately implement the law's provisions. Indeed, the level of analysis of children's health issues in the cases prior to the enactment of the FQPA is much more robust than in cases brought under the FQPA itself. While this will certainly change as more agency actions are taken under the FQPA, for now it may be prudent to consider whether lawsuits beyond challenging EPA's administration of the FQPA may help spur additional data collection and promote protection of children's health.

### C. DATA GAPS AND PREEMPTION: THE MANUFACTURER CASES

Lawsuits seeking damages for pesticide exposure have been around since before the 1972 FIFRA amendments. Problems of proof, even in meritorious cases, have historically posed significant barriers. This is particularly true for cases involving children, when even less scientific evidence on exposure levels and effects is available.<sup>86</sup> As shown below, the problem is circular. Because pesticide manufacturers still have not conducted sufficient studies in many cases to establish a link or lack thereof between pesticide exposure and harm to children, such data is not available to plaintiffs when such harm may occur. For instance, EPA does not require even basic neurotoxicity testing in order to register a pesticide under FIFRA, even though a protocol for conducting such tests was extensively validated years ago.<sup>87</sup> This lack of data makes such lawsuits expensive, difficult, and in the end, often (but not always) unsuccessful. The problem is, of course, exacerbated by the fact that in the absence of regulatory requirements, pesticide manufacturers have no incentive to conduct testing,

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actions challenging EPA's August 10, 2005 Order in the Court of Appeals for the Ninth Circuit); Amended Petition for Review, *Natural Res. Def. Council v. United States Env'tl. Prot. Agency*, No. 05-4773 (2d Cir. Aug. 31, 2005); *see also* EPA, Notice to the Judicial Panel on Multidistrict Litigation of Multicircuit Petitions for Review (Sept. 27, 2005).

86. *See, e.g.,* WARGO, *supra* note 1, at 177-78 (stating there is no systematic method or model appropriate to predict variation in age-related susceptibility to toxins); Schon, *supra* note 3, at 708-09 (noting that it was not until the 1990s that studies and publicity emphasized that children were not "little adults" for purposes of data collection and regulation with regard to pesticides).

87. *See* WALLINGA, *supra* note 4, at 61.

even when protocols are available, because such data could then be used against them in lawsuits or in efforts to cancel the pesticide registration.<sup>88</sup>

Moreover, until recently, federal preemption under FIFRA posed a nearly insurmountable barrier to many claims for pesticide damages against manufacturers. As discussed below, although evidentiary problems remain a significant hurdle, the federal preemption problem has lessened significantly as a result of the Supreme Court's 2005 decision in *Bates*. Thus, *Bates* provides an opening for the common law to act as a catalyst to improve pesticide testing and design that better protect children's health.

### 1. Scientific Evidence Hurdles

Examples of children who have been prevented from proceeding to trial against manufacturers for alleged pesticide-related damages are easy to find. This is in large part a result of the impact of the Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*<sup>89</sup> In *Daubert*, the Court announced a new standard for admissibility of scientific evidence in federal court based on Federal Rules of Evidence 702 and 703. In order to allow expert, scientific testimony to be presented at trial, the trial judge must determine at the outset whether the reasoning or methodology underlying the testimony is scientifically valid and whether that reasoning or methodology properly can be applied to the facts.<sup>90</sup> Thus, before admitting scientific evidence, the trial judge must act as a "gatekeeper"<sup>91</sup> regarding what scientific evidence can be presented to the jury.

The Court further refined this direction in *General Electric*

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88. See, e.g., Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 CORNELL L. REV. 773, 805 (1997) (noting the irony in the current common law tort system—requiring a plaintiff to prove causation in all cases allows a manufacturer to escape liability when the plaintiff cannot prove the manufacturer's product caused the plaintiff's harm, "even though this proof problem is a direct result of the manufacturer's inadequate testing"); Wendy E. Wagner, *Common Ignorance: The Failure of Environmental Law to Produce Needed Information on Health and the Environment*, 53 DUKE L.J. 1619, 1639 (2004) ("Remaining ignorant about the potential harms caused by one's products and activities increases the likelihood that the actor can avoid tort suits and stay out of the range of plaintiffs' attorneys' radar.").

89. 509 U.S. 579 (1993).

90. See *id.* at 592-93; see also *id.* at 593-94 (discussing the four factors courts are directed to consider when evaluating whether to admit testimony).

91. See *id.* at 597.

*Co. v. Joiner*,<sup>92</sup> in which it affirmed the trial court's rejection of each of the plaintiff's proffered animal and epidemiological studies in support of plaintiff's claim that exposure to PCBs caused his cancer. In doing so, the Court let stand the trial court's rejection of a weight-of-the-evidence approach to reach conclusions on causation and risk in favor of making each study stand on its own.<sup>93</sup> Because the defendants were able to attack each of the plaintiff's studies separately (for example, based on the age of the animals tested in one study, and the circumstances of the humans impacted in another), the ability to evaluate the evidence based on its totality was lost.<sup>94</sup>

Commentators have persuasively argued that this study-by-study approach prevents experts in toxic tort cases from applying a cumulative weight-of-the-evidence approach that is used overwhelmingly in risk assessments by scientists and agencies.<sup>95</sup> As a result, judges who may lack any scientific expertise are using non-scientific methods to prevent scientific testimony from being heard at trial.<sup>96</sup> Certainly one can persuasively argue that the standard for holding a defendant legally liable for significant damages in a toxic tort case should require more evidence than that used by a regulatory agency to set standards prospectively. However, the *Daubert* standard was designed to address only the *admissibility* of scientific evidence, not require plaintiffs' experts to demonstrate before trial that each study relied upon can on its own prove the plaintiff's case. Thus, using the arguably unscientific and narrow inquiry reflected in *Joiner* is both counterproductive to the goals of the tort system and excessively burdensome for plaintiffs in many pesticide cases.

Two Eighth Circuit cases demonstrate the significant impact of *Daubert* and *Joiner* in cases involving children's

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92. 522 U.S. 136 (1997).

93. *See id.* at 144-46.

94. *See* Thomas O. McGarity, *Proposal for Linking Culpability and Causation to Ensure Corporate Accountability for Toxic Risks*, 26 WM. & MARY ENVTL. L. & POL'Y REV. 1, 19-23 (2001) (discussing *Joiner's* "corpuscular" approach to *Daubert* and arguing that such an approach to determining the admissibility of expert testimony results in courts imposing a much less scientific approach to causation than regulatory agencies charged with protecting citizens from risk).

95. *See, e.g.,* Thomas O. McGarity, *Daubert and the Proper Role for the Courts in Health, Safety, and Environmental Regulation*, 95 AM. J. PUB. HEALTH S92, S95 (Supp. 1 2005).

96. *See id.*



health and pesticides. In two cases involving different plaintiffs, the court of appeals held that the plaintiffs, each who suffered from birth defects allegedly resulting from the mother's exposure to pesticides containing the chemical Dursban during the early stages of pregnancy, could not go forward with a negligent design claim against the manufacturer.<sup>97</sup> In the first Dursban case, the court reasoned that three scholarly articles discussing the connection between the chemical and the birth defects did "not provide the requisite support" to show causation.<sup>98</sup> In the second case, the court of appeals affirmed the lower court's determination that the causation opinions of the physician and chemist hired by plaintiffs did not meet the scientific methodology required by *Daubert*.<sup>99</sup>

Notably, in the latter case, the lower court concluded that the plaintiffs' experts did not present sufficient evidence that Dursban is capable of causing birth defects or that the mother's exposure to Dursban during pregnancy caused the birth defects at issue.<sup>100</sup> The court rejected the plaintiffs' reliance on studies conducted by Dow, letters from Dow to EPA, and articles written by one of the plaintiffs' experts on the subject. The court found that the experts were not able to point to "epidemiological studies consistently and repeatedly demonstrating any statistical association between the exposure of pregnant women to Dursban and any increase in human birth defects."<sup>101</sup> The court also held that there were no appropriate animal models because the dose amounts were not comparable.<sup>102</sup>

In discussing the available evidence, the court noted that although Dursban had been on the market for over thirty years, there was no data showing that increases in the type of birth defects at issue in the case paralleled the increase in sales and use of Dursban.<sup>103</sup> The court noted an epidemiological

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97. See *National Bank of Commerce, of El Dorado, Ark. v. Dow Chem. Co.*, 165 F.3d 602, 610 (8th Cir. 1999); *National Bank of Commerce, of El Dorado, Ark. v. Dow Chem. Co.*, 133 F.3d 1132, 1132 (8th Cir. 1998) (per curiam), *aff'g* 965 F. Supp. 1490 (E.D. Ark. 1996).

98. *National Bank of Commerce*, 165 F.3d at 609.

99. See 133 F.3d at 1132.

100. See *National Bank of Commerce, of El Dorado, Ark. v. Dow Chem. Co.*, 965 F. Supp. 1490, 1519 (E.D. Ark. 1996).

101. *Id.* at 1528.

102. See *id.*

103. See *id.* at 1552 app. F. Significantly, there is no national tracking

study had been conducted on Dursban which failed to find any link between the pesticide and birth defects. In response to the plaintiffs' argument that the study was not reliable and should not be given weight, the court stated that it would be better if more studies were available, but the study was "the only such study," so it had to be carefully considered.<sup>104</sup>

Similarly, in a case from the District Court for the District of West Virginia, the court held that the plaintiffs' animal studies and *in vitro* tests tending to show that the plaintiffs' birth defects were caused by the mother's exposure to the fungicide Benlate were not reliable.<sup>105</sup> While acknowledging that animal testing and *in vitro* studies can often be useful in the field of human toxicology, the court held that the proffered studies were not reliable because the dose rates were not comparable to human exposure levels and because other human and animal studies tended to show no link between the pesticide and birth defects.<sup>106</sup>

These cases are merely examples of the difficulties children face in simply getting to a jury, much less recovering damages, from alleged exposure to pesticides. Certainly, it is improper to hold manufacturer defendants liable for damages if the plaintiffs cannot present sufficient evidence to establish causation. The problem, however, is that the lack of data is not always a function of a lack of causal connection between the

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system for birth defects resulting from pesticides or other factors, making such data virtually impossible to collect. See, e.g., *Services, Education, and Related Agencies Appropriations for 2002: Before the Subcomm. on the Departments of Labor, Health and Human Services, Education, and Related Agencies of the H. Comm. on Appropriations*, 107th Cong. 322 (2002) (statement of Louis Stokes, H. Rep. from Ohio).

104. See *National Bank of Commerce*, 965 F. Supp. at 1554 app. F.

105. See *Bourne v. E.I. Du Pont de Nemours & Co., Inc.*, 189 F. Supp. 2d 482, 495-99 (S.D. W. Va. 2002), *aff'd*, 85 F. App'x 964 (4th Cir. 2004).

