FIFRA'S PREEMPTION OF COMMON LAW TORT ACTIONS INVOLVING GENETICALLY ENGINEERED PESTICIDES

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The purpose of this Note is to analyze the relationship between the federal regulation of genetically engineered organisms ("GEOs"),[1] and the availability of common law damage actions. Although federal regulations of GEOs are numerous and complex,[2] this Note will examine the preemptive effect of one federal regulation, the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"),[3] on state damage actions. Because there is a dearth of case law analyzing actual harm caused by genetically engineered pesticides, this Note will evaluate this preemptive effect by examining state damage claims involving chemical pesticides. This analysis will subsequently be adjusted to accommodate the differences between chemical pesticides and genetically engineered pesticides. The final section of this Note will estimate and evaluate the available legal remedies for harms caused by GEOs.

Researchers in genetic engineering promise many benefits[4] but ecologists warn that there is much uncertainty about the potential risks to the ecosystem and public health.[5] Genetic engineering[6] deliberately alters an organism's genetic

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1. JANE RISSLER & MARGARET MELLON, PERILS AMIDST THE PROMISE 12–13 (1993) (GEOs are organisms genetically engineered to contain traits from unrelated organisms. Genetic engineering is the sophisticated scientific technique of transferring genes from one organism to another.).

2. Martina McGloughlin & Roy H. Doi, *Genetically Engineered Microorganisms, Environmental Introduction,* 2 ENCYCLOPEDIA OF MICROBIOLOGY 259, 261–69 (1992) (Genetically engineered organisms are regulated by many federal agencies, including the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the United States Department of Agriculture (USDA), and the National Institutes of Health (NIH). Each agency has numerous acts that regulate these organisms, including the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Toxic Substance Control Act (TSCA), the Animal and Plant Health Inspection Service (APHIS), and the Federal Food, Drug and Cosmetic Act (FDCA).).

3. 7 U.S.C. §§ 136–136y (1988).

4. SHELDON KRIMSKY, BIOTECHNOLOGY AND SAFETY ASSESSMENT 88–89 (1991) (The potential benefits of genetic engineering include: remediation of ecological harm, improvements to existing plants, modification of animals, and the development of microorganisms to mine the earth.).

5. Scott D. Deatherage, *Scientific Uncertainty in Regulating Deliberate Release of Genetically Engineered Organisms: Substantive Judicial Review and Institutional Alternatives,* 11 HARV. ENVTL. L. REV. 203, 206 (1987) (studies have shown how slight changes in the genetic structure of a benign organism have caused serious ecological imbalances; examples include the Southern corn leaf blight and insects developing resistance to pesticides).

6. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (1986) (genetic engineering is the use of in vitro techniques for the deliberate manipulation of

material. Commercial use of this technology involves the release of GEOs into the environment.[7] The environmental release of GEOs may cause new and untreatable diseases, seriously alter the balance of nature or develop new strains of super pests.[8] Although the probability of harm is slight, the consequences could be disastrous and possibly irreversible.[9]

I. GENETICALLY ENGINEERED ORGANISMS

A. The Benefits and Risks of Genetically Engineered Organisms

Recent advances in precise techniques for genetic manipulation could radically change industry, agriculture and medicine.[10] For example, genetic engineering can create bacteria capable of digesting petroleum and producing insulin.[11] It can also create pest-resistant crops, tomatoes with a shelf-life of three weeks and viruses that act as insecticides.[12] These capabilities offer tremendous potential for addressing many pressing societal needs, including increased efficiency and sustainability of agriculture, methods to monitor and reduce pollution, and new ways to fight infectious agents.[13]

Because genetically altered organisms must survive in the environment to do their work, limiting the ability of researchers to predict or control the results of their research, the risks of biotechnology are uncertain.[14] Initially, researchers conducted genetic engineering experiments in enclosed structures but field testing has become a necessity,[15] greatly increasing the type and magnitude of potential risks from biogenetic engineering.[16] The exact nature and quantity of risk is hard to estimate because of (1) the large number and variety of GEOs,[17] (2) the high number of genes in each GEO,[18] (3) the reproductive capacity of GEOs,[19] (4) the complexity of environmental relationships and the unpredictability of novel genetic interactions,[20] (5) the latency in the expression of many qualities,[21] and (6) the lack of long-term data.[22]

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genes within or between species for the purpose of gene analysis and product improvement) [hereinafter Framework].

7. McGloughlin & Doi, *supra* note 2, at 260.

8. Deatherage, *supra* note 5, at 207; Harvard Law Review Association, *Designer Genes That Don't Fit: A Tort Regime for Commercial Releases of Genetic Engineering Products,* 100 HARV. L. REV. 1086, 1086 (1987).

9. Harvard Law Review Association, *supra* note 8, at 1086–87.

10. Judy J. Kim, *Out of the Lab and into the Field: Harmonization of Deliberate Release Regulations for Genetically Modified Organisms,* 16 FORDHAM INT'L L.J. 1160 (1993).

11. THE PRESIDENT'S COUNCIL ON COMPETITIVENESS, REPORT ON NATIONAL BIOTECHNOLOGY POLICY 2–3 (1991).

12. Kim, *supra* note 10, at 1160.

13. McGloughlin & Doi, *supra* note 2, at 260.

14. RISSLER & MELLON, *supra* note 1, at 12–13.

15. McGloughlin & Doi, *supra* note 2, at 261.

16. RISSLER & MELLON, *supra* note 1, at 12–13.

17. *Id.* at 39.

18. *Id.*

19. KRIMSKY, *supra* note 4, at 98.

20. *Id.* at 98–99.

21. *Id.* at 189 (latency means that the effects from genetic engineering might not be evident for years, making it difficult to determine the risks involved).

22. RISSLER & MELLON, *supra* note 1, at 12.

The uncertainty of the risks inherent in this process poses a significant problem in determining the type of regulation required to adequately protect society. Knowledgeable individuals concerned with public and private safety, as well as intellectual and economic progress, must balance these risks against the potential benefits of biogenetic engineering in order to create effective regulations.[23] Consequently, any introduction of GEOs into the environment should be undertaken only within a regulatory framework designed to protect the environment and any human and animal life that may come into contact with GEOs.[24]

B. The History Of The Regulation Of Genetically Engineered Organisms

The United States has chosen to use a product specific approach to the regulation of GEOs, relying on preexisting statutes[25] and focusing on the product rather than the process by which the product was created.[26] The assumption underlying federal regulation of GEOs is that the products of recombinant DNA ("rDNA") technology[27] are not risky per se and that as a result biotechnology does not require any unique or new regulatory system.[28]

Since biotechnology regulation is risk-based, the federal government exercises supervision only to the extent that the regulation promotes a net social benefit[29] or when restrictions are necessary to protect against "unreasonable adverse effects on the environment."[30] Biosafety regulations have focused on supporting economic development and "the U.S. global competitive leadership"[31] but have not addressed private or public redress.[32] Therefore, injured plaintiffs must rely on the tort system for compensation.[33] When deciding the potential liability of the defendant, courts must first establish which agency and regulations control the product causing the damage. Second, the courts must determine if the regulations define, modify or limit state common law.

Today, many different federal agencies regulate biotechnology.[34] In 1986, due to the numerous federal agencies involved, the divergence in standards, and the gaps and overlaps between and among agencies, the Office of Science and

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23. Ruth E. Harlow, *The EPA and Biotechnology Regulation: Coping with Scientific Uncertainty*, 95 YALE L.J. 553, 560 (1986).
24. Valerie M. Fogleman, *Regulating Science: An Evaluation of the Regulation of Biotechnology Research*, 17 ENVTL. L. 183, 202 (1987).
25. For example, EPA regulates biotechnology with TSCA and FIFRA, which were designed to regulate chemicals. 15 U.S.C.A. §§ 2601–92 (1988) (TSCA); 7 U.S.C.A. §§ 136–136y (1988) (FIFRA).
26. Peter Mostow, *Reassessing the Scope of Federal Biotechnology Oversight*, 10 PACE ENVTL. L. REV. 227, 237 (1992).
27. McGloughlin & Doi, *supra* note 2, at 259 (recombinant DNA technology is the set of techniques that permit the formation of novel DNA sequences by in vitro combination of two nonhomologous DNA molecules).
28. Mostow, *supra* note 26, at 240.
29. *Id.* at 237.
30. 7 U.S.C.A. § 136x (1988).
31. KRIMSKY, *supra* note 4, at 194.
32. Joan Ferretti, *Looking for the Big Picture: Developing a Jurisprudence for a Biotechnological Age*, 10 PACE ENVTL. L. REV. 711, 721 (1993).
33. *Id.* at 714.
34. Agencies regulating biotechnology include: the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the United States Department of Agriculture (USDA), and the Occupational Safety and Health Administration (OSHA). *See supra* note 2.

Technology Policy (OSTP) created an overall policy for regulation of biotechnology in the United States.[35]

This policy, the Coordinated Framework for the Regulation of Biotechnology,[36] established four major principles for the regulation of genetic engineering.[37] First, the OSTP found that existing laws are sufficient to regulate GEOs.[38] The basic premise supporting the development of this principle was the belief that genetic engineering techniques are equivalent to the traditional techniques of selective breeding and hybridization, and that operative laws could regulate GEOs.[39] Second, the OSTP determined that federal agencies should regulate the products, not the process, of biotechnology.[40] Third, the policy assumed that a federal agency should determine the safety of all genetically engineered products on a case-by-case basis.[41] Finally, the OSTP created the Biotechnology Science Coordinating Committee (BSCC), composed of senior officers from the United States Department of Agriculture (USDA), Environmental Protection Agency (EPA), National Institutes of Health (NIH), and the National Science Foundation (NSF).[42] The duties of the BSCC are to coordinate science policy and reconcile review procedures within and between agencies, but it has no regulatory power over any of the agencies.[43]

Three agencies supervise the majority of regulations for GEOs, whether contained in a closed system or released into the environment: the Food and Drug Administration (FDA), the USDA, and the EPA.[44] All of these agencies function under the umbrella of the National Environmental Policy Act (NEPA),[45] which requires all federal agencies to evaluate the environmental consequences of any action they take.[46] The EPA regulates the registration and labeling of pesticides under FIFRA.[47]

II. FIFRA AND PREEMPTION

Congress enacted FIFRA, a pesticide labeling and registration statute, in 1947, and in 1972 adopted major revisions.[48] These changes strengthened the Act's regulatory structure and shifted its policy emphasis from the promotion of agriculture to the protection of health and the environment.[49]

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35. Office of Science & Technology, Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50,856 (1984).
36. Framework, *supra* note 6, at 23,302.
37. *Id.*
38. *Id.*
39. Karen G. Herman, *Issues in the Regulation of Bioengineered Food,* 7 HIGH TECH. L.J. 107, 116 (1992).
40. Framework, *supra* note 6, at 23,302.
41. *Id.*
42. *Id.* at 23,306.
43. *Id.*
44. McGloughlin & Doi, *supra* note 2, at 262.
45. Pub. L. No. 91–190, 83 Stat. 852 (codified at 42 U.S.C.A. §§ 4321–47 (1977)).
46. McGloughlin & Doi, *supra* note 2, at 262.
47. 7 U.S.C. §§ 136–136y (1988).
48. Ch. 125, 61 Stat. 163 (1947), as amended by the Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92–516, 86 Stat. 975 (1972) (codified at 7 U.S.C.A. §§ 136–136y (1994)).
49. S. REP. NO. 838, 92d Cong., 2d Sess. 1 (1972), *reprinted in* 1972 U.S.C.C.A.N. 3993, 3993 (citing protection of "man and his environment" as FIFRA's purpose).

