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**Looking for the Big Picture —
Developing a Jurisprudence for a
Biotechnological Age**

Joan M. Ferretti*

I. Purpose

Biotechnology is rapidly emerging and becoming a part of our daily life.¹ Investment decisions are made everyday while legal commentators comment, criticize, and propose new legislative and regulatory responses to govern the biotechnology arena.² This article posits for biotechnology: (a) that in terms of the regulatory and legal system's responsibility to society,

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1. See, e.g., *Biosurface Technology - Fledgling Company*, NEWSWEEK, Mar. 1, 1993, at 40; Anita M. Samuels, *The Grower of Grease-Eating Bacteria*, N.Y. TIMES, Oct. 25, 1992, at 8F.

2. See, e.g., the existing regulations are summarized and suggestions made in, Linda Maher, *Environmental Concerns: The Domestic Regulatory Framework for Biotechnology*, 12, no. 4 NYSBA ENVTL. L. SEC. J. 16 (Nov. 1992); Peter Mostow, *Reassessing the Scope of Federal Biotechnology Oversight*, 10 PACE ENVTL. L. REV. 227 (1992); Lawrence Fisher, *The Fragile, Beleaguered Biotech*, N.Y. TIMES, Mar. 30, 1993, at D1, D17.

valuable lessons can be learned from our experience with organic chemical technology from the 1940s up to the present; (b) that it would be a mistake to embark on a regulatory program for biotechnology without establishing, in a forward-looking way, the appropriate relationship between regulations and the common law; and, (c) where appropriate, statutes should be enacted that specify rights, remedies, and applicable evidentiary standards. This article does not present a legislative proposal. Instead, it sets out a series of questions that must be addressed to develop a jurisprudence for the biotechnological era.

II. The Historical Perspective of 50 Years of Organic Chemical Technology

A. The Introduction of Organic Chemical Technology to Post-War American Society

During World War II, the need for rubber substitutes, pharmaceuticals, and materials for aviation provided an incentive for basic organic chemical research. After the war, war-time technologies were converted for peace-time uses and, almost overnight, organic chemicals became part and parcel of everyday life. Various synthetic fabrics, wrappings and packagings for industrial, commercial and household use followed rapidly. Organic chemicals became standard worldwide as agricultural pesticides and fertilizers. Synthetic fuel additives, pesticides for household, commercial and medical uses, plastics, synthetic pharmaceuticals, and cosmetics became common place. Paints, inks, solvents, greasers and de-greasers, adhesives, floorings, and sidings can be and are derived from organic chemicals. Almost overnight, whole industries became dependent upon organic chemicals.³ Previously non-existent industries became significant market players⁴ due to lu-

3. See, e.g., *Draft Environmental Impact Statement on Amendments to 6 N.Y. Comp. Codes R. & Regs. Part 326 Relating to the Restriction of the Pesticides Aldrin, Chlordane, Chloropyrifos, Dieldrin and Heptachlor*, N.Y. Dep't of Env'tl. Conservation, at 308-14 (Feb. 1986) [hereinafter *Draft EIS*].

4. *Analysis of the Risks and Benefits of Seven Chemicals Used for Subterranean Termite Control*, United States Env'tl. Protection Agency, EPA-540/9-83-005

crative sales of these new commercial products. Organic chemicals and their products promised to enhance the American Dream.

Meanwhile, the nation was engaged in large scale post-war growth, development, and euphoria. Highways were built, and whole new communities emerged, as Levittowns (housing developments) began to surround many major metropolitan centers. Suburbs expanded and began to crowd out farm lands, making increased farm production a necessity. Gas rationing ceased and Americans demanded more automobiles. Home improvements, lawn care, furnishings and trappings, ignored and threadbare through years of war and depression, suddenly took on new life. Consumer demand increased. Men resumed their places in the work force, while "Rosie-the-Riveter" went back into the home and the baby boom generation was born.⁵ At this time, the nation's focus was on growth and development, not on the potential for environmental harm or the health consequences which could result from the wide-scale use of organic chemicals. In fact, such concerns did not come into national focus until nearly thirty years later.

B. Why Organic Chemical Technology is an Appropriate Model for Biotechnology

The science of organic chemical production is essentially simple. It is the science of carbon rings or chains, which, by the addition or subtraction of hydrogen, oxygen, halogens or phosphates through mixing or distilling, produces products as diverse as pesticides and plastic wraps, but also produces wastes even more diverse than the products.⁶ Despite the

(Nov. 1983); *Draft Technical Support Document for Chlordane, Heptachlor, Aldrin and Dieldrin*, United States Env'tl. Protection Agency, EPA-OPP I-12, III-2 to III-5 (July 1987) [hereinafter *Technical Support Document*]; J. Everett Bussart & A. Schor, *Chlordane*, SOAP AND SANITARY CHEMICALS, Aug. 1948, at 16 (authors are employees of Velsicol Chem. Corp).

5. See ALISTAIR COOKE'S AMERICA 373-75 (Alfred A. Knopf, N. Y. 1974).

6. See generally MORRISON & BOYD, ORGANIC CHEMISTRY (Allyn & Bacon, Inc. ed. 1966); *Farm Chemicals Handbook*, 1984; THE MERCK INDEX: AN ENCYCLOPEDIA OF CHEMICALS AND DRUGS (8th ed. Merck & Co., Inc. 1968); *Recognition and Management of Pesticide Poisonings*, United States Env'tl. Protection Agency, Office of Pes-

simplicity of the production methods, organic chemical technology has created several complicated problems which have continually challenged regulators, courts, and communities. These can be summarized as follows:

(a) The formulation processes are imprecise, yielding mixtures with varying chemical percentages in different batches.⁷

(b) The industry was capable of making and selling products long before it could even identify the compounds in the mixtures and by-products, and long before it could adequately test and assess their individual toxicities and the potential adverse effects on the environment and people.⁸

(c) Manufacture and marketing of organic chemicals predated society's ability to accurately measure residues in the environment or living tissue.⁹

(d) Evaluation of the health or environmental effects of exposure to organic chemicals is complicated by the similarity of responses between and among exposure to different chemicals, metabolic changes, and the latency pe-

ticide Programs, EPA-540/9-77-013, (2d ed. Aug. 1977). See also *Technical Support Document*, *supra* note 4, at A-1, A-6; *Draft EIS*, *supra* note 3, at 15; *Carcinogenicity Assessment of Chlordane and Heptachlor/Heptachlor Epoxide*, United States Envtl. Protection Agency, Carcinogen Assessment Group, Office of Health and Environmental Assessment, OHEA-C-204, Dec. 1986 at 3-1 thru 3-3 [hereinafter *CAG Report*].

7. See *CAG Report*, *supra* note 6, at 3-1 to 3-4; Plaintiff's Exhibit # 7, at A-796 to A-835, *Jones v. Arrow Exterminating Co.*, No. 92-02133 (N.Y. Sup. Ct., Nassau County, Sept. 5, 1991) (Standard for Technical Chlordane (Aug. 1971)); Plaintiff's Exhibit # 8, at A-761 to A-795, *Jones v. Arrow Exterminating Co.*, No. 92-02133 (N.Y. Sup. Ct., Nassau County, Sept. 5, 1991) (Standard for Technical Chlordane July 1979)); see also *Jones v. Arrow Exterminating Co.*, No. 92-02133, Record on Appeal 754-59, 486-93 (pending N.Y. App. Div., 2d Dep't).

8. Tomoyuki Miyazaki et al., *Isolation and Structure Elucidation of Some Components in Technical Grade Chlordane*, 14 ARCHIVES OF ENVTL. CONTAMINATION & TOXICOLOGY 475 (1985); William P. Cochrane & Roy Greenhalgh, *Chemical Composition of Technical Chlordane*, 59 J. OF THE AOAC 696 (1976); Dearth & Hites, *Complete Analysis of Technical Chlordane Using Negative Ionization Mass Spectrometry*, 25 ENVIRON. SCI. TECHNOL. 245-54 (1991); see also *Jones*, No. 92-02133, Record on Appeal 754-59, 486-93, 503-05.

9. See generally *supra* note 8; *Draft EIS*, *supra* note 3; C. G. Wright & R. B. Leidy, *Chlordane and Heptachlor in the Ambient Air of Houses Treated for Termites*, 28 BULL. ENVIRON. CONTAM. TOXICOL. 617-23 (1982).

riods which accompany the development of many chemically-induced diseases.¹⁰

The science of biotechnology is multi-dimensional and more complex than the science of organic chemical technology. Its processes include work and manipulation at the tissue, cellular, ultra-cellular, (*i.e.*, the organs of the cell) and biochemical (as distinguished from organic chemical) levels.¹¹ Its products include genetically-altered viruses and bacteria, which could potentially perform a whole host of environmentally, commercially or agriculturally valuable services, cultured or genetically altered cells which could be implanted in plants, animals or humans, for a variety of medical or commercial purposes, and much more.¹² Its waste stream potentially includes not only the solvents, nutrients and culture media involved in the process, but also off-spec, unsatisfactory living materials, and spent or used living material.¹³ Despite its heightened scientific complexity, biotechnology will also be complicated by the difficulties of identification, detection, and latency of manifestation, which complicate evaluations in organic chemical technology. To this level of unpredictability, biotechnology adds the potential for regeneration, recombination and mutation in uncontrolled or loosed cells or orga-

10. See *CAG Report*, *supra* note 6, at 3-4 to 3-8; E. P. Savage et al., *National Study of Chlorinated Hydrocarbon Insecticide Residues in Human Milk, USA*, 113 AM. J. OF EPIDEMIOLOGY 413 (1981); See also *Technical Support Document*, *supra* note 4, at II-1-169; *CAG Report*, *supra* note 6, at 4-32 to 4-62, 4-63 to 4-81, 6-1 to 6-7; see also *Jones*, No. 92-02133, Record on Appeal 532-34.