106. See *id.* For criticism of courts rejecting animal studies despite the fact that many scientists consider animal studies more reliable than epidemiological studies, see Margaret A. Berger, *What Has a Decade of Daubert Wrought?*, 95 AM. J. PUB. HEALTH S59, S61-S62 (Supp. 1 2005) (giving an example of a court rejecting that animal studies can ever support causation); Carl Cranor, *Scientific Inferences in the Laboratory and the Law*, 95 AM. J. PUB. HEALTH, S121, S123-S124 (Supp. 1 2005) (citing court requirements for human epidemiological evidence even where such evidence is less reliable than other existing evidence or unavailable); and Ronald L. Melnick, *A Daubert Motion: A Legal Strategy to Exclude Essential Scientific Evidence in Toxic Tort Litigation*, 95 AM. J. PUB. HEALTH, S30, S31 (Supp. 1 2005) (stating that while some judges may have claimed that results from animal studies cannot be extrapolated to humans, "this opinion is contrary to the positions of all public health agencies, both national and international").

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pesticide and harm, but simply a lack of available data because the studies have not been required by EPA or anyone else as part of the FIFRA registration process.

Indeed, the epidemiological studies many courts appear to require cannot even be conducted because of ethical problems with exposing humans to potentially harmful pesticides for scientific purposes.<sup>107</sup> Moreover, manufacturers currently have no incentive to undertake many available animal and *in vitro* studies that could potentially provide valuable data because such studies are not required by EPA.<sup>108</sup> In the absence of any regulatory requirement to perform toxicological studies or other studies before or after the registration process is complete, any additional data that calls into question the pesticide's safety only serves to threaten the pesticide's registration as well as provide ammunition to plaintiffs who allege they have been damaged by the pesticide.<sup>109</sup>

Imposing requirements that plaintiffs provide data that is best collected by the manufacturer or data that cannot be collected at all under current ethical policy is directly contrary to the statutory directive in the FQPA that in the face of scientific uncertainty, protection of children's health should prevail. Instead, many courts presently err on the side of no protection for children's health. This problem has only been exacerbated by *Daubert*,<sup>110</sup> which has been used successfully by

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107. See *Croplife Am. v. Evtl. Prot. Agency*, 329 F.3d 876, 884-85 (D.C. Cir. 2003); Miller, *supra* note 8, at 696 (discussing ethical debates over accepting data from epidemiological studies using paid volunteers).

108. See TED SCHETTLER ET AL., GREATER BOSTON PHYSICIANS FOR SOC. RESPONSIBILITY, IN HARM'S WAY: TOXIC THREATS TO CHILD DEVELOPMENT 107-08 (2000); WALLINGA, *supra* note 4, at 62.

109. See McGarity, *supra* note 94, at 35 (stating that the absence of empirical evidence in toxic tort cases is not surprising because "a company has very little to gain and nothing to lose from keeping itself and the world ignorant of the risks that its products pose to others" (citing Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 CORNELL L. REV. 773, 774, 794-95 (1997))).

110. See Cunningham-Parmeter, *supra* note 3, at 494 (citing MARK J. CARPENTER & GEORGE W. WARE, DEFENDING PESTICIDES IN LITIGATION § 9:10, at 217 (2003)) (noting that *Daubert*, in practice, has been used "to exclude testimony by scientific experts who fail to rely on the expensive, conventional studies that are conspicuously absent in pesticide research"); see also PAUL C. GIANNELLI, UNDERSTANDING EVIDENCE § 24.04[5] (2003) (stating that while some believed *Daubert* was a more lenient standard than the *Frye* standard when *Daubert* was decided in 1993, subsequent Supreme Court decisions and lower court implementation of the new standard show that *Daubert* "erects a formidable barrier to the admissibility of expert testimony").

defendant manufacturers to prevent plaintiffs from presenting their evidence to the jury because of the unavailability of data that only the manufacturers themselves are in a position to collect.<sup>111</sup> This current state of affairs serves neither science nor children and prevents the tort system from playing any significant role in shaping corporate behavior.

However, the potential of such claims to succeed is evidenced by cases in which the plaintiff has overcome the legal hurdles to recover damages. In a 2003 case, *Castillo v. E.I. Du Pont de Nemours & Co.*,<sup>112</sup> the Florida Supreme Court held that the plaintiffs' evidence that a child's rare birth defect was caused by his mother's exposure to Benlate during pregnancy was sufficient to support a damages award.<sup>113</sup> The child was born with microphthalmia, a rare birth defect involving severely underdeveloped eyes.<sup>114</sup> The plaintiffs obtained a \$4 million verdict against DuPont and the farm that sprayed the chemical, but the court of appeals reversed on the grounds that the scientific evidence should not have been admitted.<sup>115</sup>

In reversing the court of appeals, the supreme court analyzed the standard for admission of scientific evidence applicable in Florida<sup>116</sup> and held that human epidemiological studies were not necessary in this case because pesticide exposure of this kind was rare to begin with, and it would be unethical to expose humans to a substance known to cause birth defects in animals for testing purposes.<sup>117</sup> In response to the defendants' challenge to the use of *in vitro* test results, the court rejected the argument that the technique used was invalid simply because it was new. The court stated that if it accepted the defendants' position, every new scientific method would be denied.<sup>118</sup> The court ultimately concluded that the lower appellate court had held the plaintiffs to a standard

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111. See *supra* note 84 and accompanying text.

112. 854 So. 2d 1264 (Fla. 2003).

113. See *id.* at 1280.

114. See *id.* at 1266.

115. See *id.* at 1267-68. The verdict allocated 99.5% of the damages against Du Pont and 0.5% against the farm. See *id.* at 1267.

116. Florida, like many other states, still relies on the test set forth in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), for admission of scientific evidence at trial. Under the *Frye* test, the court must find that the scientific evidence is based on methods generally accepted by the relevant members of the particular field. See *id.* at 1268.

117. See *Castillo*, 854 So. 2d at 1270.

118. See *id.* at 1272-73.

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above and beyond the requirements for scientific evidence in Florida.<sup>119</sup>

Similarly, in a 2000 case, the Nebraska Court of Appeals affirmed a verdict for the plaintiffs against a city for negligent spraying of the pesticide malathion, which allegedly resulted in a child developing a generalized seizure disorder.<sup>120</sup> In holding the evidence on exposure and effects of malathion sufficient to support a verdict for the plaintiff, the court focused on scientific evidence regarding the known effects of malathion, the child's symptoms, and the amount of exposure.<sup>121</sup> At trial, the child was described as mild-mannered, affectionate, and loving, while after he was sprayed with malathion, he experienced seizures, irritability, and severe intellectual defects.<sup>122</sup> In rejecting the defendant's arguments that the plaintiffs had failed to prove sufficient levels of exposure, the court stated that it was "not prepared to hold that a plaintiff must prove a mathematically precise level of exposure in order to recover in a toxic tort case."<sup>123</sup>

The Florida and Nebraska cases stand in contrast to the federal cases discussed earlier in that the courts allowed the plaintiffs to go forward on claims based on scientific evidence even where that evidence was not "perfect." In each case, the court recognized that the optimal studies might not be available, so the plaintiffs could rely on evidence that was "reliable." Although the difference in outcomes between the two sets of cases may be attributable in part to the *Daubert* standard applicable in federal court, the latter cases recognize that the absence of a large body of research data does not mean the evidence that is available is so unreliable that the plaintiff is prevented from having his or her day in court. The need to exercise such discretion in favor of admissibility is arguably greater in cases involving the impacts of pesticides on children, where the FQPA not only recognizes the link between pesticides and harm to children as a general matter, but announces a precautionary principle when it comes to data uncertainty.

In the end, the message to take away from the cases is

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119. *See id.* at 1276.

120. *See Amateis v. City of Bridgeport*, No. A-98-1270, 2000 WL 868510, at \*1, \*17 (Neb. Ct. App. June 27, 2000).

121. *See id.* at \*5-13.

122. *See id.* at \*10-13.

123. *Id.* at \*15.

somewhat mixed. Liability verdicts against manufacturers can influence which products are on the market and what warnings accompany those products.<sup>124</sup> Although manufacturers warn that valuable products will not be available to consumers at low costs without a full suite of pesticides,<sup>125</sup> it is not difficult to posit that higher consumer costs may be a legitimate tradeoff for the removal of products that are harmful to children's health and that quite possibly incur even larger and longer-term health-related costs to society. Certainly it is within the province of EPA to set that balance in the first instance under FIFRA's cost-benefit provisions as well as the precautionary principle embodied in the FQPA. However, the fact that successful lawsuits can prompt manufacturers to voluntarily remove pesticides from the market means that litigation can often remove a harmful pesticide from production more quickly than an EPA cancellation proceeding.<sup>126</sup>

## 2. Breaking Apart FIFRA Preemption

For nearly twenty years, there has been a massive amount of litigation over the extent to which FIFRA preempts state law tort claims under the supremacy clause of the U.S. Constitution.<sup>127</sup> Although some early cases had interpreted

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124. See Brief of Amici Curiae Natural Resources Defense Council, et al. in Support of Petitioners at 13-23, *Bates v. Dow Agrosciences LLC*, 125 S. Ct. 1788 (2005) (No. 03-388) (using examples of pesticides voluntarily taken off the market as a result of tort lawsuits but prior to EPA action to show the ability of state tort actions to create additional incentives for manufacturers to protect human health and the environment).

125. See *National Ass'n of Farmworkers Org. v. Marshall*, 628 F.2d 604, 616 (D.C. Cir. 1980) (arguing that additional burdens on growers will result in higher consumer prices); Brief of CropLife America and National Pest Management Association as Amici Curiae in Support of Respondent at 17-18, *Bates v. Dow Agrosciences LLC*, 125 S. Ct. 1788 (2005) (No. 03-388) (arguing that without federal preemption, pesticide manufactures would be confronted with different standards in different states and might be forced to forgo sales in some states, thus depriving farmers of effective pesticides).

126. For instance, the numerous lawsuits by children born without eyes or severely underdeveloped eyes allegedly resulting from their mothers' exposure to benomyl can be seen as one of the factors that led to Du Pont requesting cancellation of all its product registrations containing that pesticide even though EPA was prepared to address the matter through label warnings. See, e.g., *Castillo v. E.I. Du Pont de Nemours & Co.*, 854 So. 2d 1264 (Fla. 2003); Brief of Amici Curiae Natural Resources Defense Council, et al. in Support of Petitioners, *supra* note 124, at 13-29 (using the benomyl lawsuits and other examples to show the ability of state tort actions to create additional incentives for manufacturers to protect human health and the environment).

127. See 7 U.S.C. § 136v(b) (2000) (providing the basis for FIFRA

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FIFRA preemption narrowly to retain a significant role for common law tort claims, they were quickly followed by decisions in nearly every federal circuit applying FIFRA preemption broadly to prevent plaintiffs from using the tort law system to obtain compensation for pesticide-related harm and shape corporate behavior. This changed in April 2005 with the Supreme Court's *Bates* decision. *Bates* has the potential to significantly expand the role tort law can play in encouraging pesticide manufacturers to better assess the health risks their products pose and develop new products through testing. Such pressure has the potential to help protect children's health from the adverse effects of pesticides and fill in some of the gaps created by EPA shortcomings in this area.

## a. The Early FIFRA Preemption Cases

The first federal cases to consider whether FIFRA preempted common law claims against manufacturers for pesticide damages were decided in the 1980s and early 1990s. These cases often rejected preemption arguments and held that the plaintiffs could recover damages based on failure to warn theories.<sup>128</sup> In a well-known case, *Ferebee v. Chevron Chemical Co.*,<sup>129</sup> the D.C. Circuit Court of Appeals held that state common law claims and FIFRA have separate functions, and while FIFRA served to ensure a pesticide did not have unreasonable adverse effects based on a net benefit analysis,

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preemption). For a detailed discussion of the history of federal preemption under FIFRA, see Klass, *supra* note 11.