FIFRA broadly defines pesticides as: "(1) any substance or mixture of substances intended for preventing, destroying, repelling or mitigating any pest, and (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant."[50] Since this definition does not depend on the process by which pesticides are made, the EPA has included biological and genetically engineered pesticides in this category.[51] The EPA classifies three distinct products as biological pesticides: microbial pesticides,[52] biochemical pesticides,[53] and plant pesticides.[54]

The EPA's general view has been that the potential risks of biological pesticides are lower than those for chemical pesticides; however, until recently they had stricter requirements for biological pesticides that were genetically engineered.[55] In 1994, the EPA issued the final FIFRA biotechnology rule, which reduces the regulatory oversight for GEOs. This rule also has provisions which may exempt many GEOs from regulation under FIFRA.[56]

Because only a brief time has elapsed since scientists began the deliberate release of GEOs into the environment,[57] and because of the latency in expression of many genetically engineered traits,[58] no reported damage claims of actual harm from genetically engineered pesticides have been recorded at this time.[59] However, since FIFRA regulates pesticides based on the product, not the process, this Note considers the analogy of the preemptive effect of this Act on damage claims due to injury from FIFRA-approved chemical pesticides.

The science of organic chemical production and the science of biotechnology have many similarities. Both sciences stimulated new technological eras, creating similar risks and benefits,[60] and the government has chosen to regulate both areas under FIFRA. Although regulation of biotechnology is proceeding with more foresight than was shown in the regulation of chemical production,[61] biotechnology is also a more complex

50. 7 U.S.C. § 136u (1988).

51. Linda J. Fisher et al., *A Practitioner's Guide to the Federal Insecticide, Fungicide, and Rodenticide Act: Part III*, 24 ENVTL. L. REP. 10,629, 10,650 (1994).

52. *Id.* at 10,650 ("This subcategory covers both microorganisms (including bacteria, fungi, algae, and protozoa) and viruses that are used for pesticidal purposes." This subcategory includes genetically engineered microorganisms.).

53. *Id.* (The distinction between biochemical and traditional chemical pesticides is not always clear. A biochemical pesticide must be of natural origin, produced by the plant or animal, "and must operate through a non-toxic mechanism in order to be classified as a biochemical.").

54. *Id.* (A plant can contain a substance that kills, injures or repels the target pest. Plant pesticides include pesticidal substances produced in the plant and the genetic material necessary for the production of those substances, as well as pesticidal substances that are introduced into a plant through genetic engineering.).

55. *Id.* at 10,650–10,651.

56. *Id.* at 10,653.

57. Department of Health, Education, and Welfare (National Institutes of Health), Recombinant DNA Research, Proposed Revised Guidelines, 43 Fed. Reg. 33,041, 33,107 (1978).

58. RISSLER & MELLON, *supra* note 1, at 38.

59. KRIMSKY, *supra* note 4, at 182–83.

60. Ferretti, *supra* note 32, at 715–16 (both sciences are unpredictable and capable of causing pollution and health problems and yet offer benefits to society and economic gains).

61. *Id.* at 716.

science, with the additional risks of self-reproduction,[62] recombination,[63] mutation,[64] and difficulty of identification.[65]

Under FIFRA, the EPA must approve labeling on all pesticides sold in the United States.[66] FIFRA does not expressly provide private damage remedies for injuries caused by substances it regulates,[67] and no court has read the Act to contain an implied private right of action.[68] FIFRA does not specifically address the issue of private rights or remedies for harm caused by regulated pesticides.[69] Due to the lack of a statutory damage provision and the apparent unavailability of receiving damages from the federal government under the Federal Torts Claims Act,[70] an injured plaintiff must rely on state common law for redress. However, many defendants have used preemption of state common law by FIFRA as an affirmative defense in product liability lawsuits.[71]

Section 136v of FIFRA[72] contains the savings clause:[73] "a State may regulate the sale or use of any federally registered pesticide" not prohibited by FIFRA.[74] FIFRA also contains a preemption clause:[75] a state "shall not impose...any requirements for labeling or packaging in addition to or different from those" in this subchapter.[76] These two clauses create a dichotomy within the internal structure of FIFRA by first giving the states the power to regulate the use

62. KRIMSKY, *supra* note 4, at 98 (because they can reproduce, biological agents cannot be removed with the same methods as used with inert chemicals, such as geographical isolation and community evacuation).

63. WILLIAM K. PURVES & GORDON H. ORIANS, LIFE: THE SCIENCE OF BIOLOGY 1231 (1987) (defining recombination as the process where an individual, meiotic product, or single chromosome in which genetic materials originally present in two individuals end up in the same haploid complement of genes—a genetic reshuffling. More simply, rDNA techniques produce hybrid DNA by joining pieces of DNA from different organisms.).

64. KRIMSKY, *supra* note 4, at 97–99 (mutation, the sudden variation in an inheritable characteristic, makes the range of possibilities for unexpected outcomes much broader for biological entities than for inert chemicals).

65. *Id.* (identification is difficult because microorganisms are classified by their phenotype [physical characteristics], so that a change in genetic structure will not necessitate a change in classification and will make it difficult to establish an inventory of safe or unsafe GEOs).

66. 40 C.F.R. § 168.65(b) (1993) (explaining how EPA interprets and will enforce FIFRA labeling requirements).

67. *In re* "Agent Orange" Prod. Liab. Litig., 635 F.2d 987, 992 (2d Cir. 1980).

68. WILLIAM H. RODGERS, JR., ENVIRONMENTAL LAW, PESTICIDES AND TOXIC SUBSTANCES 92 (1988); *see also* Rodriguez v. American Cyanamid Co., 858 F. Supp. 127 (D. Ariz. 1994) (holding that Congress did not intend to create a private right of action under FIFRA and that a violation of the statute may not be the basis for a negligence per se claim in a personal injury suit for damages).

69. 7 U.S.C. § 136n (1988).

70. 60 Stat. 843, 28 U.S.C.A. § 1346 (West 1976 & Supp. 1993).

71. *See, e.g.*, Papas v. Upjohn Co., 985 F.2d 516 (11th Cir. 1993); Chemical Specialties Mfrs. Ass'n v. Allenby, 958 F.2d 941 (9th Cir. 1992); MacDonald v. Monsanto Co., 813 F. Supp. 1258 (E.D. Tex. 1993).

72. 7 U.S.C.A. § 136v(a) (West 1996).

73. BLACK'S LAW DICTIONARY 934 (abridged 6th ed. 1991) ("In a statute, an exception of a special thing out of the general things mentioned in the statute." In this statute, saving power for the state in the field of pesticide regulation.).

74. 7 U.S.C.A. § 136v(a) (West 1996).

75. BLACK'S LAW DICTIONARY, *supra* note 73, at 934 (preemption doctrine adopted by U.S. Supreme Court, holding that certain matters are of such a national, as opposed to local, character that federal laws preempt or take precedence over state laws).

76. 7 U.S.C.A. § 136v(b) (West 1996).

or sale of pesticides[77] and then denying the states the power to regulate labeling or packaging. The legislative history illustrates that the savings clause was intended to allow the state to impose stricter regulations for the sale or use of pesticides,[78] and that the preemption clause precludes any labeling or packaging requirements differing from the Act.[79] Nothing in the language or history of the Act indicates whether section 136v preempts state common law in addition to positive enactments.[80]

A. Preemption Overview

Under the Supremacy Clause of the United States Constitution, federal law may supplant state law in a number of situations. Some federal regulations expressly prohibit states from imposing safety requirements on manufacturers that differ from those established by federal law.[81] These statutes obviously preempt nonconforming state and local statutes, ordinances, and administrative regulations; however, it is questionable whether they preempt all state damage claims against a manufacturer whose products meet applicable federal standards.

The Supremacy Clause of the United States Constitution provides that the laws of the United States "shall be the supreme Law of the Land...anything in the Constitution or laws of any state to the contrary notwithstanding."[82] However, in fields traditionally occupied by the state, such as protecting the health and safety of its citizens, there is a "presumption against preemption" unless there is clear and manifest intent by Congress to preempt.[83]

Preemption can occur in three ways.[84] First, when federal law specifically excludes state law in a particular area, there is express preemption.[85] In this case, the only task left to the court is to determine the scope of the preemption. Second, in the absence of express statutory preemption, courts may infer a congressional intent to preempt state law when the federal regulation "occupies

77. 7 U.S.C.A. § 136v(a) (West 1996).

78. S. REP. NO. 838, 92d Cong., 2d Sess. 1 (1972), *reprinted in* 1972 U.S.C.C.A.N. 3993, 4021.

79. S. REP. NO. 970, 92d Cong., 2d Sess. 1 (1972), *reprinted in* 1972 U.S.C.C.A.N. 4092, 4128.

80. NATIONAL AGRIC. CHEM. ASS'N, FEDERAL ENVTL. PESTICIDE CONTROL ACT OF 1972, A COMPILATION OF THE STATUTE AND LEGISLATIVE HISTORY 205–23 (1972).

81. *See, e.g.*, Federal Cigarette Labeling and Advertising Act, 15 U.S.C. §§ 1381–1392(d) (1988); Consumer Product Safety Act, 15 U.S.C. §§ 2051–2075 (1988 & Supp. III 1991); Medical Device Amendments of 1976, 21 U.S.C. §§ 360c–k (1988 & Supp. III 1991).

82. U.S. CONST. art. VI, cl. 2.

83. Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947).

84. *See generally* English v. General Elec. Co., 496 U.S. 72, 78–79 and n.5 (1990) (describing the three basic categories); S. Candice Hoke, *Preemption Pathologies and Civic Republican Values*, 71 B.U. L. REV. 685, 733–37 (1991) (criticizing the incoherence of the Court's preemption categories); Paul Wolfson, *Preemption and Federalism: The Missing Link*, 16 HASTINGS CONST. L.Q. 69, 70–88 (1988) (stating that defects in the federal preemption doctrine are attributable to the Supreme Court's "lack of appreciation for preemption as a matter of constitutional dimension").