11. J.N. DAVIDSON, *THE BIOCHEMISTRY OF NUCLEIC ACIDS* (Academic Press 1972); U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, *NEW DEVELOPMENTS IN BIOTECHNOLOGY: 5 PATENTING LIFE - SPECIAL REPORT*, OTA-BA-370, at 93-102 (Washington, D.C., U.S. Printing Office, Apr. 1989); U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, *NEW DEVELOPMENTS IN BIOTECHNOLOGY, 1 OWNERSHIP OF HUMAN TISSUES AND CELLS-SPECIAL REPORT*, OTA-BA-337, at 5-6 (Washington, D.C., U.S. Printing Office, Mar. 1977); U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, *NEW DEVELOPMENTS IN BIOTECHNOLOGY, 4 U.S. INVESTMENT IN BIOTECHNOLOGY*, OTA-BA-360, at 3 (Washington, D.C., U.S. Printing Office, July 1988).

12. See *supra* note 1. See, e.g., Geoffrey Cowley, *Progress on Parkinson's*, NEWSWEEK, Dec. 7, 1992 at 68; *Soil Decontamination of Heavy Metals*, undated, with permission of Summit Environmental Evaluations, Inc.; Sharon Begley et al., *Cures from the Womb*, NEWSWEEK, Feb. 22, 1993, at 49-51; see also *It's a (Blonde-Haired, Blue-Eyed, Even-Tempered, Ivy-Bound) Boy*, N.Y. TIMES MAG., Feb. 7, 1993, § 6, at 20.

13. See, e.g., Samuels, *supra* note 1, at 8F; see also Shanks, *infra* note 114.

nisms, and the same phenomena in their hosts or targets.¹⁴

Like the situation at the end of World War II, the nation is now on the brink of a new technological era, with a developing technology which has a similar potential for becoming commonplace, beneficial, profitable, and problematic. The science of biotechnology is more complex than the science of organic chemical technology because it has the potential to alter living processes, re-program DNA molecules, select for altered cells or genes, predict biological events, splice living tissues into different organisms, farm and harvest bacteria and viruses, and effect genetic engineering.¹⁵ However, similar to organic chemical technology, biotechnology is unpredictable, risky, and capable of causing pollution and harm to health and the environment. Also, like organic chemical technology, biotechnology offers benefits to society and huge profits to investors. The countervailing pressures are, therefore, virtually identical. For these reasons, our societal-legal experience with organic chemical technology is an appropriate model for evaluation of legislative responses to biotechnology.

C. Overview of Backward-Looking Regulatory Responses to Organic Chemical Technology

At the outset, organic chemical technology was devoid, for all practical purposes, of regulatory limitations. From the 1940s until the mid-1960s, the nation was seemingly oblivious to its developing legacy of abandoned hazardous waste dumps, fields and by-ways wasted by excessive pesticides, fish and wildlife threatened by pesticides and fertilizers, and of a population exposed to unquantified, unevaluated, unstudied, and unexplained risks of harm.¹⁶ In the heat of the World War II

14. See, e.g., U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY, 3 FIELD TESTING ENGINEERED ORGANISMS: GENETIC AND ECOLOGICAL ISSUES, OTA-BA-350, at 11-18, 71-108 (Washington, D.C., U.S. Printing Office, May 1988).

15. E.g., *supra* notes 1, 12.

16. See, e.g., RACHAEL CARSON, SILENT SPRING - 25TH ANNIVERSARY EDITION, Houghton-Mifflin Company, 1962; see generally Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) §§ 103-405, 42 U.S.C. §§ 9601-9675 (1988); Resource Conservation and Recovery Act (RCRA) §§ 1002-11012, 42

effort, a regulatory approach to organic chemicals was not a priority. Even after the war, it was still not a consideration.

The price the nation has incurred for its lack of organic chemical foresight is now being paid by Potentially Responsible Parties (PRPs)¹⁷ at waste sites across the nation. This has resulted in a diversion of resources away from investment and economic growth. The nation's health care system, its taxpayers, its natural resources, and its citizen's health, enjoyment and prosperity have also paid the price for the lack of organic chemical foresight.

This lack of foresight is illustrated by the fact that the United States Environmental Protection Agency (EPA) was not created as the lead federal environmental agency until 1970.¹⁸ Moreover, until 1972, there were no real federal regulatory programs that addressed organic chemicals. In 1972, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was enacted.¹⁹ The Resource Conservation and Recovery Act (RCRA) and the Toxic Substances Control Act (TSCA) were not enacted until 1976²⁰ and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) was not enacted until 1980.²¹ The predecessor

U.S.C. §§ 6701-6999k (1988). This is further supported by the legislative history of CERCLA and RCRA. *See generally* 1980 U.S.C.C.A.N. 6119-6240; 1976 U.S.C.C.A.N. 6252 and the Hazardous and Solid Waste Amendments of 1984, Pub. L. No. 98-616, 1984 U.S.C.C.A.N. 5576-5702.

17. "PRPs" or Potentially Responsible Parties are those parties who, generally without conceding liability, are participating in the clean-up of waste sites on the National Priority List. CERCLA §§ 105, 107, 42 U.S.C. §§ 9605, 9607 (1988); *see* 40 C.F.R. § 300.425 (1992) (National Priority List requirements) and 40 C.F.R. pt. 300 (1992) (National Contingency Plan).

18. President Nixon's Reorg. Plan No. 3 of 1970, 40 C.F.R. 1.1 (1970), *reprinted in* 5 U.S.C. app. at 99 (1989 Supp.) and 84 Stat. 2086 (1970); *see also* SHELDON NOVICK, *LAW OF ENVIRONMENTAL PROTECTION* §§ 2.01, 15.01 (1987 & 1992).

19. *See* Pub. L. No. 92-516, 86 Stat. 973 (1972) (current version codified as amended at Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) §§ 2-31, 7 U.S.C. §§ 136-136y (1988)).

20. *See* Pub. L. No. 94-469, 90 Stat. 2003 (1976) (current version codified as amended at Toxic Substances Control Act §§ 2-311, 15 U.S.C. §§ 2601-2671 (1988)); Pub. L. No. 94-580, 90 Stat. 2795 (1976) (current version codified as amended at RCRA §§ 1002-11012, 42 U.S.C. §§ 6901-6999k (1988)).

21. Pub. L. No. 96-510, 94 Stat. 2767 (1980) (current version codified as amended at CERCLA §§ 101-618, 42 U.S.C. §§ 9601-9675 (1988)).

statutes were administered on a fragmented basis and were largely unenforceable. Furthermore, the implementing regulations for RCRA and TSCA did not take effect until 1980,²² nearly forty years after the first synthetic derivatives of organic chemicals were manufactured and the first organo-chlorinated pesticides were applied to fields in the United States.²³ Moreover, in 1991, the Clean Air Act (CAA) regulations for toxic air pollutants were still under development.²⁴

The direct regulatory approaches to organic chemicals have included: registration of pesticides (1972),²⁵ bans on toxic substances (1976),²⁶ regulation of the generation, transportation, treatment, storage, and disposal of hazardous waste (1976),²⁷ and establishment of a revolving fund for cleaning up past and inactive hazardous waste sites (1980).²⁸ Incidental regulations impose specific requirements for work places, interstate carriers, food and drug additives, air emissions, effluent discharges, and oil spills.²⁹

Each statute was enacted as a fire-fighting device after

22. Consolidated Permit Regulations, 45 Fed. Reg. 33,066-36,588 (May 19, 1980).

23. *Id.*

24. See, e.g., Edward F. Premo, II, *The Clean Air Act Amendments of 1990: Hazardous Air Pollutants Controls and New Permit Program*, 11, no. 2 NYSBA ENVTL. L. SEC. J. 3-7 (Aug. 1991); see also *Environmental Defense Fund v. EPA*, 598 F.2d 62 (D.C. Cir. 1978) (toxic water pollutants - PCB's).