128. See *Thornton v. Fondren Green Apts.*, 788 F. Supp. 928, 932 (S.D. Tex. 1992); *Montana Pole & Treating Plant v. I.F. Laucks & Co.*, 775 F. Supp. 1339, 1343-45 (D. Mont. 1991), *aff'd on other grounds*, 993 F.2d 676 (9th Cir. 1993); *Riden v. ICI Ams., Inc.*, 763 F. Supp. 1500, 1503-09 (W.D. Mo. 1991); *Evenson v. Osmose Wood Preserving, Inc.*, 760 F. Supp. 1345, 1347-48 (S.D. Ind. 1990); *Cox v. Velsicol Chem. Corp.*, 704 F. Supp. 85, 86-87 (E.D. Pa. 1989); *Roberts v. Dow Chem. Co.*, 702 F. Supp. 195, 196-99 (N.D. Ill. 1988); *Wilson v. Chevron Chem. Co.*, No. 83 Civ. 762, 1986 WL 14925, at \*5-6 (S.D.N.Y. Dec. 17, 1986). *But see Papas v. Upjohn Co.*, 926 F.2d 1019, 1024-26 (11th Cir. 1991) (holding state law claims impliedly preempted), *vacated by Papas v. Zoecon Corp.*, 505 U.S. 1215 (1992); *Hurt v. Dow Chem. Co.*, 759 F. Supp. 556, 558-60 (E.D. Mo. 1990) (finding some state claims preempted, but not others); *Herr v. Carolina Log Bldgs., Inc.*, 771 F. Supp. 958, 960-61 (S.D. Ind. 1989) (same); *Kennan v. Dow Chem. Co.*, 717 F. Supp. 799, 803-07 (M.D. Fla. 1989) (holding state failure to warn claim impliedly preempted); *Fisher v. Chevron Chem. Co.*, 716 F. Supp. 1283, 1287-89 (W.D. Mo. 1989) (same); *Fitzgerald v. Mallinckrodt, Inc.*, 681 F. Supp. 404, 406-08 (E.D. Mich. 1987) (holding both failure to warn and negligent labeling claims preempted).

129. 736 F.2d 1529 (D.C. Cir. 1984).

state tort law provided compensation for injury for failure to warn against a known and significant risk.<sup>130</sup> The court stated that a pesticide manufacturer faced with damage awards could assess whether to continue to sell the product or change the label to limit its liability.<sup>131</sup> In rejecting preemption, the court also reasoned that even though FIFRA does not allow states to directly impose additional labeling requirements, it does allow states to impose more stringent constraints on the use of pesticides within its jurisdiction.<sup>132</sup>

#### b. The Era of Broad FIFRA Preemption

The FIFRA preemption landscape changed dramatically with the Supreme Court's 1992 decision in *Cipollone v. Liggett Group, Inc.*<sup>133</sup> The Court held that a smoker's claim for damages against a cigarette manufacturer under a failure to warn theory was preempted by section 5(b) of the Public Health Smoking Act of 1969, which prohibited state regulation of advertising or promotion of cigarettes labeled in conformity with the federal law.<sup>134</sup> In holding that the 1969 law preempted the plaintiff's failure to warn claim, the Court found that the phrase "[n]o requirement or prohibition" did not distinguish between positive enactments and common law claims for damages.<sup>135</sup> The Court reasoned that state regulation "can be as effectively exerted through an award of damages as through some form of preventative relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy."<sup>136</sup>

*Cipollone* had an immediate impact on common law tort claims against pesticide manufacturers. After the decision, virtually all the federal circuit courts and many state supreme

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130. *See id.* at 1540-41.

131. *See id.* at 1541.

132. *See id.*

133. 505 U.S. 504 (1992).

134. *See id.* at 524-25. The operative language in the Public Health Cigarette Smoking Act of 1969 stated that "[n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." *Id.* at 515 (quoting the Public Health Cigarette Smoking Act of 1969 § 5(b), Pub. L. No. 91-222, 84 Stat. 87 (codified at 15 U.S.C. § 1334(b) (2000))).

135. *See Cipollone*, 505 U.S. at 521.

136. *Id.* (quoting *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 247 (1959)) (internal quotation marks omitted).



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courts held that state law tort claims challenging pesticide product labels were preempted by FIFRA,<sup>137</sup> although there was a split among the courts over whether claims related to product efficacy, non-label-related consumer fraud, and voluntary label statements (as opposed to those required by FIFRA) were preempted.<sup>138</sup>

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137. See, e.g., *Dow Agrosciences LLC v. Bates*, 332 F.3d 323 (5th Cir. 2003), *vacated and remanded*, 125 S. Ct. 1788 (2005); *Lowe's Home Ctrs., Inc. v. Olin Corp.*, 313 F.3d 1307 (11th Cir. 2002); *Netland v. Hess & Clark, Inc.* 284 F.3d 895 (8th Cir. 2002); *Hawkins v. Leslie's Pool Mart, Inc.*, 184 F.3d 244 (3rd Cir. 1999); *Kuiper v. Am. Cyanamid Co.*, 131 F.3d 656 (7th Cir. 1997); *Grenier v. Vt. Log Bldgs., Inc.*, 96 F.3d 559 (1st Cir. 1996); *Taylor AG Indus. v. Pure-Gro*, 54 F.3d 555 (9th Cir. 1995); *Lowe v. Sporicidin Int'l*, 47 F.3d 124 (4th Cir. 1995); *Papas v. Upjohn Co.*, 985 F.2d 516 (11th Cir. 1993); *Arkansas-Platte & Gulf P'ship v. Van Waters & Rogers, Inc.*, 959 F.2d 158 (10th Cir. 1992), *vacated by Arkansas-Platte & Gulf P'ship v. Dow Chem. Co.*, 506 U.S. 910 (1992), *adhered to by* 981 F.2d 1177 (10th Cir. 1993); *Etcheverry v. Tri-Ag Serv., Inc.*, 993 P.2d 366 (Cal. 2000); *Banks v. ICI Ams., Inc.*, 450 S.E.2d 671 (Ga. 1994); *Kawamata Farms, Inc. v. United Agri Prods.*, 948 P.2d 1055 (Haw. 1997); *Wright v. Am. Cyanamid Co.*, 599 N.W.2d 668 (Iowa 1999); *Jenkins v. Amchem Prods., Inc.*, 886 P.2d 869 (Kan. 1994), *cert. denied*, 516 U.S. 820 (1995); *Hopkins v. Am. Cyanamid Co.*, 666 So. 2d 615 (La. 1996); *Hochberg v. Zoecon Corp.*, 657 N.E.2d 1263 (Mass. 1995); *Goeb v. Tharaldson*, 615 N.W.2d 800 (Minn. 2000); *Eyl v. Ciba-Geigy Corp.*, 650 N.W.2d 744 (Neb. 2002); *Davidson v. Velsicol Chem. Corp.*, 834 P.2d 931 (Nev. 1992); *Lewis v. Am. Cyanamid Co.*, 715 A.2d 967 (N.J. 1998); *Eide v. E.I. Du Pont de Nemours & Co.*, 542 N.W.2d 769 (S.D. 1996); *Quest Chem. Corp. v. Elam*, 898 S.W.2d 819 (Tex. 1995); *Goodwin v. Bacon*, 896 P.2d 673 (Wash. 1995).

138. Compare *Dow Agrosciences LLC v. Bates*, 332 F.3d 323, 331-32 (5th Cir. 2003), *vacated and remanded*, 125 S. Ct. 1788 (2005) (holding FIFRA does preempt claims for crop damage because even though EPA has chosen not to review product efficacy data, a judgment against the manufacturer would be an incentive for it to alter its label to avoid future liability), *Nathan Kimmel v. DowElanco*, 275 F.3d 1199, 1204-07 (9th Cir. 2002) (holding claim for intentional interference with business advantage impliedly preempted by FIFRA where claim was premised on manufacturer's change in label so that plaintiff's pesticide bags could no longer be used with the product), and *Dahlman Farms, Inc. v. FMC Corp.*, 240 F. Supp. 2d 1012, 1019-21 (D. Minn. 2002) (same), with *Kawamata Farms, Inc. v. United Agri. Prods.*, 948 P.2d 1055, 1078-80 (Haw. 1997) (finding no FIFRA preemption for voluntary label statements), *Walker v. Am. Cyanamid Co.*, 948 P.2d 1123, 1128 (Idaho 1997) (same), *Peterson v. BASF Corp.*, 675 N.W.2d 57, 70-71 (Minn. 2004), *vacated*, 125 S. Ct. 1968 (2005) (holding FIFRA did not preempt consumer fraud claim based on allegations that manufacturer's marketing of herbicides misled farmers into believing that another cheaper herbicide by same manufacturer could not be used on their crops), and *American Cyanamid Co. v. Geye*, 79 S.W.3d 21, 24-25 (Tex. 2002) (holding FIFRA does not preempt state law claims for crop damage because EPA has chosen not to regulate product effectiveness).

c. A Renewed Judicial Role: *Bates v. Dow Agrosciences, LLC*

In April 2005, the Supreme Court decided *Bates*, a case in which herbicide manufacturers sought a declaratory judgment against Texas peanut farmers who were threatening to sue for crop damage caused by the herbicide “Strongarm.”<sup>139</sup> The plaintiffs brought counterclaims including negligence, strict liability, breach of warranties, and fraud.<sup>140</sup> The District Court for the Northern District of Texas found the plaintiffs’ state law claims were preempted by FIFRA, and the Fifth Circuit Court of Appeals agreed.<sup>141</sup> In finding the plaintiffs’ claims preempted, the court of appeals held that even when EPA has not imposed a labeling requirement,<sup>142</sup> for a state to authorize recovery under any of the state law claims would clearly impose a requirement “in addition to or different from” those required under FIFRA, in part because it might cause the manufacturer to seek a change in the label language.<sup>143</sup>

The Supreme Court disagreed.<sup>144</sup> The decision, authored by Justice Stevens, soundly rejected the Fifth Circuit’s broad view of FIFRA preemption. The Court began by stating clearly that nothing in FIFRA itself “would prevent a State from making the violation of a federal labeling or packaging requirement a state offense, thereby imposing its own sanctions on pesticide manufacturers who violate federal law.”<sup>145</sup> The Court acknowledged that under *Cipollone*, the term “requirements” in section 136v(b) of FIFRA reaches beyond positive enactments, such as statutes or regulations, to embrace judge-made rules or jury verdicts, but it is crucial to determine the scope of that preemption.<sup>146</sup> Thus, the Fifth Circuit was “quite wrong when it assumed that any event, such as a jury verdict, that might ‘induce’ a pesticide manufacturer to change its label should be viewed as a requirement.”<sup>147</sup>

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139. See *Bates v. Dow Agrosciences LLC*, 125 S. Ct. 1788, 1793 (2005).

140. See *id.*

141. See *id.*

142. Plaintiffs had argued that their common law claims were not related to the pesticide label because the claims were based on the pesticide’s efficacy, which EPA has expressly declined review in the registration process. See *id.* at 1796.