85. *See, e.g.*, Pacific Gas & Elec. Co. v. State Energy Resources Conservation & Dev. Comm'n, 461 U.S. 190, 206 (1983); Shaw v. Delta Air Lines, Inc., 463 U.S. 85, 108 (1983); Jones v. Rath Packing Co., 430 U.S. 519, 530–32 (1977).

the field."[86] This occurs whenever there is a dominant federal interest[87] or when federal regulation is so pervasive it completely excludes even supplementary or parallel state regulations.[88] Federal regulatory standards can preempt state standards if Congress intends the federal standards to create uniformity.[89] Finally, even in the absence of implied preemption of an entire field, federal regulations preempt state law to the extent that there is an actual conflict between state and federal laws. In this situation federal law is supreme.[90] Conflicts exist when compliance with both laws is impossible,[91] when state law interferes or diminishes the exercise of federally created rights[92] or when state law is an obstacle to the federal method of implementation.[93]

Although the Court's Supremacy Clause jurisprudence dates back nearly two centuries, and courts have recognized the preemption of state law for over a century,[94] federal preemption of state common law tort claims is a recent development. Other than the preemption of claims under particular federal statutes which provided exclusive remedies,[95] the Court did not directly confront this issue until 1984.[96]

The Supreme Court has presented numerous fluctuating tests for determining whether state law was preempted, shifting between periods of state and federal dominance.[97] In *Cipollone v. Ligett Group, Inc.*,[98] the Supreme Court held that the Public Health Cigarette Smoking Act of 1969, which contained a preemption clause similar to that in FIFRA, expressly preempted products liability action grounded on failure to warn claims.[99] Recent courts have applied the *Cipollone* preemption analysis of the 1969 Cigarette Act to FIFRA, without making any adjustments for the differing requirements under FIFRA.[100] When the Cipollone preemption analysis is directly applied to FIFRA it creates harsh results, foreclosing common law remedies even where federal safety standards have been violated.[101] In order to assess other possible interpretations of FIFRA's preemption of tort claims this Note will explore some pre-*Cipollone* case law on FIFRA preemption.

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86. *See, e.g.*, Schneidewind v. ANR Pipeline Co., 485 U.S. 293, 300 (1988); Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947).

87. *See, e.g.*, International Paper Co. v. Ouellette, 479 U.S. 481, 494 (1987); San Diego Bldg. Trades Council v. Garmon, 359 U.S. 236, 240 (1959); Hines v. Davidowitz, 312 U.S. 52, 67 (1941).

88. *Schneidewind*, 485 U.S. at 300.

89. Ray v. Atlantic Richfield Co., 435 U.S. 151, 163 (1978).

90. Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 153 (1982).

91. *See, e.g.*, McDermott v. Wisconsin, 228 U.S. 115 (1913).

92. *See, e.g.*, Southland Corp. v. Keating, 465 U.S. 1, 16 (1984).

93. *See, e.g.*, City of Burbank v. Lockheed Air Terminal, Inc., 411 U.S. 624, 633 (1973).

94. Stephen A. Gardbaum, *The Nature of Preemption*, 79 CORNELL L. REV. 767, 785–805 (1994).

95. *See, e.g.*, Pilot Life Ins. Co. v. Dedeaux, 481 U.S. 41, 47–48 (1987) (holding that ERISA preempts common law tort and contract claims for the failure of an employee plan to pay benefits).

96. Lars Noah, *Reconceptualizing Federal Preemption of Tort Claims as the Government Standards Defense*, 37 WM. & MARY L. REV. 903, 907–08 (1996).

97. John A. Chatowski, Cipollone *and the Clear Statement Rule: Doctrinal Anomaly or New Development in Federal Preemption?*, 44 SYRACUSE L. REV. 769, 769 (1993).

98. 505 U.S. 504 (1992).

99. *See infra* notes 141–63 and accompanying text.

100. *See infra* notes 163–95 and accompanying text.

B. Traditional Reluctance to Find FIFRA Preemption of Tort Claims

The leading case on FIFRA and preemption of state law in the 1980s was *Ferebee v. Chevron Chemical Company*.[102] Ferebee, an agricultural worker, contracted pulmonary fibrosis after long-term skin exposure to an herbicide distributed solely by Chevron.[103] Ferebee claimed that Chevron's failure to adequately label the pesticide caused the injury, and that Chevron was strictly liable.[104]

The Circuit Court ruled that FIFRA did not expressly preempt state tort claims based on inadequacy of an EPA approved label. Accordingly, an analysis of the purpose of FIFRA and state tort law was necessary to see if state damage actions would present an obstacle to the accomplishment of the federal purposes.[105] The court found that the purpose of FIFRA is to insure against "unreasonable" adverse effects on the environment, as determined by a cost-benefit analysis.[106] But the court also noted that the purpose of state tort law is compensation to individuals for losses they have suffered.[107] The court also found that since compliance with both federal and state law was possible, Chevron could petition for a more comprehensive label and avoid future liability or continue to use the present label and pay the damages.[108]

Taking into consideration the different purposes of the state and federal laws, the ability of Chevron to comply with both laws, and the lack of an explicit preemption against state damage actions, the court found FIFRA did not preempt failure to warn claims based on inadequate labeling.[109] The Circuit Court found additional support for this reasoning in the traditional role of states in protecting the health and welfare of their citizens.[110] Tort remedies to compensate for personal injury traditionally fall within the scope of state protection.[111] When assessing a preemption of traditional state roles, the court should rule against preemption unless there is a clear statement from Congress to the contrary.[112]

The *Ferebee* court found that Chevron could comply with both federal and state law in two ways: (1) by keeping the label and paying damages, or (2) by petitioning the EPA to approve a more comprehensive label.[113] Although subsequent courts[114] have criticized this reasoning, two factors strongly support encouraging the second alternative. As Judge Weinstein stated in *Burke v. Dow Chemical Co.*,[115] the EPA does not conduct any testing or even verify testing of

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101. Noah, *supra* note 96, at 62.
102. 736 F.2d 1529 (D.C. Cir. 1984).
103. *Id.* at 1531.
104. *Id.* at 1532.
105. *Id.* at 1540.
106. *Id.*
107. *Id.*
108. *Id.* at 1541, 1543.
109. *Id.* at 1542.
110. *Id.*
111. Burke v. Dow Chem. Co., 797 F. Supp. 1128, 1131–32 (E.D.N.Y. 1992) (stating that, in looking at preemption of state common law by FIFRA, the court must bear in mind that the protection of the public against toxic substances has traditionally been a matter left to the states).
112. *Ferebee*, 736 F.2d at 1543.
113. *Id.* at 1541, 1543.
114. *See, e.g.*, Papas v. Upjohn, 985 F.2d 516 (11th Cir. 1993); Arkansas–Platte & Gulf Partnership v. Van Waters & Rogers, Inc., 981 F.2d 1177 (10th Cir. 1993).
115. *Burke*, 797 F. Supp. at 1134.

pesticides.[116] The EPA relies on the company to do research, provide information, and draft the labels.[117] Unless the manufacturer provides all relevant information which would alert the EPA to the need for special restrictions, the EPA has no reason to restrict either the label or the product.[118] Since the EPA functions in a passive role under FIFRA, the only motivation for the manufacturer to request a new, more restrictive label would be fear of liability based on failure to warn. The manufacturer would need to rewrite the label they prepared in the first instance, but this would not affect FIFRA's goal of uniformity because it would not "add to nor differ from the EPA's current requirements."[119]

The *Ferebee* court supported its decision on the fact that a failure to warn claim is limited to what the manufacturer knew or should have known about at the time of the injury.[120] Under FIFRA, in order to register a pesticide, the manufacturer is required to give the EPA all the information the manufacturer knew or should have known concerning the ingredients and potential risks of the pesticide.[121] Therefore, common law damage claims based on failure to warn would promote the purposes of FIFRA by motivating the manufacturer to discover and disclose any information relating to the potential dangers of their product.

Several courts followed the ruling of *Ferebee* and held that FIFRA does not preempt state court actions.[122] In their decisions, these courts support and refine the reasoning of *Ferebee.* Subsequent courts also agreed with *Ferebee* that state damage actions, including those based on inadequate labeling, do not conflict with the federal purpose to protect human health and the environment by preserving the integrity and force of the information in the FIFRA label.[123]

C. Expansion of FIFRA's Preemptive Scope

Commencing with *Fitzgerald v. Mallinckrodt, Inc.*[124] courts began to rule that FIFRA preempted tort claims based on failure to warn and negligent labeling.[125] In this case the plaintiff, a maintenance worker at a golf course, was injured after an accidental exposure to a fungicide. He claimed he would not have been injured if the company had designed the warning label properly.[126] The district court held that FIFRA preempts state law claims based on negligent labeling and failure to warn.[127]

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116. *Id.* at 1134 (information regarding pesticide testing or registration is often withheld from public scrutiny as a trade secret).
117. *Id.*
118. *Id.* at 1135.
119. Riden v. ICI Americas, Inc., 763 F. Supp. 1500, 1508 (W.D. Mo. 1991).
120. Ferebee v. Chevron Chem. Co., 736 F.2d 1529, 1536 (D.C. Cir. 1984).
121. 7 U.S.C.A. § 136a (West 1994).
122. Thorton v. Fondren Green Apartments, 788 F. Supp. 928 (S.D. Tex. 1992); Riden v. ICI Americas, Inc., 763 F. Supp. 1500 (W.D. Mo. 1991); Cox v. Velsicol Chem. Corp., 704 F. Supp. 85 (E.D. Pa. 1989); Ciba-Geigy Corp. v. Alter, 834 S.W.2d 136 (Ark. 1992).
123. *Ciba-Geigy Corp.*, 834 S.W.2d at 144; *Riden*, 763 F. Supp. at 1508 (Although FIFRA's preemption section is labeled "uniformity," FIFRA regulations have always allowed manufacturers some discretion in drafting labels.).
124. Fitzgerald v. Mallinckrodt, Inc., 681 F. Supp. 404 (E.D. Mich. 1987).
125. Fisher et al., *supra* note 51, at 10,650.
126. *Mallinckrodt*, 681 F. Supp. at 406.
127. *Id.* at 407–08.

The *Fitzgerald* court expressly rejected the holding of *Ferebee*[128] and relied instead on *Palmer v. Liggett Group, Inc.*,[129] a preemption case involving the 1969 Cigarette Act.[130] In the latter case, Joseph Palmer allegedly died of lung cancer caused by smoking three to four packs of cigarettes a day.[131] His estate contended that Liggett had failed to warn adequately of the health consequences of cigarette smoking.[132]

The *Palmer* court had distinguished the Cigarette Act from FIFRA as the basis for their rejection of the *Ferebee* reasoning.[133] However, the *Fitzgerald* court preferred the reasoning of the circuit court interpreting the Cigarette Act in *Palmer* to the analysis of the Supreme Court interpreting FIFRA in *Ferebee*. The *Fitzgerald* court held that "[w]here the Federal Government has preempted any state regulation, there can be no recovery in tort. Allowing recovery under state tort law where Congress has preempted state law would effectively authorize the state to do through the back door exactly what it cannot do through the front."[134]

The Eleventh Circuit followed the *Fitzgerald* court's reasoning in *Papas v. Upjohn Co.*[135] and held that FIFRA impliedly preempts all state tort claims based on defective labeling.[136] The plaintiff in Papas was a kennel worker at a humane society.[137] He claimed that his illness was a result of exposure to pesticides used to rid dogs of fleas, which would not have happened if there had been adequate labeling.[138] In this case the court held that implied preemption had occurred because the federal government, by enacting FIFRA, has occupied the entire field of labeling regulations.[139] Consequently, this tort action was in direct conflict with federal law.[140]

D. Preemption of Common Law Tort Claims in Cipollone v. Liggett Group, Inc.

The United States Supreme Court has not specifically addressed FIFRA's preemption of state law damage actions, but the Court has remanded several cases to lower courts to address this issue in light of its ruling in *Cipollone v. Liggett Group, Inc.*[141] In *Cipollone,* the Supreme Court considered the preemptive effect of the Public Health Cigarette Smoking Act of 1969,[142] which contains a preemption clause similar to that in FIFRA.