25. FIFRA §§ 2-31, 7 U.S.C. §§ 136-136y (1988).

26. TSCA §§ 2-311, 15 U.S.C. §§ 2601-2671 (1988).

27. RCRA §§ 3001-3021, 42 U.S.C. §§ 6921-6939b (1988).

28. CERCLA § 111, 42 U.S.C. § 9611 (1988).

29. FIFRA §§ 2-31, 7 U.S.C. §§ 136-136y (1988); CERCLA §§ 101-405, 42 U.S.C. §§ 9601-9675 (1988); RCRA §§ 1002-11012, 42 U.S.C. §§ 6901-6999k (1988); Federal Water Pollution Control Act (FWPCA) §§ 311, 402, 33 U.S.C. §§ 1321, 1342 (1988) (oil spills and effluent discharges respectively); Clean Air Act (CAA) §§ 101-618, 42 U.S.C. §§ 7401-7671q (1988), CAA § 112, 42 U.S.C. § 7412 (1988 & Supp II. 1990) (Toxic Air Emissions); Toxic Substances Control Act (TSCA) §§ 2-311, 15 U.S.C. §§ 2601-2671 (1988); see also Hazardous Materials Transportation Act (HMTA), 49 U.S.C. §§ 1801-1813 (1988); Occupational Safety and Health Act (OSHA), 29 U.S.C. § 651 (1988); Safe Drinking Water Act (SDWA) §§ 1401-1465, 42 U.S.C. §§ 300f-300j-25 (1988) (also referred to as the Public Health Service Act (PHSA)); and The Marine Protection Research and Sanctuaries Act (MPRSA) §§ 2-205, 33 U.S.C. §§ 1401-1445 (1988) (also commonly referred to as The Ocean Dumping Act). See generally SHELDON NOVICK, *LAW OF ENVIRONMENTAL PROTECTION* (1992); DONALD W. STEVER, *THE LAW OF CHEMICAL REGULATION AND HAZARDOUS WASTE* (1992).

the legacy of waste sites and water pollution was unearthed,³⁰ after the annual commerce in toxic or hazardous substances was documented,³¹ after industry standards and practices had evolved independently,³² after exposure of the entire population to certain pesticides was documented,³³ and after it was belatedly recognized that exposure of organisms and the environment to organic chemicals was dangerous and unhealthy. Consequently, the approach has been reactive at best. The response so far has been to clean up abandoned waste sites, impose a manifest system and treatment, storage and disposal standards on an industry already in place, require "registration" of pesticides already in use, and to create and implement a permit program for discharges of pollutants into water and emissions of air pollutants into the atmosphere from industrial processes long in use. These were all reactive measures caused by a lack of foresight and were not "forward looking."³⁴ Little reflection was given to the burdens of establishing the efficacy and safety of processes or products, enforcement, or public and private redress. Consequently, as explained below in Part II.D., courts are split over the extent to which individuals and communities may recover for risks and damages caused by organic chemical technology.³⁵ Society has

30. See *supra* note 16 and accompanying text; UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, EVERYBODY'S PROBLEM: HAZARDOUS WASTE, EPA-SW-826 (1980); AMENDING THE SAFE DRINKING WATER ACT, S. REP. NO. 161, 96th Cong., 1st Sess. 2-3 (May 15, 1979).

31. TSCA § 2(a), (b), 15 U.S.C. § 2601(a), (b) (1988).

32. See *supra* notes 16, 30.

33. See Savage et al., *supra* note 10; CAG Report, *supra* note 6, at 3-6; Draft EIS, *supra* note 3, at xiv; Registrations of Pesticides Containing Heptachlor or Chlordane - Intent to Suspend - Findings of Imminent Hazard, 40 Fed. Reg. 34,456, 34,457-34,459 (Aug. 15, 1975); August Curley, et al., *Chlorinated Hydrocarbon Insecticides in Organs of Stillborn and Blood of Newborn Babies*, 19 ARCH. ENVIRON. HEALTH, 628-32 (1969); Z.W. Polishuk et al., *Organochlorine Compounds in Mother and Fetus During Labor*, 13 ENVTL. RESEARCH 278-84 (1977); Walter Melvin, Jr., *Chlordane: Review of the Literature*, USAF, (Oct. 1974) (military housing); *Chlordane in Military Housing*, Subcomm. on Chlordane in Military Housing, Comm. on Toxicology, Nat'l Research Council, Nat'l Academy of Sciences, (Wash. D.C. Aug. 1979) (military housing). See also *Environmental Defense Fund v. EPA*, 598 F.2d 62 (D.C. Cir. 1978); *Shell Chem. Co. v. EPA*, 510 F.2d 1292, 1300-01 (D.C. Cir. 1975).

34. See *supra* notes 16, 30.

35. See *infra* part II.D.

never really come to grips with the concepts of risk and unforeseeability, which are now known to be inherent in organic chemical technology.³⁶ As a result, only one organic chemical was ever banned under TSCA.³⁷ Under FIFRA, numerous pesticides whose components were known and/or unknown have been registered for wide-scale use, despite the fact that on its face FIFRA incorporates a rebuttable presumption against registration of pesticides.³⁸ Even as the nation is grappling with the efficacy of garbage incinerators as a waste disposal tool, the CAA's toxic air pollutant standard-setting requirements remain largely unimplemented.³⁹ With the exception of the Clean Water Act's (CWA) construction grants, the "technology forcing" elements of the CWA and the CAA, and some "innovative enforcement" in the 1970's, there has not been any truly affirmative approach to organic chemical technology. There are no permitted treatment, storage and disposal (TSD) facilities on industrial Long Island, even though the application process has been in place for thirteen years.⁴⁰ Because each of these devices, although prospective in application, are backward-looking in development and implementation (*i.e.*, designed to redress an existing problem), they were, therefore, limited in technological scope, unable to project or allow for what might have been, unable to maximize productivity, and have typically been opposed by unforgone investors and others who have funded them.⁴¹

36. See *supra* part II.B.; see, *e.g.*, Ellen Silbergeld, *The Uses and Abuses of Scientific Uncertainty in Risk Assessment*, 2 ABA NAT. RESOURCES & THE ENV'T 17-20, 57-59 (Fall 1986).

37. TSCA § 6(e)(3)(A), 15 U.S.C. § 2605(e)(3)(A) (1988). See generally SHELDON NOVICK, *LAW OF ENVIRONMENTAL PROTECTION* § 15.05(4) (polychlorinated biphenyls (PCB's)) and § 15.08, pages 15-26, 27, 40, 41 (EPA has also instituted a production phase down for chlorofluorocarbon propellants) (1992).

38. FIFRA §§ 2-31, 7 U.S.C. §§ 136-136y (1988).

39. See Premo, *supra* note 24, at 3.

40. Verified Petition, Request for Declaratory Judgment and Motion for Preliminary Injunction at 11, para. 39, *Chemical Pollution Control, Inc. v. New York State Dep't of Env'tl. Conservation*, Index No. 92-13109 (N.Y. Sup. Ct., Suffolk County, May 22, 1992) (Article 78 proceeding pending).

41. See, *e.g.*, the protracted litigation of *State of New York v. Shore Realty Corp.*, 759 F.2d 1032 (2d. Cir. 1985). Although the matter was settled in 1992, the settlement of the litigation was preceded by years of costly litigation, in which basic

D. Overview of Backward-Looking Judicial Responses to the Impacts of Organic Chemical Technology

The legislative and subsequent regulatory responses to organic chemical technology did not take place until the mid-1970s, thirty years after the first wide-scale uses of organic chemicals.⁴² The courts were then called upon for many years to adjudicate rights and liabilities and to fashion remedies in individual cases, with limited guidance from the "official" law and policy makers, the state legislatures and the Congress.

When it finally arrived, most environmental legislation specifically declined to address private rights or remedies, and instead reserved such remedies as may have been available in state courts under state common law.⁴³ Thus, while many federal environmental statutes created private rights of action to enforce the law, remedies were typically limited to injunctive relief and to civil penalties which went directly to the United States Treasury.⁴⁴ Injured plaintiffs were left to traditional state common law remedies for the collection of damages or other personal relief, and the courts were not afforded any guidance on when or to what extent the increasingly pervasive regulatory requirements or standards should be invoked on behalf of private litigants. Congress has almost uniformly declined to articulate whether violation of federal environmental laws constitutes an act actionable by private parties in tort.

Today's common law is complicated by the existence of

legal questions were exhaustively litigated, hundreds of parties were impleaded, and the site went unremediated. Relatively speaking, this was a minor site.

42. See *supra* notes 16, 30.

43. See, e.g., FWPCA § 505(e), 33 U.S.C. § 1365(e) (1988); SDWA § 1449(e), 42 U.S.C. § 300j-8(e) (1988); RCRA § 7002(f), 42 U.S.C. § 6972(f) (1988); CAA 304(e), 42 U.S.C. § 7604(e) (1988 & Supp. II 1990). See also FIFRA § 16, 7 U.S.C. § 136n (1988), OSHA, 29 U.S.C. §§ 657(f)(1), 660(a) (1988); CERCLA §§ 107(f), 113(g), 42 U.S.C. §§ 9607(f), 9613(g) (1988); TSCA § 20(c)(3), 15 U.S.C. § 2619(c)(3) (1988); MPRSA § 106, 33 U.S.C. § 1416 (1988). CERCLA's provision for payment of damages to states for resource damages falls short of providing a personal remedy for injury to person or damage to property. See also *infra* note 44.

44. CERCLA § 113, 42 U.S.C. § 9613 (1988); TSCA § 20, 15 U.S.C. § 2619 (1988); FWPCA § 505, 33 U.S.C. § 1365 (1988); MPRSA § 105(g), 33 U.S.C. § 1415(g) (1988); SWDA § 1449, 42 U.S.C. § 300j-8 (1988); RCRA § 7002, 42 U.S.C. § 6972 (1988); CAA § 304, 42 U.S.C. § 7604 (1988 & Supp. II. 1990).

statutory and regulatory laws that address the same subject matters (e.g., pesticides, hazardous waste leachate). However, because Congress has provided no guidance as to the appropriate relationships between common law jurisprudence and the standards, requirements and burdens established by statute and regulation, *de facto* social policy decisions have been and are being made by the courts. Courts, however, are ill-equipped to create a jurisprudence embodying social value considerations which, in a democracy, are primarily the province of the legislature. Legislation is supposed to represent collective wisdom, borne of the full and public explication of the many facets of an issue. Judges, in contrast, are intentionally isolated and constrained in their ability to consider and review controversies placed before them. It is axiomatic that good judges search for the narrowest basis for a ruling, avoiding any issue which is not essential to a holding. Further, development of a jurisprudence by the courts in a new area of the law is, of necessity, a painfully slow process. Litigants do not always appeal erroneous rulings to the highest level courts, and when they do, appellate courts in search of the "narrowest" basis for a ruling, often side-step the seminal issue or provide unclear guidance to lower courts through split opinions.⁴⁵

When the courts were called upon to adjudicate with respect to the impacts of organic chemical technology, this result was exacerbated. The attendant scientific issues are very complex and not easy for lay jurists and jurors to readily understand. The scientific uncertainties inherent in the technology and the fact that our knowledge of these uncertainties developed *after* the initial investment decisions were made, has made courts reluctant to ascribe financial liability to parties in the absence of legislative directive, even though they may have profited handsomely from organic chemical technology.⁴⁶ Because regulatory requirements are variable and standards for ascribing fault and assessing evidence in administrative

45. The costs of prosecuting appeals in civil toxic tort actions with lengthy trial records often prove prohibitive to private plaintiffs. See *infra* note 50.