143. *Dow Agrosciences LLC v. Bates*, 332 F.3d 323, 329 (5th Cir. 2003), *vacated and remanded*, 125 S. Ct. 1788 (2005).

144. See *Bates*, 125 S. Ct. at 1804 (vacating and remanding the case).

145. *Id.* at 1797.

146. See *id.* at 1798.

147. *Id.*

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According to the Court, in order for a “requirement” to be preempted it must be a requirement for “labeling or packaging” and must be “in addition to or different from” those required under FIFRA.<sup>148</sup>

In reviewing the plaintiffs’ state law claims, the Court held that the common law claims for defective design, defective manufacture, negligent testing, and breach of express warranty were not requirements for “labeling or packaging” and thus, were not preempted.<sup>149</sup> Even if a verdict in favor of the plaintiffs on such claims might induce the manufacturer to alter its label, the Court rejected such an “effects-based” test, choosing instead to focus on whether the elements of the common law claim imposed labeling or packaging requirements more burdensome than federal law.<sup>150</sup> Indeed, the Court stated that the threat of damages may give manufacturers an additional reason to comply with federal requirements, and private remedies to enforce federal misbranding requirements “would seem to aid, rather than hinder, the functioning of FIFRA.”<sup>151</sup> The Court made clear that although FIFRA does not provide a federal remedy to those injured by manufacturers’ violations of FIFRA’s requirements, “nothing in [section] 136v(b) precludes States from providing such a remedy.”<sup>152</sup>

The Court also looked to the “long history of tort litigation against manufacturers of poisonous substances” to “emphasize[] the importance of providing an incentive to manufacturers to use the utmost care in the business of distributing inherently dangerous items.”<sup>153</sup> The Court noted with approval that common law tort suits could spur

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148. *Id.* (citing 7 U.S.C. § 136v(b) (2000)).

149. *Id.*

150. *See* Bates, 125 S. Ct. at 1799. For instance, if state law claims for fraud and failure to warn are equivalent to FIFRA’s requirements that a pesticide label not contain “false or misleading” statements, 7 U.S.C. § 136(q)(1)(A) (2000), or inadequate instructions or warnings, 7 U.S.C. § 136(q)(1)(F), (G), such claims would not be preempted. *See* Bates, 125 S. Ct. at 1800.

151. Bates, 125 S. Ct. at 1800-02. The Court noted that the United States’ argument in favor of broad preemption in this case was “particularly dubious given that just five years ago the United States advocated the interpretation that we adopt today.” *Id.* at 1801 & n.24 (citations omitted).

152. *Id.* at 1801; *see id.* at 1800 (relying upon its earlier decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), for the conclusion that state law tort claims that imposed “parallel requirements” to FIFRA’s labeling provisions were not preempted).

153. Bates, 125 S. Ct. at 1801-02.

manufacturers to “gain more information about their products’ performance in diverse settings.”<sup>154</sup> The Court concluded by confirming that FIFRA did preempt competing state labeling standards as well as “any statutory or common-law rule that would impose a labeling requirement that diverges from those set out in FIFRA and its implementing regulations.”<sup>155</sup>

The Supreme Court’s decision in *Bates* thus expressly permits state legislatures and courts to create statutory and common law damage remedies for violations of federal labeling requirements or violations of state law requirements unrelated to labeling. The decision has significant implications for plaintiffs seeking to recover against pesticide manufacturers for failure to conduct adequate testing or for defective design of pesticides leading to the injury of children. While these claims once would have been contained under the umbrella of “labeling” claims preempted by FIFRA, they can now stand on their own and provide incentives for manufacturers to conduct appropriate testing for children’s health impacts or face the alternative of potential damage awards at trial.

#### IV. THE COMMON LAW AND A CHILDREN’S HEALTH AGENDA

Up until now, the children’s health agenda with regard to pesticides has been played out mainly on the legislative and regulatory front. Lawsuits were generally limited to those against agencies to impact policy changes, as previously discussed. Continued pursuit of policy improvements through those channels remains crucial. However, developments in FIFRA preemption and the common law as a result of *Bates* makes common law tort claims against manufacturers a more promising approach today than it was prior to the Court’s decision.

Since *Bates*, there is little question that most negligent testing and negligent design claims are not subject to FIFRA preemption, as most of these claims are unrelated to the pesticide label. Thus, this Section proposes a framework for pursuing negligent testing and negligent design claims specific to children’s health issues. Moreover, this Section argues that

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154. *Id.* at 1802; *see also* Brief of Amici Curiae Natural Resources Defense Council, et al. in Support of Petitioners, *supra* note 124, at 9 (quoting Letter from Lynn R. Goldman, Assistant Administrator of Environmental Protection Agency for Pesticides and Toxic Substances (Jan. 7, 1994)).

155. *Bates*, 125 S. Ct. at 1803.

courts should recognize the precautionary principle embedded in the FQPA and use it to exercise their discretion under *Daubert*, allowing such cases to reach a jury. The burden of proof should then be shifted to defendant manufacturers where the lack of “ideal” data can be attributed to the defendant.

#### A. DEFECTIVE DESIGN AND NEGLIGENT TESTING CLAIMS

Even before the *Bates* decision, the majority of state and federal courts around the country had held that unlike claims for failure to warn or breach of warranty that were based on alleged deficiencies in the pesticide label, claims for negligent design or negligent testing not based on label defects were free from FIFRA preemption.<sup>156</sup> Although some other courts held that if such a claim might have the “effect” of causing the manufacturer to change the label, thereby preempting the claim, such reliance on an “effects-based” test for preemption appears to have been overruled by *Bates*.<sup>157</sup>

While each state formulates the cause of action slightly differently, claims for defective design generally allege that

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156. See, e.g., *Ruiz-Guzman v. Amvac Chem. Corp.*, No. 98-35088, 2000 WL 1763212, at \*1 (9th Cir. Nov. 28, 2000); *Papas v. Upjohn Co.*, 985 F.2d 516, 520 (11th Cir. 1993); *Worm v. Am. Cyanamid Co.*, 970 F.2d 1301, 1306 (4th Cir. 1992); *Jeffers v. Wal-Mart Stores, Inc.*, 171 F. Supp. 2d 617, 621-25 (S.D. W. Va. 2001); *Lyall v. Leslie's Poolmart*, 984 F. Supp. 587, 595 (E.D. Mich. 1997); *Reutzel v. Spartan Chem. Co.*, 903 F. Supp. 1272, 1281-82 (N.D. Iowa 1995); *Helms v. Sporicidin Int'l.*, 871 F. Supp. 837, 842-44 (E.D.N.C. 1994); *Higgins v. Monsanto Co.*, 862 F. Supp. 751, 757-60 (N.D.N.Y. 1994); *Burke v. Dow Chem. Co.*, 797 F. Supp. 1128, 1141-42 (E.D.N.Y. 1992); *Kennan v. Dow Chem. Co.*, 717 F. Supp. 799, 811-12 (M.D. Fla. 1989); *Arnold v. Dow Chem. Co.*, 110 Cal. Rptr. 2d 722, 740-41 (Ct. App. 2001); *Ackerman v. Am. Cyanamid Co.*, 586 N.W.2d 208, 215-16 (Iowa 1998); *Eide v. E.I. Du Pont de Nemours & Co.*, 542 N.W.2d 769, 772 (S.D. 1996); *All-Pure Chem. Co. v. White*, 896 P.2d 697, 702 (Wash. 1995).

157. See, e.g., *Hardin v. BASF Corp.*, 397 F.3d 1082, 1086 (8th Cir. 2005) (holding defective design claim preempted as an indirect challenge to EPA-approved pesticide label); *Netland v. Hess & Clark, Inc.*, 284 F.3d 895, 900 (8th Cir. 2002) (stating that the question to ask is “whether in seeking to avoid liability for any error, would the manufacturer choose to alter the label or product” (citing *Worm v. Am. Cyanamid Co.*, 5 F.3d 744, 747-48 (4th Cir. 1993))); *Akee v. Dow Chem. Co.*, 272 F. Supp. 2d 1112, 1131-32 (D. Haw. 2003) (holding negligent testing and negligent design claims preempted as implied attacks on the pesticide label). *But see* *Bates v. Dow Agrosiences LLC*, 125 S. Ct. 1788, 1799 (2005) (rejecting “effects-based test” as having no support in FIFRA which speaks only of “requirements” (citing 7 U.S.C. § 136v(b) (2000))); *Wuebker v. Wilbur-Ellis Co.*, 418 F.3d 883, 886-87 (8th Cir. 2005) (holding, post-*Bates*, that FIFRA does not preempt plaintiff's defective design claims because legal rules underlying those claims do not require the defendant to label or package the product in any particular way).

either the product failed to perform safely when used in its intended or reasonably foreseeable manner or the defendant manufactured the pesticide knowing of the adverse health impacts.<sup>158</sup> Such claims are often coupled with claims for negligent testing alleging that the manufacturer failed to conduct appropriate testing in designing the product.<sup>159</sup>

In these cases, the remedy sought is not a change in the label that would warn future users of the potential harms of the product but a change in the design of the product itself. Some jurisdictions allow at least two ways to establish a claim for defective design—the consumer expectation test and the risk-utility test.<sup>160</sup> Under the consumer expectation test, the fact-finder considers whether the product was unsafe to an extent beyond that which would be contemplated by the ordinary consumer. Because consumer expectations rest in part on the product label, some courts held that defective design claims based on the consumer expectation test are preempted.<sup>161</sup>

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158. See *Jeffers v. Wal-Mart Stores, Inc.*, 171 F. Supp. 2d 617, 620 (S.D. W. Va. 2001) (articulating plaintiff's design defect claim as being based on the fact that even if pesticide was properly labeled in conformity with FIFRA, some humans are particularly, but unknowingly, susceptible to harmful effects of exposure to Dursban); *Arnold v. Dow Chem. Co.*, 110 Cal. Rptr. 2d 722, 736 (Ct. App. 2001) (setting out design defect claim under California law); *Ackerman v. Am. Cyanamid Co.*, 586 N.W.2d 208, 215-16 (Iowa 1998) (articulating that plaintiff's defective design claim based on allegations that proper design would have caused defendant to alter the product, not change the label).

159. See, e.g., *Bates*, 125 S. Ct. 1788, 1798 (2005) (discussing defective design and negligent testing cases together).

160. See, e.g., *Ruiz-Guzman v. Amvac Chem. Corp.*, 7 P.3d 795, 798-800 (Wash. 2000) (setting out elements of both consumer expectation test and risk-utility test for defective design claims under Washington law). *But see* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 & cmt. G (1998) (stating that under Restatement, consumer expectations do not constitute an independent standard for judging the defectiveness of product designs); DAVID G. OWEN, M. STUART MADDEN & MARY J. DAVIS, 1 MADDEN & OWEN ON PRODUCTS LIABILITY § 8:3 (3rd ed. 2000) ("Although most modern courts have abandoned consumer expectations as the basic test of design defectiveness . . . some courts occasionally still use this test in certain cases, and the test is legislatively prescribed in a small number of states." (citations omitted)).