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128. *See supra* text accompanying notes 96–115.
129. 825 F.2d 620 (1st Cir. 1987).
130. *See infra* notes 129–35 and accompanying text.
131. *Palmer,* 825 F.2d at 622.
132. *Id.*
133. *Id.* at 623 (The court distinguishes this case from *Ferebee* because the two Acts are so different: "the very fact that Congress mandated the precise wording required in a label, rather than merely establishing the 'minimum requirements' standard often found in labeling acts distinguishes the (Cigarette) Act from cases relied on by the Palmers," referring to *Ferebee* as involving the "FIFRA minimum labeling standards.").
134. Fitzgerald v. Mallinckrodt, Inc., 681 F. Supp. 404, 407 (E.D. Mich. 1987).
135. Papas v. Upjohn Co., 926 F.2d 1019 (11th Cir. 1991) [hereinafter *Papas I*].
136. *Id.* at 1026.
137. *Id.* at 1020.
138. *Id.*
139. *Id.* at 1020–21.
140. *Id.* at 1025.
141. Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992).
142. Pub. L. No. 91–222, 84 Stat. 87 (1970) (codified as amended at 15 U.S.C. §§ 1331–1341 (1994)).

In *Cipollone,* the question before the court was whether the Federal Cigarette Labeling and Advertising Act preempted common law tort claims.[143] Since 1965, Congress has precisely specified the warnings that must appear on the labels of cigarette packages.[144] Section 5(b) of the Act, as amended in 1969, provides 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."[145]

In *Cipollone,* the plurality, led by Justice Stevens, held that the 1969 Act expressly preempts products liability actions grounded on failure to warn claims because the statutory phrase "requirement or prohibition" is broad enough to include state common law claims as well as positive enactments.[146] However, the plurality also stated that the 1969 Act did not preempt express warranty claims or misrepresentation claims based on a duty not to conceal material facts.[147] Therefore, the 1969 Act would not foreclose recovery on a fraud claim alleging a failure "to disclose material facts about smoking and health to an administrative agency" if state law created a duty to disclose such information.[148]

As Justice Scalia[149] and Justice Blackmun[150] predicted, the *Cipollone* ruling has left both sides of product liability actions with great uncertainty regarding the validity of product claims.[151] Despite this confusion, the Supreme Court in *Cipollone* established a few rules on the preemption doctrine to aid lower courts in construing how federal regulations affect state common law claims. First, Justice Stevens noted the importance of the "presumption against pre-emption of...state police power regulation" when Congress' intent to preempt is not clear from the statutory language.[152] Second, when the scope of preemption is expressed in the statute, no justification exists for considering implied preemption. Thus the plain language of a statute preempting state law as to a specific section may eliminate the court's ability to imply preemption. Therefore, if FIFRA expressly preempts labeling and packaging requirements, the court cannot imply preemption of state law under other sections of FIFRA.[153]

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143. *Cipollone,* 505 U.S. at 504–05.

144. Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89–92, 79 Stat. 282 (1965); The Public Heath Cigarette Smoking Act, Pub. L. No. 91–222, 84 Stat. 87 (1970).

145. 15 U.S.C. § 1334b (1988). By contrast, the 1965 version provided that "[n]o statement relating to smoking and health" shall be required in the labeling or advertising of cigarettes labeled in conformity with the Act, and the Court held that this language did not preempt tort claims. *Cipollone,* 505 U.S. at 519 (the court held that the term "statement" in the 1965 version referred to positive enactments by state or local authorities, not to common law damage actions).

146. *Cipollone,* 505 U.S. at 521–22.

147. *Id.* at 525–29.

148. *Id.* at 528.

149. *Id.* at 544.

150. *Id.* at 531.

151. Linda Greenhouse, *Court Opens Way for Damage Suits over Cigarettes,* N.Y. TIMES, June 25, 1992, at A6 (reporting that both sides to the product liability conflict claimed a significant victory in the *Cipollone* decision due to widely divergent interpretations of the decision).

152. *Cipollone,* 505 U.S. at 518.

153. *Id.* at 2617. *But cf.* Myrick v. Fruehauf Corp., 115 S. Ct. 1483, 1488 (1995) (The Court explained that *Cipollone* "instead of announcing a categorical rule precluding the coexistence of express and implied pre-emption," meant only that an express preemption provision "supports a reasonable inference" that "Congress did not intend to pre-empt other matters.").

Finally, Congressional intent, whether Congress intended that federal regulations supersede state law,[154] remains the Court's primary consideration in determining a statute's preemptive scope.[155]

Nevertheless, courts must still decide in each case whether federal requirements apply so as to trigger preemption and also what types of claims are then foreclosed. This task is extremely difficult because the *Cipollone* court failed to clarify how to apply the presumptions to common law claims absent clear congressional language.[156] The level of complexity and confusion surrounding the application of *Cipollone* will vary under different statutory preemption provisions. As a result of this confusion, this Note will focus on the preemptive effect of FIFRA on common law damage claims.

Although FIFRA's labeling requirement is broad, it does not seek to create absolute uniformity, as did the previously mentioned Cigarette Acts.[157] FIFRA applies to 50,000 different products with at least 600 different active ingredients,[158] and permit requirements allow variation of labels even among products containing the same active ingredient.[159] The EPA does not specify the exact wording for labels and requires the manufacturer to submit a draft label for EPA approval under FIFRA § 136a(c).[160]

The lack of a strict uniformity requirement in FIFRA and the ability of states to enforce stricter regulation on the use of FIFRA-approved pesticides is in stark contrast to the Public Health Cigarette Smoking Act of 1969.[161] The 1969 Cigarette Act regulates only one product, specifies the exact words on the label, and prevents states from altering the federally mandated cigarette warning,[162] establishing a more precise and restrictive regulatory scheme than that created under FIFRA.[163]

E. Cipollone, *FIFRA, and Preemption*

Following its decision in *Cipollone,* the Supreme Court remanded *Papas I*[164] to the Eleventh Circuit for reconsideration of FIFRA's preemption of state common claims in light of *Cipollone.*[165] In *Papas II,*[166] the court concluded that FIFRA expressly preempted the Papas's claims of negligence, strict liability, and breach of implied warranty based on inadequate labeling.[167]

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154. Papas v. Upjohn Co., 926 F.2d 1019, 1022 (1991).
155. *Cipollone,* 505 U.S. at 516 (quoting Malone v. White Motor Corp., 435 U.S. 497, 504 (1978)).
156. R. David Allnutt, *FIFRA Preemption of State Common Law Claims After* Cipollone v. Liggett Group, 68 WASH. L. REV. 859 (1993).
157. *See supra* notes 130–44 and accompanying text.
158. Riden v. ICI Americas, 763 F. Supp. 1500, 1508 (W.D. Mo. 1991).
159. Palmer v. Liggett Group, Inc., 825 F.2d 620 (1st Cir. 1987).
160. U.S.C.A. § 136a(c)(1)(C) (West 1994) (each applicant for registration of a pesticide shall file with the Administration a statement which includes...a complete copy of the labeling of the pesticide, a statement of all claims to be made for it and directions for its use).
161. *See supra* notes 130–44 and accompanying text.
162. *Palmer,* 825 F.2d at 628.
163. *Id.*
164. *See supra* notes 127–29 and accompanying text.
165. *See supra* notes 130–44 and accompanying text.
166. Papas v. Upjohn Co., 985 F.2d 516 (11th Cir. 1993) [hereinafter *Papas II*].
167. *Id.* at 517.

The court in *Papas II* based this decision on a comparison between the preemption clause in FIFRA[168] and the preemption clause in the Public Health Cigarette Smoking Act of 1969.[169] The *Papas II* court equated the phrase "any requirements"[170] in FIFRA section 136(v) with "no requirements and prohibitions"[171] in the 1969 Cigarette Act, without analyzing the other differences between the Acts.[172] The court held that FIFRA preempts all common law damage claims which "depend upon a showing that a pesticide manufacturer's 'labeling or packaging' failed to meet a standard 'in addition to or different from' FIFRA requirements."[173]

The Supreme Court also remanded *Arkansas–Platte & Gulf Partnership v. Dow Chemical Co.*[174] for further proceedings in light of their ruling in *Cipollone*. In this case a landowner brought an action against a chemical manufacturer, alleging that the manufacturer failed to warn about the potential environmental risks and hazards to the landowner's property resulting from the use of the defendant's pesticide.[175] The Tenth Circuit ruled that FIFRA expressly preempted a landowners' state law tort claims against pesticide manufacturers for inadequate labeling and failure to warn of environmental harm.[176] This preemption is limited to claims which require a showing that defendants' labeling and packaging should have included warnings other than those required under FIFRA.[177]

Although there are great differences between FIFRA and the 1969 Cigarette Act,[178] most lower courts[179] have applied the reasoning of *Cipollone* directly to FIFRA cases because the preemption provisions are substantially similar. In spite of the fact that this interpretation of FIFRA has been roundly criticized,[180] courts currently find that FIFRA preempts any claims that arise under state law and "relate to" labeling and packaging.[181] The direct application of the *Cipollone* ruling to FIFRA should still allow some common damage remedies such as: claims based on express or implied warranty,[182] intentional fraud and misrepresentation,[183] failure to warn resting solely on respondents'

168. 7 U.S.C.A. § 136v(b); *see supra* notes 73–77 and accompanying text.
169. *See supra* notes 134–37 and accompanying text.
170. *See supra* notes 70–74 and accompanying text.
171. *See supra* notes 131–37 and accompanying text.
172. *Papas II*, 985 F.2d at 518.
173. *Id.*
174. 981 F.2d 1177 (10th Cir. 1993).
175. *Id.* at 1177.
176. *Id.* at 1179.
177. *Id.*
178. *See supra* notes 145–59 and accompanying text.
179. *See, e.g.*, King v. E.I. DuPont De Nemours & Co., 996 F.2d 1346 (1st Cir. 1993); Shaw v. Dow Brands, Inc., 994 F.2d 364 (7th Cir. 1993); *Arkansas–Platte*, 981 F.2d 1117 (10th Cir. 1993); *Papas II*, 985 F.2d 516 (11th Cir. 1993).
180. *See, e.g.*, Allnutt, *supra* note 157, at 869–76; Noah, *supra* note 96, at 26; Stephen D. Otero, Note, *The Case Against FIFRA Preemption: Reconciling* Cipollone's *Preemption Approach with Both the Supremacy Clause and Basic Notions of Federalism*, 36 WM. & MARY L. REV. 783 (1995).
181. Jillson v. Vermont Log Bldgs. Inc., 857 F. Supp. 985 (D. Mass. 1994).
182. Cipollone v. Liggett Group, Inc., 505 U.S. 504, 525–27 (1992).
183. *Id.* at 527–29.

testing or research practices,[184] and strict liability[185] or negligence based on design defect.[186]

The first problem is that some courts have already expanded the preemptive scope of FIFRA, barring many of these remaining common law claims such as express warranty claims,[187] implied warranty claims,[188] and misrepresentation claims.[189] Another problem is that strict liability and negligence claims for personal injury and property damage claims are extremely dependent upon failure to warn theories.[190] In all fields of environmental law, causation is very difficult to prove because scientific uncertainty is involved,[191] creating a need for experts and extensive complications in tracing complex causal links. In the area of biotechnology, the estimation of potential risks encompasses substantial scientific uncertainty because the science is new, complex, and involves long-term effects on the ecosystem.[192]

Some courts have tried to ameliorate the harsh results of FIFRA preemption of failure to warn claims by broadly interpreting state regulations of "use" and "sale."[193] In addition, other courts have used the theory of equitable estoppel to restrict the protection preemption might give a culpable defendant.[194] The next two sections of this Note will examine these two ways of mitigating the consequences of FIFRA's preemption; however, recent rulings have limited both of these avenues of redress.[195]

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184. *Id.* at 524–25.