46. See *infra* notes 68-69.

proceedings differ from those in civil suits, courts are reluctant to ascribe civil liability based on regulatory standards absent an expressed legislative directive. As a result, courts tend to bar plaintiffs from relying on such standards for fear of confusing the jury.⁴⁷ Conversely, precisely because the actual science is too complex for ready understanding by lay jurists and jurors, government "findings" of safety or standards are readily translated into findings of no negligence or no harm when proffered as a shield by defendants. This result occurs even when the findings are out-dated or contradicted by conflicting scientific data proffered at trial.⁴⁸ Taken together, the inherent characteristics of organic chemical technology and the regulatory response to it have yielded some paradoxical results in the contexts of common law liability, damages, and the applicable evidentiary principles.

1. Liability

When called upon to adjudicate private claims arising from exposure to organic chemicals in the environment, the home, the workplace or in products (*e.g.*, cigarettes, cosmetics, fruits and vegetables), state court judges and federal judges, applying state substantive law, have been called upon to make certain threshold decisions regarding the potential liability of defendants. First, courts must decide whether Congress has enacted any pervasive statutory law that manifests an intent to pre-empt the common law claims of negligence, products liability, and failure to warn. Second, a court must determine if any statutory requirements or governmental standards define, modify, or have any relationship to the common law elements of reasonableness, foreseeability and duty. Finally, a court must determine to what extent the elements of foreseeability and reasonableness can be given meaning when applied to a technology whose very processes have rendered, at relevant points in time, the specific biological end point or outcome unknown.

47. See *infra* notes 72, 93, 97.

48. See *infra* notes 86, 97, 117.

a. Pre-emption

Ironically, even though Congress declined to pre-empt the authority of state common law for private redress, some courts have held that federal statutory law pre-empts common law damage actions sounding in theories of negligence, defective product, and failure to warn.⁴⁹

Simple questions, like whether government approval of a label precludes a common law action for failure to warn, have received different answers in different courts, have travelled up to and down from the Supreme Court, and have nearly bankrupted many plaintiffs and their attorneys in the process.⁵⁰ Other troubling questions are whether government approval of a process, procedure or product precludes a common law action for a defective product or ultra hazardous activity, or even, taken to the extreme, whether the absence of a prohibitory statute or standard, when theoretically one could have been enacted, precludes a finding of unreasonableness.⁵¹

49. *Cipollone v. Liggett Group, Inc.*, 789 F.2d 181 (3d Cir. 1986), *cert. denied*, 479 U.S. 1043 (1987) (cigarettes); *Davidson v. Velsicol Chem. Corp.*, 834 P.2d 931 (Nev. 1992) (FIFRA implicitly pre-empts state tort claims based on failure to adequately label pesticides); *Fitzgerald v. Mallinckrodt, Inc.*, 681 F. Supp. 404 (E.D. Mich. 1987) (finding that FIFRA's labelling requirements pre-empt failure-to-warn actions premised on state law); *Kennan v. Dow Chem. Corp.*, 717 F. Supp. 799 (M.D. Fla. 1989); *Fisher v. Chevron Chem. Co.*, 716 F. Supp. 1283 (W.D. Mo. 1989) (FIFRA's labelling requirements pre-empt failure-to-warn actions based on state law, but FIFRA's registration and safety requirements do not pre-empt actions based on a "defective product" theory); *Palmer v. Liggett Group, Inc.*, 825 F.2d 620 (1st Cir. 1987) (because cigarette warnings are written by the federal government, failure-to-warn action premised on state law is pre-empted).

50. *E.g.*, *Cipollone*, 789 F.2d 181 (3d Cir. 1986), *cert. denied*, 479 U.S. 1043 (1987). Plaintiffs may recover for injuries from cigarette smoking on a theory of negligent failure to warn when the warning label was approved by the U.S. Government, only upon a showing that the defendant willfully concealed facts which should have been disclosed. The case was remanded for further proceedings. After more than twelve years of litigation, plaintiffs and their attorneys voluntarily discontinued the case citing financial inability to proceed.

51. See generally *SHELDON NOVICK, THE LAW OF ENVIRONMENTAL PROTECTION* §§ 13.01(6), 13-16 thru 13-18; *Pennington v. Vistrion Corp.*, 876 F.2d 414, 424-25 (5th Cir. 1989) (federal labelling did not pre-empt plaintiff's state law claims based on inadequacy of pre-1966 warnings on "defective product" theory); *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984) (pesticides); *Burke v. Dow Chem. Co.*, 797 F. Supp. 1128 (E.D.N.Y. 1992) (pesticides). See also *Hall v. Ashland Oil Co.*, 625 F. Supp. 1515, 1520 (D. Conn. 1986); *Billsborrow v. Dow*,

These defenses are routinely interposed with varying success in private litigation throughout the country.

Although governmental approval of a product or its label or compliance with regulation is not generally deemed conclusive on the questions of product fitness, failure to warn or negligence,⁵² the fact that the government has approved labels, products or methodologies has frequently been asserted as a defense in actions for damages premised on theories of strict products liability, failure to warn, breach of implied warranty of fitness, negligence, trespass or nuisance. Plaintiffs typically counter with the following: (a) government rules and standards expressly establish minimum standards for both safety and labelling requirements; (b) Congress did not intend to pre-empt private remedies at common law; (c) state courts are free to impose more stringent rules for the protection of their citizens through the tort law system; and (d) most defendants could have warned and restricted, or limited or discontinued the product's use, without incurring multiple inconsistent burdens.⁵³

527 N.Y.S.2d 352, 357, 139 Misc. 2d 488, 495 (N.Y. Sup. Ct., 1992); *Samuels v. American Cyanamid Corp.*, 495 N.Y.S.2d 1006, 1012, 130 Misc. 2d 175, 183 (N.Y. Sup. Ct. 1985); see *supra* notes 49-50. The converse question is whether plaintiffs may introduce subsequent deregistration or banning of a product or process as proof or evidence of defect or hazard. See *Jones v. Arrow Exterminating Co.*, Index no. 18111/84 (N.Y. Sup. Ct., Nassau County, Sept. 5, 1991). See also *Cover v. Cohen*, 61 N.Y.2d 261, 473 N.Y.S.2d 378, 461 N.E.2d 864 (1984) and progeny.

52. See, e.g., *Jackson v. New Jersey Mfrs. Ins. Co.*, 400 A.2d 81 (N.J. Super. Ct. App. Div. 1979), *cert. denied*, 407 A.2d 1204 (N.J. 1979) (compliance with [OHSA] regulations would not preclude a finding of negligence if there is competent proof that a reasonable manufacturer would have taken additional precautions).

53. See *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984). See generally *Cox v. Velsicol Chem. Corp.*, 704 F. Supp. 85 (E.D. Pa. 1989) (FIFRA); *Roberts v. Dow Chem. Co.*, 702 F. Supp. 195 (N.D. Ill. 1988) (FIFRA); *New York State Pesticide Coalition, Inc. v. Jorling*, 874 F.2d 115 (2d Cir. 1989) (FIFRA); EPA General Counsel opinion, No. 74-6 (May 13, 1979); *Wells v. Ortho Pharmaceutical Corp.*, 788 F.2d 741, 746 (11th Cir. 1986) (lack of warning on spermicide may be sufficient for the purpose of meeting federal regulatory standards, but not for state tort law purposes); *Macgillivray v. Lederle Labs*, 667 F. Supp. 743, 746 (D.N.M. 1987) (warnings approved by Federal Food and Drug Administration establish minimum standards); compare *International Paper Co. v. Ouellette*, 479 U.S. 481 (1987). E.g., *Merrell v. Thomas*, 608 F. Supp. 644 (D. Or. 1985), *aff'd*, 807 F.2d 776 (9th Cir. 1986), *cert. denied*, 615 U.S. 848 (1987) (FIFRA exists for the protection of man and his environment); *Continental Chemists Corp. v. Ruckelshaus*,

In *Silkwood v. Kerr-McGee Corp.*,⁵⁴ the Supreme Court articulated a two-part test for determining whether a federal statute pre-empted state common law claims for personal injury. First, "[i]f Congress evidences an intent to occupy a given field, any state law falling within that field is pre-empted."⁵⁵ Alternatively,

[i]f Congress has not entirely displaced state regulation over the matter in question, state law is still pre-empted to the extent it actually conflicts with federal law, that is, when it is impossible to comply with both state and federal law . . . or where the state law stands as an obstacle to the accomplishment of the full purposes and objectives of Congress.⁵⁶

In its analysis, the *Silkwood* court determined the pre-emptive posture of the Atomic Energy Act. In *Ferebee v. Chevron Chemical Co.*,⁵⁷ the D.C. Circuit Court examined the pre-emptive power of FIFRA, the law regulating all organic pesticides. The *Ferebee* court examined the text and legislative history of the relevant FIFRA provisions, and concluded that Congress did not intend to pre-empt the regulation of pesticides or their labeling. The *Ferebee* court then explored the alternative method of finding pre-emption, taking its cue from the conflicting analysis in *Silkwood*, which required pre-emption only when it was "physically impossible" to comply with potentially conflicting law. The court held that FIFRA created no such physical impossibility.⁵⁸

Nevertheless, courts have found private tort claims pre-

461 F.2d 331 (7th Cir. 1972) (purpose of FIFRA is to keep unsafe products off the market); N.Y. ENVTL. CONSERV. LAW § 33-0301 (McKinney 1984) (purpose is "to regulate the registration, commercial use, purchase and customer application of pesticides."); *Train v. Natural Resources Defense Council*, 421 U.S. 60 (1975); *Union Elec. Co. v. EPA*, 427 U.S. 246 (1976). See also *Jones*, Index no. 18111/84, Trial Transcript at 35-40 (Murphy, J. ruling from the bench) (appeal pending App. Div. 2d Dep't).