161. See, e.g., *Ruiz-Guzman v. Amvac Chem. Corp.*, No. 98-35088, 2000 WL 1763212, at \*1 (9th Cir. Nov. 28, 2000) (finding Washington's consumer expectation test preempted by FIFRA); *Lescs v. Dow Chem. Co.*, 976 F. Supp. 393, 399 (W.D. Va. 1997) (holding defective design claim for alleged injuries from Dursban based on consumer expectation test preempted by FIFRA). *But see* *Arnold*, 110 Cal. Rptr. 2d at 742-45 (holding consumer expectation testing not preempted); RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY, *supra*

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However, there is authority based on the risk-utility test and other more general formulations of a defective design claim that can support such claims with regard to pesticides and children. Generally, a product is defective under the risk-utility test if the likelihood and seriousness of the plaintiff's harm outweighs the burden on the manufacturer to design a product that would have prevented those harms and the alternative design is both practical and feasible.<sup>162</sup>

For instance, in *Ruiz-Guzman v. Amvac Chemical Corp.*,<sup>163</sup> apple farm workers sued the manufacturer of the pesticide Phosdrin, which was used to control aphid infestations on orchards, when they sustained toxic reactions after applying the pesticide.<sup>164</sup> The Washington Supreme Court accepted certification of a question of state law from the Ninth Circuit Court of Appeals regarding whether a plaintiff may rely upon an alternative product for purposes of a risk-utility test applied under Washington law.<sup>165</sup> The supreme court answered in the affirmative, holding that the plaintiff could establish Phosdrin was defectively designed and unreasonably dangerous based on the availability of other *pesticides*, not simply the availability of alternate *formulations* (designs) for the pesticide at issue.<sup>166</sup>

In so holding, the court stated that the plaintiff was allowed to establish that safer pesticides could serve the same purpose as the pesticide at issue, thus tending to show that Phosdrin was defectively designed.<sup>167</sup> Although the defendant argued such alternatives were not reasonable because a competitor had both owned the patent and allowed its EPA registration to lapse, the court held that this did not mean the defendant "was free to introduce an alternative means of killing aphids with indifference to its greater risk of harming

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note 160.

162. See *Ruiz-Guzman*, 7 P.3d at 798 (applying Washington law); RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY, *supra* note 160, § 2(b) (noting that a product "is defective in design when the foreseeable risks of harm . . . could have been reduced or avoided by the adoption of a reasonable alternative design . . . and the omission of the alternative design renders the product not reasonably safe").

163. 7 P.3d 795 (Wash. 2000).

164. See *id.* at 797. Within a year after the plaintiffs sustained their injuries, the State of Washington temporarily suspended the use of Phosdrin, and the manufacturer requested that EPA cancel the registration. The pesticide can no longer be used in the United States. See *id.*

165. See *id.*

166. See *id.* at 801.

167. See *id.* at 800.

humans.”<sup>168</sup> Moreover, the plaintiff was not obligated to prove that the safer elements of the alternative product could be incorporated into the defendant’s product, but only that other, safer products were in fact reasonably available.<sup>169</sup>

Similarly, in a recent case from the District Court for the Southern District of Alabama, the court held that a defective design claim could proceed to trial when the plaintiff died after allegedly inhaling toxic fumes from a floor cleaner containing sulfuric and hydrochloric acid that she was using at home.<sup>170</sup> In analyzing the defective design claim, the court held the plaintiff could prove that a safer, practical, alternative design was available to the manufacturer when it manufactured the product.<sup>171</sup> In finding sufficient evidence for trial, the court referred to testimony by both parties’ experts that the sulfuric and hydrochloric acids in the product rendered the product hazardous and that the product was unique among household rust removers in containing those substances.<sup>172</sup> Although the court noted that exploration of the evidence would be necessary at trial to determine whether the plaintiff could meet her burden of proof, the evidence was sufficient to overcome the defendant’s summary judgment motion.<sup>173</sup>

To the extent certain products pose more risks to children than others, the risk-utility theory supports using the less harmful products as evidence that the more harmful products are defectively designed. For instance, numerous pesticides including dieldrin, aminocarb, captan, carbaryl, lindane, malathion, and dichlorophos can induce changes in the immune and nervous systems, particularly those of infants and children.<sup>174</sup> To the extent other pesticide products that are not immunotoxic or neurotoxic are reasonably available to control target pests, such availability can be used to support the risk-utility theory for a defective design claim.

In other defective design cases, courts have focused less on

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168. *Id.*

169. *See* Ruiz-Guzman, 7 P.3d at 798.

170. *See* Gougler v. Sirius Prods., Inc., 370 F. Supp. 2d 1185, 1200 (S.D. Ala. 2005).

171. *See id.*

172. *See id.*

173. *See id.*

174. *See* NRDC Comments, *supra* note 33, at 8 (citing WORLD HEALTH ORG., WHO REGIONAL OFFICE FOR EUROPE AND EUROPEAN ENVIRONMENT AGENCY PRESENT CHILDREN’S HEALTH AND ENVIRONMENT: A REVIEW OF EVIDENCE (Apr. 2002)).



the specific elements of the defective design claims and more on the relationship between FIFRA and state tort law. For instance, in *Burke v. Dow Chemical Co.*,<sup>175</sup> the plaintiff alleged that her twin children were born severely brain damaged after she was exposed to Dursban when her home was sprayed to exterminate insects.<sup>176</sup> In denying the defendants' motion for summary judgment on the plaintiff's tort claims,<sup>177</sup> the District Court for the Eastern District of New York began its analysis by noting that protection of the public against toxic substances has traditionally been a matter left to the states.<sup>178</sup> Those states, moreover, have developed rules to compensate for injuries and "help deter injurious behavior in a complex industrial environment," where technology exceeds the average person's ability to protect against dangers.<sup>179</sup> The court contrasted this state system with federal legislation, which does not have a comprehensive program to compensate persons injured by hazardous products, and federal agencies, which neither arrange for their own testing of products nor "put their seal of approval" on products.<sup>180</sup> As a result, consumers must "still look to the great font of state tort law for protection against harmful toxic substances."<sup>181</sup>

In analyzing the plaintiff's claims under the risk-utility test for defective design, the court rejected the argument that compliance with federal standards immunizes a manufacturer from state tort liability. Simply because the EPA determines a pesticide "will perform its intended function without unreasonable adverse effects on the environment" does not "supplant the state's power to render a judgment as to the relative risks and benefits of the product."<sup>182</sup> Moreover, the court noted that with regard to testing, it is the applicants who submit scientific data and draft product labels, and EPA does not attempt to independently verify the test data provided.<sup>183</sup> As a result, "EPA oversight will not be nearly as protective of

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175. 797 F. Supp. 1128 (E.D.N.Y. 1992).

176. *See id.* at 1131.

177. *See id.* at 1134.

178. *See id.* at 1131-32.

179. *Id.* at 1132.

180. *See id.* at 1132.

181. *Burke*, 797 F. Supp. at 1132.

182. *Id.* at 1142 (quoting 7 U.S.C. § 136a(c)(5)(C)).

183. *See Burke*, 797 F. Supp. at 1132.

persons exposed to pesticides as state tort law.”<sup>184</sup>

Similarly, in *Arnold v. Dow Chemical Co.*,<sup>185</sup> the California Court of Appeals held that the plaintiff’s defective design claim was not preempted because it was based on the argument that Dursban should not have been used in the plaintiff’s home because it was unreasonably dangerous, its harms outweighed the benefits, and the plaintiff’s birth defects could have been prevented if Dursban had not been used.<sup>186</sup> The court also rejected the argument that simply because EPA registers the pesticide at issue, the manufacturer can avoid a determination that it is defectively designed under state law.<sup>187</sup>

Finally, in 1998 the Iowa Supreme Court held that claims for negligent testing against a herbicide manufacturer for alleged crop loss could go forward based on testimony from the plaintiff’s expert that numerous studies were available to the pesticide manufacturer showing the pesticide was not adequately degradable in certain weather conditions.<sup>188</sup> However, the manufacturer allegedly rushed the product onto the market without sufficient testing so that farmers would purchase its product instead of that of its competitors.<sup>189</sup> In reaching its holding, the court rejected the manufacturer’s argument that the plaintiff should “lose his claim on the merits because testing is so closely superintended by EPA.”<sup>190</sup> Instead, the court held that such cases should only be dismissed on a showing that the agency in fact “supplanted the manufacturer in matters of design and testing.”<sup>191</sup>

Indeed, the D.C. Circuit Court of Appeals articulated these same principles—that state tort law retains an important role despite the federal regulation of pesticides—in the *Ferebee* case decided in 1984,<sup>192</sup> which the *Bates* opinion cited with approval.<sup>193</sup> In *Ferebee*, the court of appeals affirmed a verdict for the plaintiff on his claim that long-term exposure to the

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184. *Id.* at 1135.

185. 110 Cal. Rptr. 2d 722 (Ct. App. 2001).

186. *See id.* at 738.

187. *See id.* at 746.

188. *See Ackerman v. Am. Cyanamid Co.*, 586 N.W.2d 208, 215 (Iowa 1998).

189. *See id.*

190. *Id.* at 216.

191. *Id.*

192. *See Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529 (D.C. Cir. 1984).

193. *See Bates v. Dow Agrosiences LLC*, 125 S. Ct. 1788, 1802 (2005).

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pesticide paraquat led to his contracting pulmonary fibrosis, and Chevron had failed to warn him of the dangers.<sup>194</sup> The court focused both on Chevron's knowledge of the dangers of paraquat at the time the plaintiff used the product and the relationship between state tort law and FIFRA.<sup>195</sup> With regard to Chevron's knowledge, the court found it highly relevant that Chevron had known the pesticide could cause the type of lung disease the plaintiff suffered and that the pesticide selectively attacks the lungs when it enters the body.<sup>196</sup> The court also focused on the reports and data in Chevron's files regarding other incidents of paraquat exposure and held that such knowledge imparted a legal duty.<sup>197</sup>

As for the relationship between state tort law and FIFRA, the court rejected the argument that EPA's registration of paraquat constituted an expert, federal determination that the product did not pose an unreasonable risk to the normal user.<sup>198</sup> Instead, the court recognized that the purpose of FIFRA is to ensure that, from a cost-benefit point of view, paraquat as labeled does not produce "unreasonable adverse effects on the environment" while state tort law "may have broader, compensatory goals."<sup>199</sup> Indeed, EPA was required to assign a "cost value" to the pesticide's risks and estimate the benefits at large to society, but there is no need for a court or a jury to "strike the same balance on these difficult questions as EPA."<sup>200</sup> The court went on to note that assignment "of values to such 'soft' variables as human health is among the most difficult tasks faced in a regulatory society."<sup>201</sup>

Finally, the court stated that tort recovery may also encourage plaintiffs to bring suits for injuries "not previously recognized as traceable" to the pesticide at issue which may "aid in the exposure of new dangers associated with pesticides."<sup>202</sup> Successful lawsuits of this kind may lead manufacturers to change their labeling or registration with EPA or cause EPA itself to require changes. Moreover, the

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194. See Ferebee, 736 F.2d at 1532.