185. Reutzel v. Spartan Chem. Co., 903 F. Supp. 1272 (N.D. Iowa 1995).

186. Burke v. Dow Chem. Co., 797 F. Supp. 1128, 1141 (E.D.N.Y. 1992).

187. Taylor AG Indus. v. Pure–Gro, 54 F.3d 555 (9th Cir. 1995) (holding that both express and implied warranty claims were preempted by FIFRA); Welchert v. American Cyanamid, Inc., 59 F.3d 69 (8th Cir. 1995) (holding that express warranty claims based on EPA-approved labeling materials are preempted).

188. *Pure–Gro,* 54 F.3d at 555 (Arizona had codified the implied warranty of merchantibility and thus it became a requirement under state law, preempted by FIFRA); *Papas II,* 985 F.2d at 516 (same).

189. *Pure–Gro,* 54 F.3d at 555 (claims that a manufacturer provided misinformation to an agency would not block preemption); *Papas II,* 985 F.2d at 516 (same).

190. William T. Smith III & Kathryn M. Coonrod, Cipollone's *Effect on FIFRA Preemption,* 61 UMKC L. REV. 489, 501 (1993).

191. PETER S. MENELL & RICHARD B. STEWART, ENVIRONMENTAL LAW AND POLICY 224–26 (1994).

192. Mostow, *supra* note 26, at 227.

193. *See, e.g.,* Chemical Specialties Mfrs. Ass'n v. Allenby, 958 F.2d 941 (9th Cir. 1992); New York State Pesticide Coalition, Inc. v. Jorling, 874 F.2d 115 (2d Cir. 1989); D-Con Co. v. Allenby, 728 F. Supp. 605 (N.D. Cal. 1989); Macias v. State, 28 Cal. Rptr. 2d 796 (Cal. Ct. App. 1994).

194. *See, e.g.,* Roberson v. E.I. DuPont De Nemours & Co., 863 F. Supp. 929 (W.D. Ark. 1994); Burke v. Dow Chem. Co., 797 F. Supp. 1128, 1141 (E.D.N.Y. 1992).

195. *Papas II,* 985 F.2d 516 (11th Cir. 1995) (holding that FIFRA preempts negligence, strict liability and breach of warranty claims even when based on the defendant's provision of misinformation to the EPA because FIFRA does not allow the states to "police manufacturer's compliance with federal procedures"); Taylor AG Indus. v. Pure–Gro, 54 F.3d 555 (9th Cir. 1995) (claims that a manufacturer provided misinformation to an agency would not block preemption); Reutzel v. Spartan Chem. Co., 903 F. Supp. 1272 (N.D. Iowa 1995) ("actual agency approval eliminates any possible claims under state law for failure to comply with federal [labeling] requirements").

F. Use or Sale/Labeling Requirements: State Authority

The internal structure of FIFRA sets up a dichotomy by first giving the states the power to regulate the use or sale of pesticides[196] and then denying the states the power to regulate labeling or packaging.[197] As a result, the issues become: when does a state regulation affect the use or sale of a pesticide, and when does it establish additional requirements for labeling or packaging.

Several courts have addressed this tension in the context of state laws requiring pesticide sellers or users to provide warnings separate from those on the FIFRA-approved label.[198] In these cases, courts have been asked to decide whether these state-imposed warnings constitute "labeling" and thus are preempted by FIFRA, or whether they merely regulate the use or sale of pesticides.[199] FIFRA defines labeling as "all labels and all other written, printed, or graphic matter...(A) accompanying the pesticide or device at any time; or (B) to which reference is made on the label or in literature accompanying the pesticide or device...."[200]

In *D-Con Co. v. Allenby*,[201] the court held that FIFRA did not preempt a California statute, Proposition 65,[202] requiring notice to consumers of certain risks involved in the use of a pesticide.[203] The manufacturers could meet the requirements of Prop. 65 without infringing on federal supremacy in the area of pesticide labeling by implementing other warning methods such as: posting of notices, placing notices in mailings to water customers, and placing notices in public news media.[204] The court found that Prop. 65 merely imposed restrictions on pesticide sales or use; it did not specifically require that notice be given on the pesticide label.[205]

The Ninth Circuit, in *Chemical Specialties Manufacturers Ass'n v. Allenby*,[206] supported this narrow interpretation of FIFRA's labeling definition in a subsequent case challenging the same California law, Prop. 65, by categorizing the state law as a "use restriction" not a "labeling requirement."[207] The policy underlying this interpretation was that the court must establish boundaries for the definition of labeling in FIFRA, or it could extend to every type of written material, including price stickers, sale sheets, or even logos.[208] However, four years later, in *Taylor AG Industries v. Pure-Gro*,[209] the Ninth Circuit held that FIFRA preempts claims for inadequate point of sale warnings because the claim

196. 7 U.S.C.A. § 136v(a) (West 1993).
197. *Id.* § 136v(a)–(b).
198. *See, e.g.*, Chemical Specialties Mfrs. Ass'n v. Allenby, 958 F.2d 941 (9th Cir. 1992); New York State Pesticide Coalition, Inc. v. Jorling, 874 F.2d 115 (2d Cir. 1989); D-Con Co. v. Allenby, 728 F. Supp. 605 (N.D. Cal. 1989).
199. *Chemical Specialties*, 958 F.2d at 944; *Jorling*, 874 F.2d at 117; *D-Con Co.*, 728 F. Supp. at 607.
200. 7 U.S.C.A. § 136p(2) (West 1994).
201. 728 F. Supp. 605 (N.D. Cal. 1989).
202. CAL. HEALTH & SAFETY CODE § 25249.6–25249.11(f) (West 1996) (California's Safe Drinking Water and Toxic Enforcement Act, enacted by voters in 1986 as Prop. 65).
203. D-Con Co. v. Allenby, 728 F. Supp. 605, 607 (N.D. Cal. 1989).
204. *Id.*
205. *Id.*
206. 958 F.2d 941 (9th Cir. 1992).
207. *Id.*
208. *Id.* at 946.
209. 54 F.3d 555 (9th Cir. 1995).

is ultimately premised on the inadequacy of the product label.[210] Consequently, although FIFRA does not preempt state laws requiring point of sale warnings, damage claims based on failure to follow these state requirements are preempted.

Nevertheless, the Second Circuit, in *New York Pesticide Coalition, Inc. v. Jorling*,[211] narrowly interpreted FIFRA's definition of "labeling." The court found that a New York regulation,[212] requiring all commercial pesticide applicators to provide certain warnings, was a permissible "use and sale restriction."[213] This New York law required pesticide users to perform specific notification procedures including providing a cover sheet with warnings and safety information, and posting signs around the perimeter of the treated area.[214] The court determined that Congress designed FIFRA labeling requirements to be read and followed by the end user.[215] However, the New York law was a notification procedure for a different audience, the general public.[216] The court established a distinction between state regulations protecting the "end users" and other state regulations designed to protect innocent members of the general public who contract to have the pesticide applied.[217] FIFRA preempts the former as a labeling requirement, but not the latter because it is a regulation of the sale or use of the pesticide.[218]

The court in this decision relied on the purpose of FIFRA's preemption, which was to protect human health and the environment by preserving the integrity and force of the information on the FIFRA label.[219] The court determined that the New York statutory regulation would only further this purpose by preventing "'unreasonable unsafe effects [of pesticide use] on the environment.'"[220]

The *Jorling* ruling comports with the leading United States Supreme Court decision dealing with FIFRA and preemption, *Wisconsin Public Intervenor v. Mortier*.[221] *Mortier* held that FIFRA does not preempt a local (or state) ordinance that, among other things, requires pesticide applicators to post warning placards on property they were treating.[222] In *Mortier*, the Supreme Court stated clearly that "FIFRA does not pre-empt the town's ordinance either explicitly or implicitly or by virtue of an actual conflict."[223]

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210. *Id.* at 561 ("any claims that point-of-sale warnings, consumer notices, or other informational materials failed adequately to warn the plaintiff necessarily challenge the adequacy of the warnings provided on the product's label or packaging").
211. 874 F.2d 115 (2d Cir. 1989).
212. 6 N.Y. COMP. CODES R. & REGS. tit. 6, § 325 (1987) ("NYCRR") (This was an addition to Article 33 of the New York Environ. 6 N.Y. Comp. Codes Mental Conservation Law ("ECL") called "Special Requirements for Commercial Lawn Applications.")
213. New York State Pesticide Coalition, Inc. v. Jorling, 874 F.2d 115, 118 (1989).
214. *Id.* at 116–17.
215. *Id.* at 119.
216. *Id.*
217. *Id.*
218. *Id.*
219. *Id.*
220. *Id.* (quoting 7 U.S.C. § 136a(c)(5) (1988)).
221. Wisconsin Pub. Intervenor v. Mortier, 501 U.S. 597 (1991) (Although the main issue in this case was whether FIFRA preempted local regulation of pesticide use, "use" was defined to include requirements to post placards giving notice of pesticide use and any label information prescribing safe reentry time.).
222. *Id.* at 615.
223. *Id.* at 606.

The preceding cases illustrate that when states place additional requirements on the sale and use of pesticides, courts narrowly construe FIFRA's definition of "labeling" to allow the state to protect the safety of its citizens.[224] However, FIFRA may still preempt damage claims for inadequate point-of-sale warnings.[225]

Nevertheless, a few courts have extended this narrow concept of "labeling" to rule that FIFRA does not preempt state common law tort actions.[226] In *Macrie v. SDS Biotech Corp.*,[227] plaintiffs were employees of a produce broker who was a middle person between farmers and consumers. The farmer, contrary to the manufacturer's directions, used the defendant's fungicide, Bravo 500, directly on his butternut squash.[228] While plaintiffs were repackaging the farmer's squash, particles of the fungicide became airborne, settling on their skin and entering their lungs, causing serious injury.[229] The court followed the reasoning of the Second Circuit in *Jorling*,[230] holding that warnings which manufacturers and applicators are required to give to persons other than the "end user" are not preempted by FIFRA because they are not "labeling" within the meaning of the Act.[231]

Another recent case which relied on the narrow definition of "labeling" to allow damage claims is *Macias v. State*.[232] James Macias, a fourteen-year-old boy, sustained permanent optic nerve damage, causing legal blindness, after an aerial helicopter sprayed malathion directly on him.[233] The State of California had ordered the spraying to eliminate the Mediterranean Fruit Fly infestation.[234] The manufacturer, American Cyanamid, had actual knowledge that the government was not giving the public the necessary warnings set out by the EPA.[235] The *Macias* court held that FIFRA did not preempt a common law negligence failure to warn claim if the claim does not directly or indirectly affect the labeling or packaging of the pesticide.[236] The court upheld this damage claim based on a failure to warn because it was an allegation of misleading the endangered public and did not affect FIFRA's labeling requirement.[237]

This discussion illustrates the confusion courts are currently experiencing in attempting to apply *Cipollone* to FIFRA. On one hand, courts are interpreting FIFRA to preempt almost any state law tort action that is related to labeling.[238]

224. Chemical Specialties Mfrs. Ass'n v. Allenby, 958 F.2d 941 (9th Cir. 1992); New York State Pesticide Coalition, Inc. v. Jorling, 874 F.2d 115 (2d Cir. 1989); D-Con Co. v. Allenby, 728 F. Supp. 605 (N.D. Cal. 1989).