54. 464 U.S. 238 (1984).

55. *Id.* at 248.

56. *Id.*

57. 736 F.2d 1529 (D.C. Cir.), cert. denied, 469 U.S. 1062 (1984).

58. *Id.* at 1540-41.

empted by pervasive regulatory law, and defendants continue to press the defense.⁵⁹ This result is rendered paradoxical because Congress has consistently indicated that private rights and remedies are appropriately adjudicated in courts of common law, and only rarely have legislative bodies imposed procedural or other limitations on recovery.⁶⁰ Three examples include: (1) the Price-Anderson Act, capping potential tort liability of persons employing the products of nuclear fission under a government licensing scheme; (2) state statutes limiting the nature of relief available from certain kinds of defendants, usually motivated by sovereign immunity concerns or other public policy notions; and (3) statutes of limitation, barring claims not asserted within a specified period following a triggering event.⁶¹

There are also circumstances where legislatures have completely or partially substituted administrative or statutory schemes for common law recovery, and have either barred or limited recovery to a specified threshold or delineated types of damage. Examples of substitution schemes include worker's compensation, no-fault automobile accident liability statutes, the federal black lung disease compensation program, and the natural resource damages scheme developed under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA).⁶² After considering proposals to include personal injury and property damage in CERCLA, Congress declined to do so, and instead merely included a provision that allowed states to recover for natural resources damages within their territories.⁶³ Thus, the prevailing view is that federal environmental statutes, including FIFRA, do not, and were not intended to circumscribe private rights at common law.

The irony, however, is that because there are diverging views, some plaintiffs have had their private rights extin-

59. *Id.* at 1542.

60. *See supra* notes 51-52.

61. Price Anderson Amendments Act of 1988, 42 U.S.C. § 2011 (1988). *E.g.*, N.Y. CIV. PRAC. L. & R. 214-a, 214-b, 214-c, 218 (McKinney 1984 & Supp. 1993).

62. *See* CERCLA §§ 107(f), 113(g)(1), 42 U.S.C. §§ 9607(f), 9613(g)(1) (1988).

63. *See* CERCLA §§ 107(f), 113(g)(1), 42 U.S.C. §§ 9607(f), 9613(g)(1) (1988).

guished precisely because Congress has seen fit to legislate in the public interest. In this author's view, the tendency to find a pre-emptive import in certain statutes is due in part to the fact that these statutes were backward-looking, enacted after the extent of damage was known, and with the express purpose of rectifying known harms. In this context, a court might be more inclined to regard legislative silence on the issue of private rights together with the pervasive nature of the statute or regulation as indicating an intent to pre-empt. Had a regulatory system been in place at the outset, where harms, risks, and damage had not yet been documented and categorized, the arguments in support of federal pre-emption would have been much weaker. Moreover, because the defense is perceived as viable, costs and litigation risks mount, discouraging as a practical matter, a full and fair hearing on the merits of claims.

b. Foreseeability and Reasonableness: Standards of Care

The basic tort elements of reasonableness and foreseeability have proven to be the thorniest issues facing the courts and litigants in tort actions arising from organic chemicals.⁶⁴ This is mainly because of the unforeseeability that was later demonstrated to be inherent in organic chemical technology.

It can be argued: who could have reasonably foreseen a

64. See, e.g., RESTATEMENT (SECOND) OF TORTS § 282 (1965). Negligence is conduct "which falls below the standard established for the protection of others against unreasonable risk of harm." A determination of whether conduct is "reasonable" involves an inquiry in which the trier of fact examines: (a) the probability that an injury will occur (foreseeability); (b) the gravity of the injury; and (c) the cost of avoiding the injury. *United States v. Carroll Towing Co., Inc.*, 159 F.2d 169, 173 (2d Cir. 1947) (Hand, J., applying New York law). "What degree of care is reasonable necessarily depends upon the peculiar attendant circumstances of the particular case. Negligence arises from breach of duty and is relative to time, place and circumstance. Ordinary care must be in proportion to the danger to be avoided from the neglect." *Rotz v. City of New York*, 143 A.D.2d 301, 304-05, 532 N.Y.S.2d 245, 248 (N.Y. App. Div. 1st Dept. 1988). One is wanton and reckless when one acts with knowledge of probable consequences and with reckless disregard for the consequences. RESTATEMENT (SECOND) OF TORTS § 908(2), comment b (1977). An unjustifiable non-consensual invasion of property is a trespass. *Phillips v. Sun Oil Co.*, 307 N.Y. 328, 331, 121 N.E.2d 249, 250-51 (1954) (citing RESTATEMENT OF TORTS § 158, comment h (1934)).

product's ability to cause specific environmental or physiological harms when its manufacturer did not even know all the ingredients that were in it, the properties of the ingredients or their relative proportions?⁶⁵ How can the reasonableness of exposure of the food chain, the environment, the populace, or an individual be proven, assessed, or adjudicated, when products (e.g. pesticides) were on the market or wastes were released into the environment decades before it was possible to accurately measure their residues?⁶⁶ The foreseeability problem is compounded by the tendency of many organic chemicals to metabolize in plant and animal tissue and to change in the environment, sometimes to become even more toxic metabolites or by-products.⁶⁷

In the face of these dilemmas, many courts have shied away from true strict liability, and some have incorporated the elements of reasonableness and foreseeability into strict products liability and ultra hazardous activities claims.⁶⁸ Other courts have held industrial defendants to the standard of an 'expert in the field' who presumably knew or should have known the harms which could flow from the use, misuse or disposal of their products.⁶⁹ This fails to solve the basic judicial dilemma, however, which occurs because the industry has historically proceeded without any regulation and the bulk of health and ecosystem impact studies were conducted after the extent of environmental and human exposure was documented by the government and third parties.⁷⁰

Thus, more often than not, industry standards evolved prior to, and independent of, regulatory standards. Therefore,

65. See *supra* notes 7, 8 and accompanying text.

66. See *supra* note 9 and accompanying text.

67. See *supra* note 10 and accompanying text.

68. *E.g.*, *Lancaster Silo & Block Co. v. Northern Propane Gas Co.*, 75 A.D.2d 55, 65 n.1, 427 N.Y.S.2d 1009, 1016 n.1 (App. Div. 4th Dep't 1980) (citing RESTATEMENT (SECOND) OF TORTS § 388 and Comment K (1965)); *Sterling v. Velsicol Chem. Corp.*, 647 F. Supp. 303, 318 (W.D. Tenn. 1986), *aff'd in part, rev'd in part*, 855 F.2d 1188 (6th Cir. 1988); *Herman v. Welland Chem., Ltd.*, 580 F. Supp. 823 (M.D. Pa. 1984).

69. *E.g.*, *Feldman v. Lederle Labs.*, 479 A.2d 374 (N.J. 1984). *But see Michalko v. Cooke Color & Chem. Corp.*, 451 A.2d 179 (N.J. 1982) (knowledge of the defect is imputed to the defendant as a matter of law).

70. See *supra* part II.C.

reasonableness tests, incorporating the foreseeability element, are ill-suited to defining liability in the now highly-regulated field of organic chemical technology. Absent express legislative directives, courts are reluctant to predicate liability on after-discovered test data or after-promulgated rules. Courts remain reluctant even when plaintiffs strenuously argue that certain defendants, as experts in the field, should have known, or should have made a point of learning about or insuring against certain generically, if not specifically, foreseeable events. Similar to pre-emption, where some private litigants have been deprived of their private causes of action precisely because Congress legislated in the public interest, some private litigants have been unable to prove the unreasonableness of conduct precisely because a regulatory body saw fit to pass a rule, after-the-fact, in response to the very problem of which the litigant is complaining.⁷¹

Had the legislative body seen fit to act in step with the newly developing industry in the 1940s, before the problems accrued, and had it seen fit to articulate the rights of private litigants, courts today would not be trying to accomplish the unenviable task of applying the tort elements of foreseeability and reasonableness to a technology we now know was fraught with unknowns and risks from the start.