195. See *id.* at 1536, 1539.

196. See *id.* at 1536-38.

197. See *id.* at 1537.

198. See *id.* at 1540.

199. *Id.*

200. Ferebee, 736 F.2d at 1540.

201. *Id.*

202. *Id.* at 1541.

threat of damages actions may provide manufacturers with added “dynamic incentives to continue to keep abreast of all possible injuries stemming from use of their product so as to forestall such actions through product improvement.”<sup>203</sup> It was this language in the *Ferebee* case that the Supreme Court cited with approval in *Bates*.<sup>204</sup>

Although *Ferebee* was rarely cited, except with disapproval, between the 1992 *Cipollone* decision and the 2005 *Bates* decision,<sup>205</sup> the Supreme Court’s positive reference to the case bodes well for efforts to utilize state tort actions, particularly defective design and negligent testing claims. Such claims, which will very seldom be subject to FIFRA preemption, can be used to pursue relief on behalf of children injured by pesticides and play a role in prompting manufacturers to engage in additional testing to defend against liability or remove those products from the market. Indeed, in *Bates*, the Supreme Court had little difficulty holding that rules requiring manufacturers to use due care in both conducting appropriate testing of their products and designing products in a reasonably safe manner are not subject to preemption and can provide incentives for better testing and products.<sup>206</sup>

#### B. USING *BATES* AND THE FQPA TO PROMOTE CHILDREN’S HEALTH IN THE COURTS BY SHIFTING THE BURDEN OF PROOF

While the obstacle of FIFRA preemption has certainly lessened in the wake of *Bates*, the scientific evidence barriers remain, and plaintiffs still need to get past *Daubert* motions to obtain compensation and help shape corporate behavior in the future. Thus, one remaining question is how scientists and nonprofit groups, who have previously focused their efforts on encouraging EPA to set more protective standards, can now turn some of those efforts to tort law to help impose those standards through the courts.

First, significant evidence has been gathered since the 1993 NAS study showing the risk pesticides pose to children. Some of this evidence is general, and other evidence is more specific—either to disease outcomes or to chemicals. For

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203. *Id.* at 1541-42.

204. *See* *Bates v. Dow Agrosciences LLC*, 125 S. Ct. 1788, 1802 (2005).

205. *See, e.g., MacDonal v. Monsanto Co.*, 27 F.3d 1021 (5th Cir. 1994); *DerGazarian v. Dow Chem. Co.*, 836 F. Supp. 1429 (W.D. Ark. 1993).

206. *See* *Bates*, 125 S. Ct. at 1798, 1802.

instance, researchers have linked environmental toxicant exposure to higher rates of low birth weight, intellectual impairment, and behavioral problems,<sup>207</sup> but EPA currently does not require “development neurotoxicity testing” using even animal experiments to provide information on how a particular chemical impacts the fetal and newborn nervous system.<sup>208</sup> In its most recent proposed regulations setting data requirements for pesticide registration, EPA included tests for developmental neurotoxicity (DNT). Such tests are not a “core” requirement but only a “conditional requirement” if other tests (which generally are less sensitive) show indications that the pesticide may result in development neurotoxicity.<sup>209</sup> Because EPA does not require this testing in connection with pesticide and other chemical registration, the most basic toxicity tests in animals are lacking for seventy-five percent of the 3,000 highest production chemicals, despite the fact that EPA acknowledges that over 140 registered pesticides are neurotoxic.<sup>210</sup>

At the same time, the European Union is proposing a much stricter regulatory framework for industrial chemicals. Under the proposal, both European and non-European manufacturers doing business in Europe would be required to submit extensive toxicity data for tens of thousands of chemicals on the market.<sup>211</sup> That such testing protocols are currently available and such data will soon exist in regulatory systems outside the United States can be used to support both negligent testing claims and defective design claims on grounds that such testing is reasonably available and would likely result in safer chemicals being designed and used in the United States.<sup>212</sup>

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207. See Lanphear, *supra* note 1, at 203.

208. See *id.* at 205; see also SCHETTLER ET AL., *supra* note 108, at 108-12 (discussing lack of toxicity data for registered chemicals and noting that “[i]t is not that there is a lack of accepted methods for testing developmental neurotoxicity”); WALLINGA, *supra* note 4, at 61 (discussing a developmental neurotoxicity study and stating that even though the study was extensively validated years ago, EPA has received data from development neurotoxicity testing for only six pesticides, with no such data on the many pesticides in use already known to be toxic to the nervous system).

209. See, e.g., Pesticides: Data Requirement for Conventional Chemicals, 70 Fed. Reg. 12,276, 12,343-45 (Mar. 11, 2005) (showing DNT as conditionally required and setting forth those conditions); Learning Disabilities Ass'n of America, Comments Re: 40 CFR Parts 152 and 158 at 3-6, <http://www.epa.gov/edocket> (Docket ID No. OPP-2004-0387).

210. See Lanphear, *supra* note 1, at 204.

211. See REACH, *supra* note 36.

212. See WALLINGA, *supra* note 4, at 61-62 (discussing the fact that the

Indeed, while EPA may or may not choose to regulate based on data collected in European countries, there is no reason such evidence would not be admissible in litigation.

Moreover, there is a growing call among academics, scientists, and policymakers that *Daubert* and our current tort system generally is contributing to an “environmental and human health crisis.”<sup>213</sup> Some have proposed that the burden of proof in toxic tort cases be modified where chemicals, including pesticides, are released into the environment and the manufacturer has failed to conduct the type of studies that would help prove or disprove a causal link between the chemical and physical harm.<sup>214</sup> In those circumstances, it would be the defendant manufacturer, not the plaintiff, who would bear the burden of scientific uncertainty.<sup>215</sup> In other words, “proof of a failure to discover and disseminate adequate health information about a substance stands in for proof of causation of harm.”<sup>216</sup> Thus, once the plaintiff makes a prima facie showing that the defendant released an inadequately investigated chemical into the environment and the plaintiff was exposed to that chemical, the defendant could avoid liability by disproving general causation or showing the plaintiff’s illness was caused by other factors.<sup>217</sup>

While such proposals may be appealing to those who are

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developmental neurotoxicity study protocol to assess the effects of pesticides on the developing brain and nervous system has been extensively validated for years, but EPA still does not require developmental neurotoxicity data for most pesticides, even those already known to be toxic to the nervous system).

213. See, e.g., Lynda M. Collins, *Strange Bedfellows? The Precautionary Principle and Toxic Tort: A Tort Paradigm for the 21st Century*, 35 ENVTL. L. REP. 10,361, 10,361-62 (2005); see also JOE THORNTON, PANDORA’S POISON: CHLORINE, HEALTH, AND A NEW ENVIRONMENTAL STRATEGY 117-20 (2000); George P. Lakoff, *A Cognitive Scientist Looks at Daubert*, 95 AM. J. PUB. HEALTH S114, S116-S117 (Supp. 1 2005) (arguing that *Daubert* and *Joiner* allow the judge, not the jury, to decide the case, discourage scientists from testifying at trial, and remove inherent fairness in the trial process).

214. See Collins, *supra* note 213, at 10,370.

215. See *id.*; see also Margaret A. Berger, *Eliminating General Causation: Notes Towards a New Theory of Justice and Toxic Torts*, 97 COLUM. L. REV. 2117, 2133-34, 2143 (1997) (proposing to eliminate the general causation requirement in toxic tort cases and imposing liability on defendants for failure to provide substantial information relating to risk); Lynda Collins, *Material Contribution to Risk and Causation in Toxic Torts*, 11 J. ENVTL. L. & PRAC. 105, 140 (2001); James M. Olson, *Shifting the Burden of Proof: How the Common Law Can Safeguard Nature and Promote an Earth Ethic*, 20 ENVTL. L. 891 (1990).

216. Collins, *supra* note 213, at 10,370.

217. See *id.*

frustrated with the inability of plaintiffs to prevail in many meritorious cases, they also are a significant departure from current tort law doctrine without any statutory or common law basis to support such a radical shift. Some may also criticize the fairly low burden placed on the plaintiff (mere exposure) to qualify for entitlement to shift the burden of proof.

Although these are obviously difficult issues, they seem somewhat less difficult in the context of pesticides and children's health because of the statutory support in the FQPA and because pesticide manufacturers are in the best position to provide the necessary scientific data.<sup>218</sup> Although FIFRA provides for a cost-benefit analysis in registering pesticides, the FQPA imposes an overlay of the precautionary principle when it comes to children's health impacts, as earlier discussed. While one may argue this should only apply to the tolerance standards EPA sets for individual pesticides, there is a good argument that the statute itself sets a different policy direction for scientific uncertainty when it comes to children's health in general. The statute, along with basic principles of fairness, provide ample room to consider some measure of burden-shifting in at least this narrow category of cases, allowing judges to err on the side of letting cases involving children's health go to the jury in the absence of "perfect" data establishing causation.

The task, then, is to create a judicial framework for state common law tort claims in which courts can evaluate not only the available scientific evidence but also any limitations on that evidence, such as the ethical concerns regarding testing on humans discussed earlier. The court could also evaluate the defendant's failure to undertake reasonable and available testing. Once the defendant's failure to undertake reasonable testing becomes relevant in response to a *Daubert* challenge, as well as causation in general, courts will become better educated with regard to evaluating the benefits and shortcomings of different types of scientific evidence (such as epidemiological versus various animal studies). Moreover, this inquiry has the potential to place significant incentives on pesticide manufacturers to conduct any testing identified by plaintiffs to avoid any burden-shifting in the case.

Courts could thus implement the following framework. The plaintiff would establish at a pretrial hearing initiated by

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218. *See id.*

the plaintiff or in response to a *Daubert* challenge that testing protocols are available or could reasonably be developed to test for the harm suffered by the plaintiff, but the defendant has neither conducted such testing nor shown similar data through other testing mechanisms that already exist. At that point, the plaintiff, through the introduction of expert testimony on the negligent testing issue, will have satisfied his burden under *Daubert*, or the applicable state standard, and the court would then shift the burden of proof on causation to the defendant at trial. In other words, the plaintiff would be entitled to a rebuttable presumption that the defendant's failure to conduct the testing was negligent, and that the testing would have resulted in data not already available that would cause a reasonable manufacturer to take the pesticide off the market or use a less harmful design that would not have caused the plaintiff's injury.

The process proposed here is not as sweeping or as comprehensive as the burden-shifting proposals previously discussed with regard to hazardous chemicals in general. However, the proposal outlined here has several benefits. First, it draws upon some statutory support, the FQPA, where the precautionary principle is strong. Second, it is within a process similar to a *Daubert* hearing, with which courts and litigants are already familiar. Third, it is a much less radical departure from current tort law jurisprudence because uncertainty alone is not enough to shift the burden of proof. Instead, the plaintiff must point to specific testing or data collection for evidence not already available through other means that the manufacturer could have conducted to shift the burden of proof. While this proposal is certainly a smaller step and would apply in a much narrower category of cases, it is a step that may be easier for courts to actually implement within our current jurisprudential framework.