225. Taylor AG Indus. v. Pure-Gro, 54 F.3d 555 (9th Cir. 1995).

226. Macias v. State, 28 Cal. Rptr. 2d 796 (Cal. Ct. App. 1994); Macrie v. SDS Biotech Corp., 630 A.2d 805 (N.J. Ct. App. 1993).

227. 630 A.2d 805 (N.J. Ct. App. 1993).

228. *Id.* at 807.

229. *Id.* at 808.

230. New York State Pesticide Coalition, Inc. v. Jorling, 874 F.2d 115 (2d Cir. 1989).

231. Macrie v. SDS Biotech Corp., 630 A.2d 805, 812 (N.J. Ct. App. 1993).

232. Macias v. State, 28 Cal. Rptr. 2d 796 (Cal. Ct. App. 1994).

233. *Id.* at 798.

234. *Id.*

235. *Id.*

236. *Id.* at 808.

237. *Id.*

238. *See, e.g.*, King v. E.I. DuPont De Nemours & Co., 996 F.2d 1346 (1st Cir. 1993); Shaw v. Dow Brands, Inc., 994 F.2d 364 (7th Cir. 1993); Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc., 981 F.2d 1117 (10th Cir. 1993); *Papas II*, 985 F.2d 516 (11th Cir. 1993).

Then, to remedy the brutal results, some courts expand the area of state regulation of sale or use.[239] However, even when the courts are willing to enforce the narrow definition of labeling, the plaintiffs face significant difficulty in proving that the manufacturer had a duty to warn downstream users of the product if the manufacturer had adequately warned their immediate vendee and sold a nondefective product.[240]

G. Estoppel as a Remedy

Another method to mediate the harsh results of FIFRA's preemption of common law damage actions is to prevent the manufacturer from asserting preemption as an affirmative defense under certain conditions. This equitable remedy is available when the plaintiff can prove that the manufacturer withheld information from or misinformed the EPA.[241] In *Roberson v. E.I. DuPont De Nemours & Co.*,[242] the plaintiffs, orchard owners, claimed that the contamination of a fungicide, Benlate, caused severe damage to their orchard.[243] The Robersons alleged that DuPont was aware that: (1) DuPont had not accurately listed the ingredients on the label; (2) the label contained an error in the proper application rate which resulted in the use of three times the intended density; and (3) the packaging was defective which led to the formation of a compound harmful to crops.[244] The *Roberson* court extended the reasoning of previous courts to conclude that FIFRA expressly preempts failure to warn claims based on inadequate packaging as well as on inadequate labeling.[245] Thus, to the extent that the Roberson's negligence or strict liability claims were based on inadequate failure to warn or inadequate packaging, they would be preempted.

The *Roberson* court decided that this outcome would not only be unfair to the plaintiff but would also "permit a manufacturer that was...aware of the dangers to refrain from informing EPA of needed changes in its product's label and then to hide behind the very label it knew to be inadequate."[246] Therefore, the court held that DuPont could be estopped from asserting preemption of packaging and labeling claims to the extent that it withheld material facts from the agency, either at the time of registration or later.[247]

The court in *Roberson* intended this ruling to protect the integrity of FIFRA's registration process because the EPA must depend on the manufacturer for information concerning the safety of its product.[248] In its decision the *Roberson* court relied on *Hurley v. Lederle Laboratory Division of American Cyanamid*[249] in which the Fifth Circuit held that a manufacturer who withholds

239. *See, e.g.*, Chemical Specialties Mfrs. Ass'n v. Allenby, 958 F.2d 941 (9th Cir. 1992); New York State Pesticide Coalition, Inc. v. Jorling, 874 F.2d 115 (2d Cir. 1989); D-Con Co. v. Allenby, 728 F. Supp. 605 (N.D. Cal. 1989); Macias v. State, 28 Cal. Rptr. 2d 796 (Cal. Ct. App. 1994).
240. *Macias*, 28 Cal. Rptr. 2d at 808.
241. Roberson v. E.I. DuPont De Nemours & Co., 863 F. Supp. 929 (W.D. Ark. 1994).
242. *Id.*
243. *Id.* at 931.
244. *Id.*
245. *Id.* at 932.
246. *Id.* at 933 (quoting Burke v. Dow Chem. Co., 797 F. Supp. 1128, 1141 (E.D.N.Y. 1992)).
247. *Id.*
248. *Id.* at 933–34; *see supra* notes 146–51 and accompanying text.
249. Hurley v. Lederle Lab Div. of Am. Cyanamid, 863 F.2d 1173 (5th Cir. 1988).

information from the FDA no longer receives preemption protection.[250] *Hurley* dealt with the Federal Food, Drug and Cosmetic Act, which has a registration procedure similar to that found in FIFRA as well as an express preemption provision.[251] The *Roberson* court held that it would not be necessary for the jury to speculate whether the information would have led the EPA to require an alteration in the label.[252] The issue was that the "EPA will have never made any determination at all with regard to the facts withheld."[253]

However, there is another line of cases that deny the remedy of estoppel even when the defendant has withheld information or intentionally misinformed the EPA.[254] The rationale for these rulings is found in the doctrine of separation of powers.[255] These courts have held that it was beyond the power of the courts to analyze the performance of an expert agency, and furthermore, that the agency's lack of proficiency is not relevant to preemption.[256]

The previous three sections of this Note describe a tension in the courts' decisions concerning the scope of FIFRA's preemption of state law damage claims.[257] On one hand, some courts strictly apply the reasoning of *Cipollone* concerning the 1969 Cigarette Act to FIFRA cases, ignoring the inherent differences between the two Acts.[258] These courts justify the current trend of expanding the scope of preemption because they see the judicial branch as technically incompetent to deal with the issue and are guilty of sending haphazard signals to manufacturers.[259] However, after observing the inequitable results of this application, other courts use either a narrow definition of labeling or equitable estoppel as a remedy.[260]

Courts are struggling to accommodate two competing interests. First, they want to avoid overregulation that creates economic burdens which restrict the growth of business or reduce the incentive for invention.[261] Second, they recognize the need to protect the public and the environment from "unreasonable

250. *Id.* at 1179–80.

251. Roberson v. E.I. DuPont De Nemours & Co., 863 F. Supp. 929, 933 (W.D. Ark. 1994) (explaining how the FDA is similar to FIFRA's procedures in that it also relies on information provided by manufacturers to make determinations).

252. *Id.*

253. *Id.* (reasoning that this determination would be beyond the competence of the jury and its requirement would present a hindrance to the critical goal of protecting the integrity of the pesticide registration process).

254. Taylor AG Indus. v. Pure–Gro, 54 F.3d 555 (9th Cir. 1995); *Papas II*, 985 F.2d 516 (11th Cir. 1993); Reutzel v. Spartan Chem. Co., 903 F. Supp. 1272 (N.D. Iowa 1995).

255. *See, e.g., Pure–Gro*, 54 F.3d at 561.

256. *See, e.g., id.*

257. *See supra* notes 161–251 and accompanying text (describing the expansion of FIFRA's preemption and the use of the narrow definition of labeling or estoppel to soften the harsh results of preemption).

258. *See, e.g.*, King v. E.I. Dupont De Nemours & Co., 996 F.2d 1346 (1st Cir. 1993); Shaw v. Dow Brands, Inc., 994 F.2d 364 (7th Cir. 1993); Arkansas–Platte & Gulf Partnership v. Van Waters & Rogers, Inc., 981 F.2d 1117 (10th Cir. 1993); *Papas II*, 985 F.2d 516 (11th Cir. 1993).

259. Mary L. Lyndon, *Tort Law and Technology*, 12 YALE J. ON REG. 137 (1995).

260. *See, e.g.*, Chemical Specialties Mfrs. Ass'n v. Allenby, 958 F.2d 941 (9th Cir. 1992); New York State Pesticide Coalition, Inc. v. Jorling, 874 F.2d 115 (2d Cir. 1989); Roberson v. E.I. DuPont De Nemours & Co., 863 F. Supp. 929 (W.D. Ark. 1994); D-Con Co. v. Allenby, 728 F. Supp. 605 (N.D. Cal. 1989); Macias v. State, 28 Cal. Rptr. 2d 796 (Cal. Ct. App. 1994).

261. McGloughlin & Doi, *supra* note 2, at 278.

risk."[262] This same tension exists in the field of biotechnology, in which uncertainty of the risks involved is increasingly apparent.[263]

III. FIFRA'S STRICT REGULATION OF GEOS

As stated previously, FIFRA defines pesticides broadly[264] so that it covers biological pesticides as well as traditional chemical pesticides.[265] The EPA classifies three discrete types of products as biological pesticides:[266] microbial pesticides,[267] biochemical pesticides,[268] and plant pesticides.[269] The EPA views the potential risks of biological pesticides as lower than those for chemical pesticides.[270] Biological pesticides tend to have greater specificity to the target pest, lower toxicity, and limited persistence in the environment.[271] As a result of these differences, the EPA has developed a reduced set of data requirements for biological pesticides.[272] However, if a biological pesticide has been genetically engineered, FIFRA contains additional requirements.[273] Thus, FIFRA imposes stricter regulations on GEOs than on the same substance produced through traditional means.[274]

This discrepancy in treatment, supported by the 1986 Framework Policy Statement,[275] has engendered much controversy between microbiologists and ecologists.[276] Microbiologists and commercial interests have argued that this policy unfairly singles out rDNA techniques for more stringent supervision.[277] They emphasize the similarities between recombinant DNA techniques and traditional plant and animal cross-breeding practices.[278] Since genetic engineering simply increases the efficiency and specificity of traditional breeding practices, it is no more dangerous than accepted cross-breeding practices and should be regulated by the same process.[279] In fact, microbiologists argue that

262. Linda J. Fisher et al., *A Practitioner's Guide to the Federal Insecticide, Fungicide, and Rodenticide Act: Part I*, 24 ENVTL. L. REP. 10,449, 10,462 (1994).
263. Ferretti, *supra* note 32, at 713.
264. *See supra* notes 49–53 and accompanying text.
265. 7 U.S.C § 136u (1994).
266. Fisher et al., *supra* note 51, at 10,650.
267. *Id.* (defining this subcategory to cover both naturally occurring and genetically engineered microorganisms).
268. *Id.* (observing that there is no definitive line between biochemical and traditional chemical pesticides but requiring that biochemical pesticides must always be of natural origin [i.e. produced by a plant or animal] and must operate through a non-toxic mechanism).
269. EPA, Statement of Policy; Plant-pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act, at 12 (Dec. 20, 1993) (draft) (plant pesticides are defined by the EPA as "pesticidal substances that are produced in the plant and the genetic material necessary for the production of those substances").
270. EPA, Proposal to Clarify the Regulatory Status of Plant-pesticides, at 3 (Nov. 20, 1992) (draft).
271. Fisher et al., *supra* note 51, at 10,650.
272. *Id.*
273. *See* 40 C.F.R. § 158.65–.740 (1993).
274. Fisher et al., *supra* note 51, at 10,650.
275. 51 Fed. Reg. 23,320 (1986).
276. William Allen, *The Current Federal Regulatory Framework for Release of Genetically Altered Organisms into the Environment*, 42 FLA. L. REV. 531 (1990).
277. *Id.* at 534–35.
278. *Id.*
279. *See* Fisher et al., *supra* note 51, at 10,650.