Finally, had Congress simply articulated to what extent statutorily mandated conduct should define, alter, or be evidence of reasonableness or due care, the courts, which apply the negligence *per se* rule only in carefully delineated circumstances, would not be forced to make the social value decisions which are necessary for this determination.⁷²

71. See *supra* note 53; see also *supra* note 16.

72. See *Jones v. Arrow Exterminating Co.*, Index no. 18111/84 (N.Y. Sup. Ct., Nassau County, Sept. 5, 1991) (Murphy, J. ruling from the bench that the cause of action sounding in negligence *per se* was dismissed); *Jones v. Arrow Exterminating Co.*, No. 92-02133, Record on Appeal at 234-48 (pending N.Y. App. Div., 2d Dep't); accord, *Walsh v. Portuese*, (N.Y. Sup. Ct. 1991, Burke, J. ruling from the bench). Compare *Martin v. Herzog*, 228 N.Y. 164, 168, 126 N.E. 814, 818 (1920); *Beauchamp v. New York City Hous. Auth.*, 12 N.Y.2d 400, 190 N.E.2d 412, 240 N.Y.S.2d 15 (1963); *Taylor v. Botnick Motor Corp.*, 146 A.D.2d 81, 84, 539 N.Y.S.2d 141, 144 (3d Dep't 1989); *Dance v. Town of Southampton*, 95 A.D.2d 442, 445, 467 N.Y.S.2d 203, 206 (2d Dep't 1983); *Cordero v. City of New York*, 112 A.D.2d 914, 916, 492 N.Y.S.2d

2. Damages

As with any claimed injury, plaintiffs in toxic tort litigation arising from the impacts of organic chemical technology must ascertain: (a) which harms are actionable, (b) what quantum of proof is necessary, and (c) what evidence will be admitted. This section will focus on the judicial response to the issues posed in (a) and (b). Admissibility of evidence is considered in the following section.⁷³

Any similarity to "traditional" torts fades rapidly because the common law limitations on recovery for increased risk of disease, fear of disease, and medical monitoring for early disease detection have been crafted explicitly to avoid speculation or fabrication in situations where no harm has yet been manifested.⁷⁴ Where the plaintiff can prove that he has already contracted cancer or another significant injury as a result of an incident or exposure, the perceivable need for such precautions should not exist. Thus, the potential scenarios may be identified as (a) those where a serious physical ailment has already resulted and (b) those where it has not yet been manifested.⁷⁵

430, 432 (2d Dep't 1985).

73. See *infra* part II.D.3.

74. See *Ferrara v. Galluchio*, 5 N.Y.2d 16, 152 N.E.2d 249, 176 N.Y.S.2d 996 (1958); see also *Trapp v. Metz*, 28 N.Y.2d 913, 271 N.E.2d 166, 271 N.Y.S.2d 697 (1971) (cancerphobia); *Askey v. Occidental Chem. Corp.*, 102 A.D.2d 130, 477 N.Y.S.2d 242 (App. Div. 4th Dep't 1984) (medical monitoring).

75. *Strohm v. The N.Y., Lake Erie & Western R.R. Co.*, 96 N.Y. 305 (App. Div. 2d Dep't 1984) (no actual injury alleged); *Reingold v. E.R. Squibb & Sons, Inc.*, Docket No. 74-3420 (S.D.N.Y. 1975) (no actual injury alleged); *Amendola v. Kansas City S. Ry. Co.*, 699 F. Supp. 1401 (W.D. Mo. 1988) (no physical injury alleged and Federal Employer's Liability Act (FELA) expressly precluded recovery for emotional distress in the absence of physical injury); *Pollack v. Johns Manville Sales Corp.*, 686 F. Supp. 489 (D.N.J. 1988); *Stites v. Sundletan*, 660 F. Supp. 1516 (W.D. Mich. 1987) (no actual injury); *Laswell v. Brown*, 524 F. Supp. 847 (W.D. Mo. 1981), *aff'd*, 683 F.2d 261 (8th Cir. 1982), *cert. denied*, 459 U.S. 1210 (1983) (Federal Tort Claims Act - limited waiver of sovereign immunity, no actual injury); *Deleski v. Raymark Indus. Inc.*, 1986 WL 1965 (E.D. Pa. 1986), *aff'd*, 819 F.2d 377 (3d Cir. 1987) (no present manifestation of illness). In *Sterling v. Velsicol Chem. Corp.*, 855 F.2d 1188 (6th Cir. 1988), multiple plaintiffs alleging injury from exposure to organo-chlorine compounds presented claims for injury including headaches, enlarged liver, coughing, nosebleeds, shortness of breath, skin rashes, nervous system disorders and one cancer. The Sixth Circuit Court of Appeals, applying Tennessee State law, expressly sus-

The claims of increased risk of illness and fear of increased risk are separate and distinct and have been distinguished by courts addressing the issue. They are (1) a claim for damage based upon an increased *risk* of cancer or other disease *per se*; and (2) a claim for damages arising from the *reasonable fear* occasioned by the increased risk of contracting cancer or any one of a number of different diseases in the future relating to a toxic exposure (and the fear that a family member would contract such a disease) and medical monitoring. Distinct criteria have been developed for each. In *Ayers v. Township of Jackson*, the New Jersey Superior Court adopted one of the earliest rules for recovering for increased risk *per se* - that it be quantifiable.⁷⁶

In *Herber v. Johns-Manville*,⁷⁷ one of the earliest cases articulating the so called "51% rule" for increased *risk* of cancer as an element of damage *per se*, the Third Circuit Court of Appeals held that the plaintiff could not recover for increased risk of cancer unless the risk was more probable than not, (*i.e.* greater than 51%). The Third Circuit also found, however, that it was an abuse of the trial court's discretion to exclude evidence of the plaintiff's increased risk of cancer, because that evidence was "highly probative" on his claim for medical monitoring even though the increased risk was less than 50%. Thus, while proof that the likelihood of future disease exceeded 50% was not a necessary element of proof on the claim for medical monitoring, it was necessary for recovery for the

tained all claims for fear of increased risk of cancer, medical monitoring and impairment of life's quality, even for those plaintiffs who had only sustained transient illness, and remanded for modification on the questions of increased risk of cancer where testimony had not satisfied Tennessee State law as to reasonable medical certainty. In *Fusaro v. Porter-Hayden Co.*, 145 Misc. 2d 911, 548 N.Y.S.2d 856, 170 A.D.2d 239 (1st Dep't, 1989), Judge Freedman sustained plaintiff's right to bring a second action for mesothelioma under the N.Y. 1986 Revival Statute where (a) he had not sustained cancer previously, asbestosis being a separate disease and (b) there was some evidence that mesothelioma was caused by exposure to different particles. See also *Rubanick v. Witco Chem. Corp.*, 593 A.2d 733 (N.J. 1991).

76. *Ayers v. Township of Jackson*, 461 A.2d 184 (N.J. Super Ct. Law Div. 1983) [hereinafter *Ayers I*], *aff'd as modified*, 493 A.2d 1314 (N.J. Super Ct. App. Div. 1985) [hereinafter *Ayers II*], *aff'd in part and rev'd in part*, 525 A.2d 287 (N.J. 1987).

77. 785 F.2d 79 (3d Cir. 1986).

exposure and concomitant risk, *per se*.⁷⁸

In *Herber*, the court also found that there was nothing unduly prejudicial about the evidence,⁷⁹ and in any event that the probative value of such evidence was so great that it could not properly exclude it under Rule 403 of the Federal Rules of Evidence.⁸⁰ In *Sterling v. Velsicol*,⁸¹ the court of appeals carefully separated the claims of increased risk and fear of increased risk:

While there must be a reasonable connection between the injured plaintiff's mental anguish and the prediction of a future disease, the central focus of a court's inquiry in such a case is not on the underlying odds that the future disease will in fact materialize. To this extent, mental anguish resulting from the *chance* that an existing injury will lead to the materialization of a future disease may be an element of recovery even though the underlying future prospect for susceptibility to a future disease is not, in and of itself, compensable inasmuch as it is not sufficiently likely to occur.⁸²

Thus, the claims for increased risk and fear of increased risk are separate claims.

As applied in various states, including New York, plaintiffs are entitled to compensation for "cancerophobia," a form of mental anguish, where there are indicia that the fear is genuine and grounded in objective physical symptomatology or scientific knowledge.⁸³ Where persons are exposed to toxins

78. *Id.* at 83. See also *Jones v. Arrow Exterminating Co.*, No. 92-02133, Record on Appeal at 251-84 (pending N.Y. App. Div., 2d Dep't); *Walsh v. Portuese*, Index No. 13183/87 (N.Y. Sup. Ct., Nassau County, May 22, 1992, Judge John W. Burke ruling from the bench), *appeal filed*, (App. Div. 2d Dep't June 12, 1992).

79. *Herber*, 785 F.2d at 83.

80. FED. R. EVID. 403. Rule 403 allows judges to exclude relevant evidence "if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury"

81. 855 F.2d 1188 (6th Cir. 1988).

82. *Id.* at 1206 (emphasis added).

83. *Ferrara v. Galluchio*, 5 N.Y.2d 16, 21-2, 152 N.E.2d 249, 252-53, 176 N.Y.S.2d 996, 1000 (1958); See also *Trapp v. Metz*, 28 N.Y.2d 913 (1971), *rev'g* 35 A.D.2d 851 (N.Y. App. Div., 2d Dep't 1970). Neither case applied a mathematical test of any sort

which give rise to an increased risk of subsequent injury such as cancer or other serious health effects, they may also be entitled to compensation for continued medical monitoring of their physical condition.⁸⁴

Social policy is served by an award of the costs of medical monitoring. As the New Jersey Superior Court noted in *Ayers I*, such costs are a small price to pay for the public benefit of early disease detection, lower costs and increased likelihood of cure.⁸⁵

The 51% rule, now applied in some jurisdictions, bears a striking resemblance to the preponderance of the evidence rule required before a party can prevail in any civil litigation proceeding. The analogy does not hold up, however, either as a matter of science or social policy. There is no scientific rationale for a requirement of 51% increased risk as a prerequisite to recovery. The term bears no relationship to statistical significance and confidence limits on the one hand, or the reality of the harm itself on the other. The 51% threshold also does not prove that, as a result of a certain defendant's acts, a particular plaintiff's risk of an adverse biological outcome has increased by some quantum. The figure may have relevance as a measure of damages, but not as a preclusionary device. The avoidance of fabrication should come from the existence of objective scientific evidence — e.g., laboratory test data, air samples, soil and surface samples, water samples, blood and tissue samples, objective symptomology (even if minor), and expert testimony — not from the arbitrary imposition of a particular numerical cut-off.