Such a framework would encourage pesticide manufacturers to engage in reasonably available testing not already required by EPA in order to meet its burden to disprove causation. This would place the burden of collecting scientific data regarding the pesticide on the party in the best position to bear it. When one considers that it is the defendant manufacturer who has introduced the pesticide into the stream of commerce and is collecting the profits, such a framework does not seem unreasonable. Doing so would allow the tort system to work as the Supreme Court promised in *Bates*—to



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put additional pressure on manufacturers to investigate and improve their products or be subject to potential liability in the face of scientific uncertainty they are in the best position to remedy.<sup>219</sup>

### C. THE PROMISE OF BURDEN-SHIFTING: PROPOSITION 65 AND CERCLA

California Proposition 65, or the Safe Drinking Water and Toxic Enforcement Act of 1986,<sup>220</sup> illustrates that shifting the burden of proof in civil liability cases can create sufficient incentives for manufacturers to collect and make available valuable data on environmental health risks and causation. The law is most well-known for the requirement that businesses give “clear and reasonable warning” to anyone they expose to chemicals known to cause cancer or reproductive toxicity.<sup>221</sup> Such warnings must be attached to the product itself, prominently displayed where the product is sold or used, or conveyed to the public in other ways through notices in the public news media, provided the warning is “clear and reasonable.”<sup>222</sup>

Businesses have had great difficulty complying with the warning requirements for environmental exposures, because they are forced to determine the affected area of emissions as well as the appropriate method of warning under the circumstances for all chemicals subject to the law.<sup>223</sup> Penalties

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219. See *Bates v. Dow Agrosciences LLC*, 125 S. Ct. 1788, 1801-02 (2005).

220. CAL. HEALTH & SAFETY CODE §§ 25249.5-.13 (2004). California voters adopted the law by ballot initiative in 1986. See Michael Barsa, Note, *California's Proposition 65 and the Limits of Information Economics*, 49 STAN. L. REV. 1223, 1223-24 (1997).

221. See CAL. HEALTH & SAFETY CODE § 25249.6; see also Bradley C. Karkkainen, *Information-Forcing Environmental Regulation*, 33 FLA. ST. U. L. REV. (forthcoming 2005); Clifford Rechtschaffen, *The Warning Game: Evaluating Warnings Under California's Proposition 65*, 23 ECOLOGY L.Q. 303 (1996); Barsa, *supra* note 220, at 1227-35.

222. See CAL. HEALTH & SAFETY CODE §§ 25249.6, 25249.11(f); see also *Ingredient Commc'ns Council, Inc. v. Lungren*, 2 Cal. App. 4th. 1480, 1495-96 (Ct. App. 1992) (holding toll-free telephone information system does not per se satisfy the warning requirement for use of chemicals covered by the law).

223. See CAL. CODE REGS. tit. 22, § 12601 (2002); see also *Consumer Cause, Inc. v. Smilecare*, 110 Cal. Rptr. 2d 627, 644-45 (Ct. App. 2001) (reversing summary judgment for defendant in case where defendant dental care providers were alleged to have violated Proposition 65 for failing to warn of mercury contained in “silver filling” dental amalgam because providers had not contended that they had performed a qualitative risk assessment, as was their burden, to establish the numeric level for “no observable reproductive

for providing an insufficient warning, which is an issue of fact for the jury, are up to \$2,500 per day, and private citizens as well as the government may initiate a suit for an alleged violation.<sup>224</sup>

The law's relevance to this Article is the exemption it provides to businesses to avoid these indeterminate warning requirements. The law states in relevant part that a warning is not required for any discharge or release where the responsible person can show the exposure poses "no significant risk" of cancer, assuming a lifetime exposure at the level in question, and the exposure will have "no observable effect" with regard to reproductive toxicity, assuming exposure at 1000 times the level in question.<sup>225</sup> Thus, to avoid the potential legal liability imposed by the law's warning requirements, the burden is placed on the manufacturer or other business to establish based on "evidence and standards of comparable scientific validity"<sup>226</sup> that the chemical poses no significant risk or no observable reproductive effect.

In order to take advantage of this exception to the warning requirement, the law authorizes California's Office of Environmental Health and Hazard Assessment (OEHHA)<sup>227</sup> to establish numerical exposure thresholds that will constitute the statutory "no significant risk" standards.<sup>228</sup> However, the burden is placed on businesses to provide adequate data to the regulators to convince them to set such numerical thresholds.<sup>229</sup> Thus, the law has "shifted the burden of proof" to the business sector to provide sufficient scientific data to avoid the threat of liability from a multitude of lawsuits over inadequate warnings.

In doing so, California has given significant incentives to the business and manufacturing sector to collect data and provide it to regulators in order to set numeric standards as quickly as possible for a whole host of chemicals to show that their emissions are under the "no risk" levels and thus "safe."<sup>230</sup>

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effects" from mercury).

224. See CAL. HEALTH & SAFETY CODE § 25249.7.

225. See CAL. HEALTH & SAFETY CODE § 25249.10(c).

226. *Id.*

227. See CAL. CODE REGS. tit. 22, pmb1. (2002).

228. See *id.* at tit. 22, § 12701.

229. See CAL. HEALTH & SAFETY CODE § 25249.10(c) (2004) ("In any action brought to enforce Section 25249.6, the burden of showing that an exposure meets the criteria of this subdivision shall be on the defendant.").

230. See CAL. CODE REGS. tit. 22, § 12703 (setting forth Quantitative Risk

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This is very different from the current framework under federal pesticide law and other environmental health and safety laws, where the government and private plaintiffs bear the burden of collecting data to either set regulatory standards or prove the product has caused harm in the context of a lawsuit.

Under Proposition 65, California has received sufficient scientific data to establish nearly 300 numeric standards for toxic pollutants without any legal challenge, prompting a review panel to state that “by federal standards, Proposition 65 has resulted in 100 years of progress in the areas of hazard identification, risk assessment and exposure assessment.”<sup>231</sup> Thus, California’s system creates uncertainty and legal liability for product manufacturers and their customers and then places the burden of proof on them to provide the data to set safety standards for those products to avoid that uncertainty and potential liability.

Other examples of burden-shifting in the environmental law and toxic tort context exist as well. For instance, even though the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)<sup>232</sup> does not expressly state that it imposes strict, joint, and several liability on owners, operators, arrangers, and transporters of hazardous substances, courts have interpreted the law to impose such liability.<sup>233</sup> As a result, once the plaintiff establishes that the defendant falls within one of the classes of persons subject to potential liability, each defendant bears the burden of disproving that its actions resulted in a release of a hazardous substance.<sup>234</sup> As one court has stated, even though placing the burden of proof with regard to causation and divisibility of harm may result in many defendants paying more than their

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Assessment requirements to determine the level of exposure that constitutes “no significant risk” of cancer for a chemical); §§ 12701-12711 (authorizing agency adoption of “no significant risk” levels for carcinogens); §§ 12801-12805 (authorizing agency adoption of acceptable exposure levels for reproductive toxicants).

231. Barsa, *supra* note 220, at 1240; *see also* Clifford Rechtschaffen, *How to Reduce Lead Exposures with One Simple Statute: The Experience of Proposition 65*, 29 *Envtl. L. Rep. (Envtl. Law Inst.)* 10,581, 10,581 (1999) (stating that Proposition 65 “has spurred faster and more significant lead reductions than federal law by prompting companies to reformulate products and change their manufacturing processes”).

232. 42 U.S.C. §§ 9601-9675 (2000).

233. *See* PERCIVAL ET AL., *ENVIRONMENTAL REGULATION: LAW, SCIENCE, AND POLICY* 257-58 (4th ed. 2003).

234. *See id.* at 258.

fair share, “Congress intended for those proven at least partially culpable to bear the cost of the uncertainty.”<sup>235</sup>

#### D. EXAMPLES OF COMMON LAW BURDEN-SHIFTING

While the examples above show how statutory burden-shifting can create real incentives for chemical manufacturers and others to produce valuable data, some may question whether it is appropriate for courts to shift the burden of proof to create such incentives as a matter of common law. However, a review of the case law reveals that courts have relied on the common law to shift the burden of proof to promote important policy goals, even in the absence of a statutory mandate like that found in Proposition 65.

For instance, in the tort law context, the landmark cases of *Summers v. Tice*<sup>236</sup> and *Sindell v. Abbott Laboratories*<sup>237</sup> show courts using their authority under the common law to place the burden of proof on the party best able to bear it. In *Summers*, the plaintiff sought recovery for an eye injury from two hunters, both of whom were hunting and only one of whom hit the plaintiff with a shot.<sup>238</sup> The trial court held that both defendants were liable for negligence, and that the plaintiff was not contributorily negligent.<sup>239</sup> On appeal, the defendants argued that because they were not acting in concert, they were not joint tortfeasors and could not be held jointly and severally liable.<sup>240</sup> In rejecting this argument, the California Supreme Court held that ordinarily “defendants are in a far better position to offer evidence to determine which one caused the injury,” and principles of “policy and justice” supported shifting the burden of proof on both causation and allocation of damages to the defendants.<sup>241</sup> The court further reasoned that if determining causation and proper apportionment of damages was difficult or incapable of proof, “the innocent wronged party should not be deprived of his right to redress,” and “the wrongdoers are not in a position to complain of uncertainty.”<sup>242</sup>

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235. O’Neil v. Picillo, 883 F.2d 176, 179 (1st Cir. 1989).

236. 199 P.2d 1 (Cal. 1948).

237. 607 P.2d 924 (Cal. 1980).

238. See *Summers*, 199 P.2d at 1-2.

239. See *id.* at 2.

240. See *id.*

241. *Id.* at 4-5.

242. *Id.* at 5; see also RESTATEMENT (SECOND) OF TORTS § 433B(3) (1965) (adopting rule from *Summers*).

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In *Sindell*, the named plaintiff in a class sought damages against drug companies seeking to recover for injuries sustained as a result of her mother taking the drug diethylstilbesterol (DES) during pregnancy.<sup>243</sup> The plaintiff was able to identify the drug involved but not the manufacturer of the precise product ingested.<sup>244</sup> On appeal from the dismissal of the action, the California Supreme Court began with the proposition that generally, imposition of liability depends on the plaintiff's ability to show that an act by the defendant caused her injuries.<sup>245</sup> The court then noted exceptions to this rule, such as the rule of *Summers v. Tice*, market-based liability, and concert of action theories, but concluded that none of those theories could help the plaintiff because she had not joined all of 200 or more DES manufacturers in the lawsuit.<sup>246</sup>

However, the court held that despite the absence of an existing theory of recovery for the plaintiff, the court was not willing to affirm the lower court's dismissal, noting that "[i]n our contemporary complex industrialized society, advances in science and technology create fungible goods which may harm consumers and which cannot be traced to any specific producer."<sup>247</sup> The court went on to proclaim that "[t]he response of the courts can be either to adhere rigidly to prior doctrine, denying recovery to those injured by such products, or to fashion remedies to meet these changing needs."<sup>248</sup> The court proceeded to set out a modified theory of market share liability that shifted the burden to the defendants to prove that they could not have caused the plaintiff's harm once the plaintiff established negligence or strict liability with regard to the drug in general.<sup>249</sup> This theory was based in part on a 1978 article in the *Fordham Law Review* setting forth a framework for liability in DES cases.<sup>250</sup> Thus, the court concluded that as between an innocent plaintiff and negligent defendants, the latter should bear the cost of the injury and that "[f]rom a

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243. See *Sindell*, 607 P.2d at 925.

244. See *id.* at 926.

245. See *id.* at 928.

246. See *id.* at 930-35.

247. *Id.* at 936.