GEOs actually bear a competitive disadvantage and are less likely to survive in the environment, thus making GEOs safer than their traditional counterparts.[280]

On the other hand, ecologists and some members of the general public support the more rigid requirements because of the heightened scientific complexity[281] and the level of unpredictability of biotechnology.[282] They focus on the unintended and unexpected environmental consequences which often accompany the introduction of non-native species into a new ecosystem. Ecologists point to the disastrous effects of such non-native species as kudzu,[283] starlings, and Dutch elm disease.[284] GEOs, like non-native species, can proliferate in a suitable ecological niche, thus creating a huge impact on the ecosystem.[285] It is virtually impossible to locate and kill a flourishing new organism and they cannot be recalled like defective automobiles.[286]

Genetically engineered organisms should elicit a higher level of concern than traditional breeding[287] for many reasons. First, the creation of GEOs expands the variety of genes and enlarges the potential combinations of genes, resulting in an exponential increase in the probability of something going wrong.[288] Second, the addition of a completely new gene, instead of replacing one version of a gene with another, amplifies the unpredictability of outcomes.[289] Third, many of these new traits give the organisms an ecological advantage.[290]

The EPA attempts to balance the facilitation of pesticide research with the protection of humans and the environment while developing its regulations.[291] The uncertainty of the risks related to genetic engineering only makes it more difficult for the EPA to strike this balance. In fact the EPA is simultaneously reducing registration requirements for GEOs,[292] while it actively solicits applications for research on estimating and assessing human health and environmental risks of GEOs.[293]

A. Regulation of Genetically Engineered Microbial Pesticides

FIFRA regulates all microbial pesticides, including genetically engineered microbial pesticides, as a subcategory of biochemical pesticides.[294] Until 1994,

280. Allen, *supra* note 276, at 535.
281. Ferretti, *supra* note 32, at 715 (explaining that the science of biotechnology is multidimensional and highly complex, simultaneously manipulating living matter at many levels).
282. *Id.* at 715–16 (explaining that latency of manifestation, recombination, and mutation are uncontrollable phenomena associated with GEOs).
283. RISSLER & MELLON, *supra* note 1, at 10.
284. Frances E. Sharples, *Regulation of Products from Biotechnology*, 235 SCI. 1329 (1987).
285. Allen, *supra* note 276, at 534.
286. Harlow, *supra* note 23, at 558.
287. RISSLER & MELLON, *supra* note 1, at 12.
288. *Id.*
289. *Id.*
290. *Id.* (stating that traits such as resistance to disease or herbicides give GEOs a competitive advantage and since these traits can be determined by only one or two genes, they would be easily transmitted).
291. Microbial Pesticides; Experimental Use Permits and Notifications, 58 Fed. Reg. 5878 (1993) [hereinafter Microbial Pesticides 1993].
292. *Id.*
293. Solicitation for applications for Biotechnology Risk Assessment Research, 59 Fed. Reg. 59,348, 59,401 (1994).
294. Fisher et al., *supra* note 51, at 10,652.

the EPA required researchers and manufacturers to notify the EPA for even small-scale testing of genetically altered microbial pesticides.[295] After reviewing more than seventy-five genetically engineered microorganisms under the 1986 policy and finding no significant risk concerns for small scale testing, the EPA decided to loosen its restrictions on genetically modified microorganisms, ("GEMs").[296] Subsequently, the EPA issued the final FIFRA rule for microbial pesticides.[297]

Under this amended rule only "microbial pesticides whose pesticidal properties have been imparted or enhanced by the introduction of genetic material that has been genetically modified" require EPA review and approval for small-scale testing.[298] The EPA had two goals in reformulating this rule. First, they wanted to limit restrictions and red tape on low risk GEOs.[299] Second, they wished to ensure that until the Agency obtained information sufficient to conclude that the use of a GEO was "safe," the stricter registration and notification process would remain intact.[300] Accordingly, the final FIFRA rule for microbial pesticides requires notification of small-scale field testing unless the EPA has determined that the GEM is unlikely to cause unreasonable adverse effects.[301] FIFRA regulates all GEMs that do not fit in these two categories by the reduced set of procedures designed for biological pesticides.[302]

B. Regulation of Genetically Engineered Plant Pesticides

The other subcategory of biochemical pesticides that involves GEOs is plant pesticides. Plant pesticides are "pesticidal substances that are produced in the plant and the genetic material necessary for the production of those substances."[303] The use of rDNA to introduce pesticidal properties into the plants themselves is one of the most promising uses of genetic technology.[304] Several companies have developed and are planning to market crops that contain an insect control protein derived from a soil bacteria, Bacillus thuringiensis (Bt).[305]

The EPA drafted a proposed rule and statement of policy concerning the genetically engineered plant pesticides in order to define the requirements for such plants.[306] The EPA, under FIFRA, will assert control only over the pesticidal substances produced by the plant, not the plant itself,[307] and intends to

295. Microbial Pesticides 1993, *supra* note 291, at 5881 (The development of a biological pesticide includes a number of steps: initial development and testing in the laboratory and the greenhouse, small scale outdoor testing, and large outdoor testing in a variety of climates. All these tests provide the data that is required by the EPA for registration and labeling.).

296. Microbial Pesticides; Experimental Use Permits and Notifications, 59 Fed. Reg. 45,600 (1994) [hereinafter Microbial Pesticides 1994].

297. *Id.*

298. Microbial Pesticides 1993, *supra* note 291, at 5882.

299. *Id.* at 5880.

300. *Id.*

301. *Id.*

302. *Id.* at 5881–82 (1993) (EPA presumes that most applications of most pesticides do not involve unreasonable adverse effects to human health or the environment.)

303. EPA, Statement of Policy, *supra* note 269, at 12.

304. Fisher et al., *supra* note 51, at 10,650.

305. National Biological Impact Assessment Program News Report (Dec. 1995).

306. EPA, Proposed Policy; Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act, 59 Fed. Reg. 60,496–60,501 (1994) [hereinafter EPA, Proposed Policy].

307. EPA, Statement of Policy, *supra* note 269, at 12.

exempt most genetically engineered plant pesticides from regulation.[308] The EPA wants to focus on those plant-pesticides that have the greatest potential for environmental or human health risks.[309] To this end, the EPA is proposing to exempt three types of plant pesticides from FIFRA regulations:[310] (1) those plant-pesticides that have been derived from a closely related plant; (2) those plant-pesticides that would not result in adverse effects to non-target organisms because they are primarily affecting the plant;[311] and (3) coat proteins which form plant viruses when produced in plants for virus coat protein mediated resistance.[312]

IV. THE EFFECT OF FIFRA'S REGULATION OF GEOS ON COMMON LAW TORT CLAIMS

There are three main issues to consider when analyzing the preemption effect which FIFRA regulation of GEOs has on state damage claims. The first issue involves the effect of the exemption of plant-pesticides and GEMs from the scope of the EPA's regulation under FIFRA.[313] The second issue concerns the effects of stricter regulation of GEOs, under some sections of FIFRA, as compared to identical chemical pesticides or biological pesticides. The final issue arises in relation to the effect of scientific uncertainty surrounding genetic engineering in combination with the potentially irreversible effects of GEOs on the environment.

The scope of FIFRA preemption on state damage actions involving genetically engineered pesticides would likely be similar to that involving traditional chemical pesticides, but the final results may differ. FIFRA regulates all genetically engineered pesticides under the same registration process as chemical pesticides,[314] unless the GEO is exempt from FIFRA's regulatory control[315] or under stricter requirements due to the uncertainty of the risks posed by GEOs.[316]

The result of FIFRA's preemption may be different with genetically engineered pesticides than with chemical pesticides. More avenues may be open

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308. *Id.* at 7.

309. EPA, Proposed Policy, *supra* note 306, at 60,500.

310. National Biological Impact Assessment Program (Feb. 1995) (EPA extended the comment period on this proposed rule until the end of February 1995).

311. EPA, Statement of Policy, *supra* note 269 (describing that these plant-pesticides work by a variety of non-toxic methods including altering plant structures to make the plant less susceptible to pests, altering plant biochemistry to make it less susceptible to toxins from the pest, or altering the plant's nutritional value to the pest to make it less attractive).

312. *Id.* (Coat proteins are those substances that viruses produce to encapsulate and protect their genetic material. When the genetic material encoding the coat protein from a plant virus is introduced into a plant's genome, the plant is able to resist infections by the virus. This process is called viral coat protein mediated resistance. There is strong opposition to the deregulation of coat proteins because of the fear that the use of two viral coat proteins could lead to the creation of new plant viruses).

313. EPA, Proposed Policy, *supra* note 306, at 60,500 (Here the EPA states that "plant-pesticides not exempt would form the scope of EPA's regulatory scrutiny under FIFRA.").

314. 7 U.S.C.A. § 136u (West Supp. 1994) (Due to the broad definition of "pesticide," which includes genetically engineered pesticides, *see supra* notes 49–53 and accompanying text.).

315. EPA, Proposed Policy, *supra* note 306, at 60,500 (plant-pests exempt from FIFRA are outside the scope of EPA's regulatory control).

316. *See supra* notes 249–53 and accompanying text.

to plaintiffs in cases involving GEOs, such as strict liability claims, if GEOs are considered abnormally dangerous,[317] or failure to warn claims when harm is caused by GEOs not regulated by FIFRA. On the other hand, plaintiffs' choices may be more limited due to difficulty in identification,[318] and the analogy of genetic engineering to traditional plant breeding techniques.[319] In addition, the presumption of reduced risks for biological pesticides may apply to GEOs[320] in the final version of FIFRA's regulation of plant-pesticides.[321] This presumption would reduce the registration requirements and the supervision of GEOs but FIFRA might still preempt many tort claims.

A. Strict Liability

According to section 402A of the Restatement (Second) of Torts, sellers are strictly liable for injuries that result from product defects.[322] Genetically engineered pesticides are produced by intellectual effort and physical labor; therefore they can be defined as a product.[323]

Strict products liability focuses on the nature of the product rather than the seller's conduct.[324] If the product is "in a defective condition unreasonably dangerous to the user" and the causal connection is sufficient, the seller is liable regardless of his care.[325] A product can be defective in three ways: (1) by containing a manufacturing defect; (2) by bearing a design defect; or (3) by failure to warn. Under the direct application of *Cipollone* to FIFRA, design defect or manufacture defect are the only forms of strict liability available to plaintiffs harmed by a FIFRA regulated, genetically engineered pesticide.[326] However, GEOs that are exempt from FIFRA regulation may not be subject to preemption by the Act, consequently allowing failure to warn claims.[327]

B. Manufacturing Defect

A manufacturing defect is an

> abnormality or a condition that was unintended...[which] makes the product more dangerous than it would have been as intended. A defect or flaw that is created in the construction or marketing process makes the

317. *See* RESTATEMENT (SECOND) OF TORTS §§ 519, 520 (1965).