This result illustrates, again, the dilemma of putting courts in the position of having to make social policy judgments in a complex scientific field pervaded by regulation

for recovery. *Ferrara* involved no risk assessment whatsoever. See also *Ayers I*, *supra* note 76 and *Ayers II*, *supra* note 76.

84. See generally *Askey v. Occidental Chem. Corp.*, 102 A.D.2d 130 (N.Y. App. Div., 4th Dep't 1984) (medical monitoring); See *Ayers I*, *supra* note 76, and *Ayers II*, *supra* note 76; *Sterling v. Velsicol Chem. Corp.*, 855 F.2d 1188 (6th Cir. 1988); *Amendola v. Kansas City S. Ry. Co.*, 699 F. Supp. 1401 (W.D. Mo. 1988); see also *supra* note 75.

85. *Ayers I*, 461 A.2d 184, 190 (N.J. Super. Ct. Law Div. 1983).

without the benefit of the legislature's views on which harms are compensable. When Congress purported to register certain pesticides or provide for the abatement of leachate from landfills, did it really intend that persons whose bodies or communities were contaminated could only recover if their increased risk of harm exceeds 51%? Because neither Congress nor state legislatures have provided otherwise, courts have and may continue to resort to the familiar comfort of the inapposite "preponderance of the evidence" rule.

3. Evidentiary Rules

Two important evidentiary issues have emerged in toxic tort actions arising from exposure to organic chemicals and other substances. First, should courts or juries be the arbiters of the credibility of the experts whose testimony is needed to prove liability or causation? Second, are government records, proceedings, documents, or actions admissible, and may experts rely upon them in formulating their opinions? That either of these questions arises at all is testament to the complexity of the scientific phenomena inherent in organic chemical technology. That either of these questions arises now, in the guise of "new" or "novel" scientific expertise or governmental action, when the technology has been in place and persons have been exposed for fifty years, is testament to the backwardness of our regulatory approach and the judiciary's role in playing catch up.

The New Jersey Supreme Court, in a series of recent decisions involving PCB's and asbestos, reviewed the attempts of several lower courts to deal with proffered plaintiffs' experts on the question of causation.⁸⁶ Some trial and appellate

86. *Landrigan v. Celotex Corp.*, 605 A.2d 1079 (N.J. 1992); *Caterinicchio v. Pittsburgh Corning Corp.*, 605 A.2d 1092 (N.J. 1992) (a companion case to *Landrigan*); *Rubanick v. Witco Chem. Corp.*, 593 A.2d 733 (N.J. 1991). See also Joseph F. Sullivan, *In Trenton, Court Takes on Toxic Damage Cases*, N.Y. TIMES, Sept. 16, 1991, at B2L. See also *Walsh v. Portuese*, Index No. 13183/87 (N.Y. Sup. Ct., Nassau County, May 22, 1992, Judge John W. Burke ruling from the bench), *appeal filed*, (N.Y. App. Div. 2d Dep't June 12, 1992). Compare *Martin v. Herzog*, 228 N.Y. 164, 126 N.E. 814 (1920); *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 727 F. Supp. 570 (S.D. Cal. 1989), *aff'd*, 951 F.2d 1128 (9th Cir.), *cert. granted*, 113 S. Ct. 320 (1992).

courts had barred the testimony of epidemiologists, statisticians, and other non-medical scientific experts on the issue of causation. These courts found that such evidence was simply inadmissible.⁸⁷ These courts and other courts that have viewed this proposed testimony as “new,” “novel,” “ingenious,” or “wacky” have demanded a rigorous pre-trial hearing outside the view of a jury, at which the court determined the admissibility of this proffered testimony.⁸⁸ These evidentiary hearings went well beyond the scope of any expert *voir dire*, in which defendant’s counsel is permitted to question the expert in order to show his or her lack of qualifications. Here, defendants were also permitted to amass and present their own experts, whose testimony was not directed to the merits of the case, but rather to the credentials and expertise of plaintiff’s experts.⁸⁹ The New Jersey Supreme Court adopted the latter view, holding, ironically, that because of the difficulties of proof in toxic torts, and the novelty of the methods of proving causation, the traditional standards of expert scrutiny should be relaxed.⁹⁰ The mere notion, that scientific testimony emerging from the application of standard scientific method to a fifty-year-old technology is novel defies belief. Second, the notion that imposing expensive and tactic revealing procedural hurdles on private litigants “eases their burden” is divorced from reality. The financial obstacles posed by the necessity of bringing experts in for additional rounds of testimony severely prejudices plaintiffs with limited resources. Moreover, giving defendants the opportunity, in addition to discovery, of creating a record for impeachment of the expert at trial and for preparing cross examination in advance, will greatly heighten a plaintiff’s litigation risk.

Ultimately, the question is whether there is any legitimate reason to subject plaintiffs’ experts in the field of organic chemical technology to a wholly different standard or

87. *E.g.*, *Rubanick*, 593 A.2d 733.

88. *See supra* note 86.

89. *Landrigan v. Celotex Corp.*, 605 A.2d 1079 (N.J. 1992); *Caterinicchio v. Pittsburgh Corning Corp.*, 605 A.2d 1092 (N.J. 1992) (a companion case to *Landrigan*); *Rubanick v. Witco Chem. Corp.*, 593 A.2d 733 (N.J. 1991).

90. *Id.*

whether, as many federal judges have noted, the issue goes to the weight of the evidence, not its admissibility. The fact that courts are being forced to grapple with these issues in the 1990's and that the defendant's proposition that plaintiff's science is "new", "novel", "junk", "wacky",⁹¹ or "martian"⁹² is given any credence whatsoever, illustrates the point that social policy making in this complex technological field should not have been left to the judiciary. This is particularly true when the technology has been in use for fifty years and government regulators have been dealing with these issues for at least twenty. Rather, the very legislative bodies which, albeit after the fact, sought to provide a public response to a public pollution problem, should have taken the next step and given more concrete guidance to the courts which would be called upon to adjudicate private claims.

The second evidentiary issue which presently challenges courts in the arena of organic chemical tort litigation flows from the following question: Are regulatory standards or requirements relevant and admissible on the issues of liability or damages, and if they are, to what extent? Although there is a general evidentiary presumption that governmental records or proceedings are reliable, defendants in organic chemical cases have pressed the point, with varying success, that government records, proceedings, findings, and rule-makings with respect to organic chemical technology are untrustworthy, unsubstantiated, unreliable, irrelevant, inadmissible, and not the proper basis of plaintiff's proffered expert opinions or testimony.⁹³

Again, there is a threshold question: Why should government records in this context be viewed by courts differently than in any other? In other words, why should this not go

91. *Id.*

92. See *Jones v. Arrow Exterminating Co.*, Index no. 18111/84 (N.Y. Sup. Ct., Nassau County, Sept. 5, 1991).

93. See *Jones v. Arrow Exterminating Co.*, No. 92-02133, Record on Appeal at 79-80, 82-94, 95-99, 102-233, 285-316, 331-38, 339-60, 482-85, 644-45, 650-55, 898-906 (pending N.Y. App. Div., 2d Dep't); *Dine v. Western Exterminating Co.*, 1988 WL 28370, at *1 (D.D.C. Mar. 18, 1988); *Conde v. Velsicol Chem. Corp.*, 804 F. Supp. 972 (S.D. Ohio 1992).

simply to the weight of the evidence rather than to admissibility?⁹⁴ This is particularly so where defendants are routinely permitted to wrap themselves in the shroud of government approval, even if it is outdated or based solely on evidence proffered by the industry. This evidence proffered by industry would never have withstood the scrutiny that defendants now urge upon courts when reviewing plaintiffs' scientific experts.⁹⁵

The reason such arguments are not dismissed out of hand is two-fold. First, the statutory and regulatory response to organic chemical technology was adopted after-the-fact as a reaction to the enormity of documented pollution and exposure problems.⁹⁶ Courts are reluctant to ascribe relevance to after-developed rules and regulations, for what they perceive are fairness and foreseeability reasons. This logic has been extended to rules and regulations which post-date the industry, even when they pre-date the activity or injury in a particular case.⁹⁷ Moreover, the regulatory response, precisely because it was a response, is more readily characterized as political over-reaction to a public problem and therefore is not relevant to the private controversy before the court. If rules had been in place at the outset of the technology, and if these rules had been forward-looking enough to, (a) specify the rights and scope of potential liability of private litigants, and (b) direct that government rules and actions regarding the technology are presumptively reliable and relevant in private lawsuits, courts would not be faced with the necessity of making these social policy judgments now, when faced with the complex scientific issues that organic chemical technology brings before

94. *Accord*, *Moore v. Velsicol Chem. Corp.*, No. H-80-415 (D. Conn. Oct. 20, 1985); *Conde v. Velsicol Chem. Corp.*, 804 F. Supp. 972 (S.D. Ohio 1992).