248. *Id.*

249. See *Sindell*, 607 P.2d at 936-37.

250. See *id.* at 927, 936-38 (citing Comment, *DES and a Proposed Theory of Enterprise Liability*, 46 *FORDHAM L. REV.* 963 (1978)).

broader policy standpoint,” defendants were better able to bear the cost of injury resulting from the creation of a defective product.<sup>251</sup>

Although courts have not universally adopted the rules set out in *Summers* and *Sindell*,<sup>252</sup> these decisions are significant as examples of courts using the common law to shift the burden of proof when plaintiffs are not at fault for the lack of evidence on causation and the defendants are in a better position to bear that risk.

Such use of burden-shifting to develop the common law is not limited to the tort arena. In the famous case of *O’Keeffe v. Snyder*,<sup>253</sup> the New Jersey Supreme Court determined that a strict application of the doctrine of adverse possession should no longer apply to cases involving recovery of chattels.<sup>254</sup> The court reasoned that the existing adverse possession rule, which placed the burden of proof on the adverse possessor to show her possession was hostile, actual, visible, exclusive, and continuous, was unworkable in the context of personal property, which is often kept in a home or other private place.<sup>255</sup> The facts of this case involved an alleged theft of a Georgia O’Keeffe painting that was later transferred to a bona fide purchaser.<sup>256</sup> In that context, the court found that a burden of establishing a continuous public display of a work of art to obtain rights of possession after expiration of the statute of limitations for replevin would impose too a heavy burden on the purchaser, who wished to enjoy the painting in her own home.<sup>257</sup>

The court thus modified the common law doctrine to place

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251. See *Sindell*, 607 P.2d at 936; see also *Beshada v. Johns-Manville Prods. Corp.*, 447 A.2d 539, 549 (N.J. 1982) (shifting burden of proof on causation to defendant in asbestos litigation case because manufacturer had been in a position to conduct additional safety research and had failed to do so); Mary L. Lyndon, *Information Economics and Chemical Toxicity: Designing Laws to Produce and Use Data*, 87 MICH. L. REV. 1795, 1817-18 (1989) (discussing *Beshada* case in the context of product liability rules and statutory frameworks that can be used to provide incentives to manufacturers to collect improved toxicity data on their chemicals and products).

252. See DAN B. DOBBS, *THE LAW OF TORTS* 428-32 (2000) (providing examples of courts placing strict limits on application of rule in *Summers* and *Sindell* or rejecting the doctrines altogether).

253. 416 A.2d 862 (N.J. 1980).

254. See *id.* at 872.

255. See *id.* at 871.

256. See *id.* at 865-66.

257. See *id.* at 871.

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the burden of proof on the plaintiff to show she had taken diligent steps to investigate and recover the painting or other chattel.<sup>258</sup> In altering the doctrine, the court was persuaded “that the introduction of equitable considerations through the discovery rule provides a more satisfactory response than the doctrine of adverse possession.”<sup>259</sup> The court was very clear that its decision was a departure from prior doctrine and stated that the decision “not only changes the requirements for acquiring title to personal property . . . but also shifts the burden of proof” to the owner, as the one seeking the benefit of the discovery rule.<sup>260</sup> Thus, the New Jersey court, like the California courts in *Summers* and *Sindell*, used the common law to shape a doctrine that better reflected the realities and social policy concerns of the day.<sup>261</sup>

There is ample precedent, then, for state common law to take on this issue and use principles of burden-shifting to allow innocent plaintiffs to obtain compensation and force defendants to bear the burden of insufficient data, thereby creating incentives to obtain better data. Moreover, there is no reason that state common law courts cannot use the existence of the FQPA as an additional reason to support a move in favor of shifting the burden of proof as a matter of state common law. Indeed, the scholarly literature and Supreme Court decisions have historically recognized the use of statutory developments to support a shift in the common law. As the Supreme Court has stated, “[i]t has always been the duty of the common-law court to perceive the impact of major legislative innovations and to interweave the new legislative policies with the inherited body of common-law principles.”<sup>262</sup>

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258. *See id.* at 872.

259. O’Keeffe, 416 A.2d at 872.

260. *Id.* at 873.

261. *See* BENJAMIN N. CARDOZO, THE NATURE OF THE JUDICIAL PROCESS 152 (1921) (“If judges have wofully [sic] misinterpreted the *mores* of their day, or if the *mores* of their day are no longer those of ours, they ought not to tie, in helpless submission, the hands of their successors.”). “I think that when a rule, after it has been duly tested by experience, has been found to be inconsistent with the sense of justice or with the social welfare, there should be less hesitation in . . . full abandonment.” *Id.* at 150.

262. *Moragne v. States Marine Lines, Inc.*, 398 U.S. 375, 392 (1970); *see* WILLIAM N. ESKRIDGE, JR. & PHILIP P. FRICKEY, CASES AND MATERIALS ON LEGISLATION: STATUTES AND THE CREATION OF PUBLIC POLICY 398-406 (2d ed. 1995) (presenting *Moragne* in the context of discussing statutes as a source of policy norms); Frank E. Horack, Jr., *The Common Law of Legislation*, 23 IOWA L. REV. 41, 54 (1937) (arguing that courts should “use the statutory

Following from this precedent, there is increasing evidence that courts do in fact apply principles contained in federal and state environmental statutes when developing common law principles in the area of environmental law. For instance, even though strict liability has been losing ground among courts in favor of negligence theory as a general matter, the trend in environmental contamination cases appears to be the opposite.<sup>263</sup> This is because since the enactment of CERCLA in 1980, courts have become increasingly more comfortable applying strict liability in contamination cases as a result of the judicial interpretations of CERCLA described above. A review of the case law shows that these same courts have used CERCLA to develop the common law doctrine of strict liability and to apply that standard of liability more frequently in environmental cases.<sup>264</sup> There is an equal ability within the common law tort system to place a similar incentive on manufacturers to collect and evaluate scientific data.

For burden-shifting to succeed in the context of a toxic tort case, however, nonprofit groups and academics in this area must work more closely with plaintiffs' lawyers to help provide the testimony and background on scientific uncertainty in the context of the FQPA plaintiffs' need to pursue their cases. Nonprofit organizations and academic institutions are in a unique position in that they often have access to scientists who can explain to the courts the level of scientific uncertainty in this area, the reasons behind it, and the reasonably available testing protocols. Such expertise can benefit the FQPA and FIFRA regulatory process along with lawsuits against EPA. Scientists can help ensure that courts hear and understand the evidence that does exist regarding the impact of pesticides on

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development as a guide in determining shifting social policy and shifting administrative demands"); see also James McCauley Landis, *Statutes and the Sources of Law*, in HARVARD LEGAL ESSAYS 213, 230 (1934) (arguing that common law courts should look to the legislative process to "strike a more favorable balance between legislative and judicial development of law"). Judge Guido Calabresi cites Landis and takes his position one step further, arguing that courts should be able to exercise their common law powers over statutes by revising them where appropriate or forcing legislatures to act, rather than being limited to interpreting existing statutory language or invalidating statutes based on constitutional grounds. See GUIDO CALABRESI, A COMMON LAW FOR THE AGE OF STATUTES 81-92 (1982).

263. See generally Alexandra B. Klass, *From Reservoirs to Remediation: The Impact of CERCLA on Common Law Strict Liability Environmental Claims*, 39 WAKE FOREST L. REV. 903 (2004).

264. See *id.* at 942-57.



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children's health and the reasons for the lack of certain types of data.

Moreover, while efforts to shape the law in this direction can start with children's claims because of the "hook" of the FQPA, any positive developments can be used to potentially expand burden-shifting more broadly to encompass a wider group of plaintiffs harmed by pesticides or other toxic chemicals. In this way, the law can develop in a manner similar to that in *Summers* and *Sindell*, in that courts first become comfortable with burden-shifting in a narrow category of cases (in *Summers*, a very limited number of potential defendants, all of whom are known) and then allow such expansion to other types of cases as justified (in *Sindell*, a larger number of defendants, some of whom are unknown).

While state common law tort law claims are a less direct approach than compelling EPA to set appropriate testing and design standards, the administrative law and political barriers to such efforts suggest that state tort law, which has often been ignored in recent decades by the volume of federal environmental statutes and regulations, still has an important role to play in regulating environmental harms.<sup>265</sup> Indeed, the tort law system has always been and can continue to be a vehicle to force pesticide manufacturers to fully take the costs of children's health into account in analyzing which products to place on the market and to conduct the scientific studies necessary to ensure their safety.<sup>266</sup>

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265. See, e.g., Andrew P. Morriss, *Lessons for Environmental Law from the American Codification Debate*, in *THE COMMON LAW AND THE ENVIRONMENT: RETHINKING THE STATUTORY BASIS FOR MODERN ENVIRONMENTAL LAW* 130, 154 (Roger E. Meiners & Andrew P. Morriss eds., 2000) (noting that the common law is "much superior to statutory law in controlling the role of interest groups" and should not be abandoned in efforts to protect the environment).

266. See, e.g., *Ileto v. Glock Inc.*, 370 F.3d 860, 868 (9th Cir. 2004) (Kozinski, J., concurring) ("Imposing novel tort theories on economic activity significantly affects the risks of engaging in that activity, and thus alters the cost and availability of the activity within the forum jurisdiction."); Berger, *supra* note 215, at 2119 (stating that reforms relating to the plaintiff's burden of proof on causation "furthers tort law's corrective justice rationale that liability is linked to moral responsibility"); Collins, *supra* note 213, at 10,362 ("Thus, more than its statutory sibling, tort has the potential to actually change the economic equation – making it cheaper to protect than to pollute the environment.").

## V. CONCLUSION

A review of the regulatory and legal history of the Food Quality Protection Act of 1996 shows that although the law was heralded with great expectations, its implementation has not yet created a sufficient structure to significantly aid in protecting children from harmful pesticide exposure. Moreover, targeted lawsuits against EPA to improve implementation of the FQPA's key provisions have had little success as a result of procedural administrative law hurdles. However, recent developments in state law tort actions to recover damages for pesticide-related harms, notably the Supreme Court's 2005 *Bates* decision, support the proposition that state law tort actions may provide a vehicle to increase protection for children's health.

In order to accomplish this goal, environmental and children's nonprofit organizations should work more closely with plaintiffs' lawyers representing children in pesticide exposure cases to present the best causation data available. Moreover, where good data is not available, such groups can help courts understand the nature of the scientific uncertainty and encourage them to implement the precautionary principle inherent in the FQPA. Plaintiffs can then argue that when currently unavailable causation data could be reasonably obtained, but the defendant has not conducted the testing to obtain such data, the plaintiff has established its burden under *Daubert* and the burden of proof on causation should be shifted to the defendant.

In this way, the tort system can encourage positive developments in testing, product availability, and regulation of pesticides as they impact children's health. This result can be realized not only because the fear of lawsuits may spur manufacturers to create safer and better products, as Justice Stevens noted in *Bates*,<sup>267</sup> but because lawsuits themselves can raise public awareness of this important issue and influence both manufacturers and policymakers to provide greater protection to our nation's children.

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267. See *Bates v. Dow Agrosciences LLC*, 125 S. Ct. 1788, 1802 (2005).