318. KRIMSKY, *supra* note 4, at 97–99 (identification is difficult because microorganisms are classified by their phenotype (physical characteristics). As a result, a change in genetic structure will not necessitate a change in classification, making it difficult to compile an inventory of safe and unsafe GEOs).

319. Allen, *supra* note 276, at 534.

320. Fisher et al., *supra* note 51, at 10,650.

321. National Biological Impact Assessment Program News Report (Apr. 1995) (FIFRA's proposed plant-pesticide rule was strongly criticized for still singling out GEOs for increased regulation. The final rule will incorporate some of these criticisms and possibly regulate rDNA plant-pesticides in the same manner as other biological or chemical pesticides).

322. RESTATEMENT (SECOND) OF TORTS § 402A (1965).

323. BLACK'S LAW DICTIONARY, *supra* note 73, at 840 ("product" is defined as something produced by physical labor or intellectual effort).

324. W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 99, at 695 (5th ed. 1984).

325. Brown v. Superior Court, 751 P.2d 470, 474 (Cal. 1988).

326. *See supra* notes 170–78 and accompanying text (illustrating that failure to warn based on inadequate labeling is preempted by FIFRA for any pesticide, including genetically engineered pesticides).

327. *See supra* note 310 and accompanying text (addressing the issue of preemption and exemption from FIFRA's regulation).

> product unreasonably dangerous as a matter of law, since it causes the product to be more dangerous than it was designed to be.[328]

Plaintiffs harmed by genetically engineered pesticides may have more difficulty proving a manufacturing defect than those harmed by chemical pesticides. The three most common methods of proving a manufacturing defect are: (1) proving that an identifiable flaw existed; (2) relying on user or observer testimony that a pesticide did not work as intended; and (3) relying on the accident itself to indicate a product failure.[329]

There are at least four reasons why these methods of evidentiary proof would be exceedingly difficult and often unsuccessful for plaintiffs harmed by GEOs. First, the victim may not be aware his injuries are rDNA related.[330] Problems caused by GEOs can appear to be commonplace occurrences, such as failed crops, a nagging cold, or a severe rainstorm.[331] Therefore, a victim may not consider or understand the possibility of harm by GEOs.[332] The combination of a lack of awareness and understanding of genetic engineering, the complexity of the science, and the difficulty in identification make it difficult to prove flaws in GEOs. Second, the complexity and uncertainty of the science forces litigants to present extensive expert testimony, creating overwhelming barriers in meeting the burden of proof.[333] Third, this technology is developing at such a rapid rate that firms must expend huge amounts of money on research and development that may not be productive.[334] This strain has resulted in many firms filing bankruptcy or selling out to larger companies that have found ways to make themselves judgment proof.[335] Under either scenario, the plaintiff will be uncompensated.

Finally, the most difficult problem is that of proving causation. Under the present tort system, a plaintiff must (1) isolate the microorganism that initiated the injury, (2) eliminate other feasible alternative causes, and (3) establish the source of the GEOs.[336] Due to the similarity of GEOs to biological or chemical pesticides, the incorporation of GEOs into the plant genomes, regeneration, recombination, and mutation, the first two elements necessary to show causation are virtually impossible to establish.[337] Additionally, many companies produce the same GEOs, so identification is extremely complex, making the third element difficult to demonstrate unless some type of tagging system is required on all GEOs.[338]

Therefore, plaintiffs harmed by genetically engineered pesticides as a result of a manufacturing defect will have many extra hurdles to overcome. These problems are caused by the difficulty in identifying GEOs,[339] the

328. KEETON ET AL., *supra* note 324, at 695.
329. *Id.* at 697. (listing these three methods of proving manufacture defect).
330. Harvard Law Review Association, *supra* note 8, at 1094.
331. *Id.*
332. *Id.*
333. *Id.*
334. *Id.*
335. *Id.*
336. *Id.*
337. *Id.*
338. *Id.*
339. Ferretti, *supra* note 32, at 712.

complexity of the science,[340] the uncertainty of the risks involved,[341] and the costs for expert witnesses required to support these types of claims.[342]

C. Design Defects

When all the products are made identically according to manufacturers' specifications, but have dangerous propensities because of their intended inherent properties, the entire line may be found to be defective because of poor design.[343] The difficult aspect of proving design defect is determining what is an "unreasonably dangerous" design.[344] The two methods used to determine this are the consumer-expectation test and the risk-utility test.[345]

Under the consumer-expectation test, a product is deceptively designed if it is more dangerous than the ordinary user would expect.[346] Due to their benign appearance and statements by microbiologists[347] and the EPA[348] that biological pesticides are safer than chemical pesticides, genetically engineered pesticides may pass this part of the test. The manufacturer may increase the defective nature of the product by introducing the pesticide into the genome of the plant,[349] because it is then exempt from FIFRA's regulation and the EPA considers it to be unlikely to "cause unreasonable adverse effects."[350] However, EPA exemption could be determined to be a judgment that the health, safety, and environmental risks were acceptable.[351] Thus state common law liability could be preempted by FIFRA because the state law would conflict with the federal regulation.[352] Additionally, causation will be more difficult to prove than with a chemical pesticide due to the uncertainty of risks posed by GEOs, as well as to the difficulty in identification inherent in the process of genetic engineering.[353]

Under the risk-utility test a product is "unreasonably dangerous" if the magnitude of the danger outweighs the utility of the product.[354] There are three primary reasons for finding a product defective: (1) the harmful consequences from intended and reasonably foreseeable uses outweigh the benefits; or (2) the harmful consequences do not exceed the benefits but alternative products were available; or (3) there was a feasible way to design the product with less harmful

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340. *Id.*
341. *Id.*
342. Harvard Law Review Association, *supra* note 8, at 1094.
343. KEETON ET AL., *supra* note 324, at 698.
344. *Id.*
345. *Id.*
346. *Id.*
347. Allen, *supra* note 276, at 536.
348. EPA, Statement of Policy, *supra* note 269, at 12.
349. Fisher et al., *supra* note 51, at 10,650; Rebecca J. Goldburg, *Attack of the Killer Tomatoes,* JAMA (1991) (referring to pesticides such as Bacillus thuringiensis [Bt]. In most plants the Bt genes are expressed throughout the plant.).
350. EPA, Proposed Policy, *supra* note 306, at 60,500.
351. Ogden Envtl. Servs. v. City of San Diego, 687 F. Supp. 1436 (S.D. Cal. 1988). This concept will be discussed more fully under the section on failure to warn, *infra* note 359 and accompanying text.
352. *Ogden,* 687 F. Supp. at 1441.
353. KRIMSKY, *supra* note 4, at 97–99 (there are at least two reasons why GEOs will be hard to identify after release into the environment: (1) the enormous potential for reconfiguration caused by mutation and recombination; and (2) biological agents tend to be classified by their phenotype (physical characteristics) rather than by a precise identification by chemical composition).
354. KEETON ET AL., *supra* note 324, at 699.

consequences.[355] As with most design defect cases, litigation on genetically engineered pesticides would center around what harms or uses were reasonably foreseeable and the feasibility of an alternative design.[356] Consequently, design defects of GEOs would be as difficult to prove as manufacture defects and for the same reasons.[357]

D. Failure to Warn

The courts have interpreted the relationship between FIFRA and liability for injuries caused by traditional chemicals in a variety of ways.[358] Presently, it seems clear that product liability litigation arising out of failure to warn claims concerning FIFRA-regulated pesticides will be preempted if the claims are based on inadequate labeling or packaging. Other avenues may exist to bring claims. For example, the manufacturer may have provided the EPA with inadequate data, the label may not be designed for a third party, or the particular pesticide may be "unreasonably dangerous." These claims are more difficult[359] and expensive to prosecute[360] and less appealing to a jury.[361]

The effect on genetically engineered pesticides is similar because they follow the same labeling requirements, unless exempt from FIFRA. The proposed FIFRA will exempt some plant-pesticides because they are "of a character which is unnecessary to be subject to the Act in order to carry out the Act."[362] These exempt plant-pesticides are not governed by FIFRA's registration requirements.

One result of a product's exemption from the scope of FIFRA's regulation could be that failure to warn claims would not be preempted by FIFRA for harms caused by the exempt product. If there are no federal control measures imposed, it appears logical that the state should be allowed to protect the health and welfare of its citizens. Although this is an unsettled issue, there is law indicating that when a federal agency finds a product exempt from a regulation, the reviewing court will hold that "the EPA has found [the product] safe."[363] Under this interpretation any state law protecting the consumer would interfere with the federal judgment of safety and be preempted by the federal determination.[364] This case law follows the recent trend toward preemption of common law actions,

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355. *Id.*
356. *Id.* at 699–700.
357. *See supra* notes 288–99 and accompanying text.
358. *See supra* notes 94–233 and accompanying text.
359. Linda Maher, *The Environment and the Domestic Regulatory Framework for Biotechnology*, 8 J. ENVTL. L. & LITIG. 133, 150 (1993) (explaining that access to the data is in the hands of the manufacturer and often protected as trade secrets).
360. Lyndon, *supra* note 259, at 141 (stating that expert testimony is very expensive especially in such a new field).
361. Maher, *supra* note 359, at 137 (Maher asserts that most jurors can be expected to presume that in order for a pesticide to be effective it is likely to be harmful to humans. A claim that the plaintiff would not have used the product if he understood the risks or had been properly warned would seem more reasonable to a jury.).
362. Proposed Policy; Plant-pesticides Subject to FIFRA, 59 Fed. Reg. 60,496, 60,499 (1994).
363. Ogden Envtl. Servs. v. City of San Diego, 687 F. Supp. 1436, 1446 (S.D. Cal. 1988).
364. *Id.*

especially failure to warn claims.[365] Therefore it is highly probable that FIFRA exemption as well as FIFRA regulation would preempt failure to warn claims.

V. ELIMINATION OF TORT CLAIMS

The United States' choice to regulate genetic engineering under existing laws has resulted in a complex set of regulations and increased the tension between the federal regulatory scheme and tort law. FIFRA is an excellent example of a law whose purpose has changed so drastically over time that it is like "using the wrong tool to repair an engine [so that] either the tool or engine ends up broken."[366]

Furthermore, the extension of FIFRA to include the regulation of GEOs makes it even less effective due to all the differences between chemical pesticides and genetically engineered pesticides.[367] The complexity and uncertainties of the science of genetic engineering enhance the difficulties of proving causation, virtually eliminating strict liability based on manufacture defect or design defect. In addition, the ever-changing nature of genetic engineering leaves the courts with no standard of care.[368] Therefore, it is unreasonable to think the plaintiff could prove negligence. As a result of the unique nature of GEOs, FIFRA's preemption of all failure to warn claims, even when the company has misinformed the EPA, appears to almost eliminate any chances of recovery from harm caused by GEOs.

FIFRA's inability to efficiently regulate GEOs, combined with the current trend of expanding FIFRA's preemption of common law damage claims, leads to an unexpected result. Ironically, many plaintiffs will have their private rights extinguished precisely because Congress has chosen to protect health and the environment.[369]

365. Lyndon, *supra* note 259, at 137.
366. S. Res. 2050, 103d Cong., 2d Sess. § 4875 (1994).
367. Allen, *supra* note 276, at 540.
368. Harvard Law Review Association, *supra* note 8, at 1094.
369. Ferretti, *supra* note 32, at 230.