95. *E.g.*, *Jones*, No. 92-02133, Record on Appeal at 396-404, 635-45. Compare scrutiny required of plaintiffs experts in cases reviewed by the N.J. Supreme Court. *Landrigan v. Celotex Corp.*, 605 A.2d 1079 (N.J. 1992); *Caterinichio v. Pittsburgh Corning Corp.*, 605 A.2d 1092 (N.J. 1992) (a companion case to *Landrigan*); *Rubanick v. Witco Chem. Corp.*, 593 A.2d 733 (N.J. 1991). For a discussion of these cases see *supra* text accompanying notes 86-90.

96. See *supra* notes 16, 33.

97. See *Jones*, No. 92-02133, Record on Appeal at 283-316, 361-94, 482-85, 650-55.

the bench.

III. Lessons to be Learned and Applied

The biotechnological era has arrived. Its terminology is moving from the rarefied spaces of high tech labs to hospitals, TV shows, and news rooms. It has invaded pop culture, from JURASSIC PARK to "Teenage Mutant Ninja Turtles".⁹⁸ Its products and processes, long used in agriculture and once solely the stuff of science fiction, are now making their way into areas of environmental management, practical medicine, commercial food production, and even homes and businesses.⁹⁹ Biotechnology issues impact the investment, insurance, and regulatory decisions which are being made everyday.¹⁰⁰

Some see the advent of practical biotechnology as the solution to hazardous waste dumps, oil spills, disease, burns, world hunger, and clogged drains.¹⁰¹ Some foretell doom and damnation (*A Brave New World*)¹⁰² while others foretell loosed pathogens (*Andromeda Strain* and *The Stand*).¹⁰³ Now is the time to look at the science, its processes, and applications, and consider *ab initio* and in light of our organic chemical experience, the appropriate guidance the legislative bodies should afford the regulators and the courts in the development of an interrelated jurisprudence which embodies societal values and concerns.

98. MICHAEL CRICHTON, JURASSIC PARK (Alfred A. Knopf, Inc. 1990); "Teenage Mutant Ninja Turtles", Comic Characters, Mirage Studios.

99. See *supra* notes 1, 12; see also U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY, 4 U.S. INVESTMENT IN BIOTECHNOLOGY, OTA-BA-360, chapters 9, 10, 11, app. A, B, C, D. (Washington, D.C., U.S. Printing Office, July 1988).

100. See U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY, 4 U.S. INVESTMENT IN BIOTECHNOLOGY, OTA-BA-360, chapter 5 (Washington, D.C., U.S. Printing Office, July 1988).

101. *Id.* See *supra* note 99.

102. ALDOUS HUXLEY, BRAVE NEW WORLD (1932).

103. MICHAEL CRICHTON, THE ANDROMEDA STRAIN (Alfred A. Knopf, Inc. 1969); STEPHEN KING, THE STAND (Compl. and Uncut ed. Doubleday 1990).

A. Regulation to be Forward-Looking - Adopting the "Seventh Generation" View of the Challenge

Regulation bears the responsibility of being precise enough to protect the commonweal from undue risks and hazards without squelching the development of valuable products and processes which have the potential for improving the human condition and increasing revenue. In the case of organic chemical technology, the respective regulatory packages were too late. As a result, they were costly, cumbersome, backward-looking, and incomplete. They took investment dollars which could have been used for economic stimulation and applied them to establishing and complying with regulatory systems (*e.g.* manifests) for industries in place and cleaning up past messes with associated transaction costs (*e.g.* consultant's and attorneys fees). Had a regulatory system grown with the industry, from the 1940s until today, the result could have been much different.

With biotechnology, the opportunity is ripe for the development of a lean, efficient, and finely tuned regulatory approach, one which is flexible enough to accommodate diverse processes and fluid enough to deal with inherent scientific complexity. The industry is young enough to grow with regulation and to anticipate regulatory costs in investment and insurance decisions. If the nation acts, it can maximize the public and private return, provide incentives for beneficial projects, and discourage troublesome ones. The "Seventh Generation" might thank us for affording it the best. Conversely, if the nation fails to act, the "Seventh Generation" may fault us, either for a mess of biological slime which needs to be mopped up or, perhaps more tragically, for the lost opportunities caused by the public's hysterical refusal to permit certain lines of research for fear of creating a doomsday result.

1. Overriding Ethical Considerations

To prevent knee-jerk reactions from driving legislative or judicial outcomes, principled ethical considerations should underlie all the issues surrounding the regulation of biotechnology. The discussion of biotechnology regulation should involve

multi-disciplined scientists, business and community policy makers, lawyers, philosophers and ethical and medical specialists. It should embrace the technology as it is now known and how it is predicted to develop.

Precisely because biotechnology, unlike organic chemical technology, is highly charged with emotion, a method should be established for articulating societal norms, consistent with the U.S. Constitution, to increase the likelihood that dangerous processes are not promoted or ill-considered reactions to aspects of the new technology do not foreclose beneficial research and development. This short discussion is intended to call attention to the need, not to establish the parameters. Clearly, knee-jerk reactions, which can change with the stroke of a political pen, are not conducive to the "Seventh Generation" view, either from the standpoint of the researcher, the investor, or the potential beneficiaries of the process or product. The Reagan-Bush Administrations' quasi-regulatory reaction to fetal tissue research, which was reversed by the Clinton Administration on its first day in office, is an example of just how quickly passion can provoke a response in the field of biotechnology.¹⁰⁴

Congress, which in our political system is the proper political entity to deal with enacting laws on socially complex matters, must articulate meaningful parameters and criteria to govern biotechnological regulation. Congress should begin the inquiry by ascertaining whether regulators should rely upon the traditional risk-benefit analysis in determining the acceptability of a process or product. In biotechnology, where risk and unforeseeability are inherent in the technology, and, because alteration of "natural" organisms or processes is contemplated, it may be that a more basic inquiry into essential judicial principles is necessary.¹⁰⁵ The starting inquiry might be whether the process/organism is inherently designed to

104. [Clinton] Executive Order, January 21, 1993; Kenneth L. Woodward *et al.*, *A Search for Limits*, NEWSWEEK, Feb. 22, 1993, at 52-53; *see also supra* note 12; *see also* U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY, 2 BACKGROUND PAPER: PUBLIC PERCEPTIONS OF BIOTECHNOLOGY - SPECIAL REPORT, OTA-BP-BA-45 (Washington, D.C., U.S. Printing Office, May 1987).

105. *See supra* notes 43-44, 49-51, 93, 95-97.

better the environment or human kind or whether it has some other design function or significant risk of perversion. If clearly the former, *e.g.* improving the nutrient quality of a food stuff or destroying accumulated hazardous waste, then the traditional risk-benefit inquiry might suffice. If the answer to the first question is unclear, the risk-benefit analysis may need augmentation by resorting to more basic principles. If the answer to the fundamental question is no, (*e.g.* the development of de-foliating organisms or biological warfare agents), the immediate solution may be to resort to more basic principles. Again, deciding what principles should apply and how they should be articulated as a conceptual framework for biotechnological advances, deserves the immediate attention of lawmakers, with the advice of philosophers, scientists, ethicists and lawyers.

Medical applications of biotechnology, while not new (all vaccinations against infectious diseases are applied biotechnology) will continue to raise new and challenging ethical questions. Medical applications raise at least a rebuttable presumption that the goal or design is the betterment of the human condition. However, additional considerations arise from the added potential for individual, rather than mere societal applications. Thus, superimposed upon the basic risk-benefit paradigm are issues such as: appropriate notice and disclosure to the patient, the confidentiality of the doctor-patient relationship, the rights of the patient and his family, the interests of the "silent" recipient or donor, (*e.g.* a fetus or incompetent), and the interests of the society, state, or third parties in the outcome or goal of a process or procedure. In the development of protocols for life and death decisions about extraordinary life support and resuscitation, and for evaluation of patient suitability and disclosure, in procedures ranging from sex changes to experimental fertility enhancing treatments, a start has already been made. The basis for these decisional processes might be explored as a springboard for further ethical consideration of new or anticipated biotechnological procedures in the medical field.

2. Overriding Regulatory Considerations

In any regulatory scheme, Congress must determine who will bear the burden of establishing the efficacy and safety of processes and products, the quantum of proof that will suffice, and who will evaluate test protocols and procedures. For biotechnology, these basic parameters should be augmented by an *a priori* determination of what degree of risk assessment or demonstrable foreseeability should be required by regulation, and how experimental technologies should, if at all, be distinguished from marketable ones.

The most obvious lesson learned from organic chemical technology was that when the waste disposal industry is unregulated, significant contamination of large land masses and water bodies results. Unregulated production processes, with their associated air and water emissions, also damaged the nation's air and water resources. Furthermore, due to the absence of a legislative directive, human health impacts were not scrutinized until after widespread pollution and exposure had already occurred.¹⁰⁶ Consequently, the most obvious area for legislative consideration and action is, from the outset, to insure that wide-scale pollution or contamination from biotechnological processes and products simply does not occur. Additionally, because of biotechnology's added level of scientific complexity and the ability of living organisms to regenerate, recombine, and mutate, special attention should be given to insure that living materials created by biotechnology are simply not allowed to escape into the environment.

Each of these goals could be accomplished either by shoring up regulatory loopholes in existing statutes or by adopting an entirely new, tightly tailored governmental strategy. At present, the federal regulatory and quasi-regulatory approach to biotechnological products and processes is segmented among a host of agencies. For example, the National Institute of Health has formed an advisory committee charged with review and approval of funding for projects involving genetic engineering. The Food and Drug Administration has authority

106. See *supra* notes 30, 31, 33.

over genetically engineered pharmaceutical products. The United States Department of Agriculture has authority to permit environmental releases under the Federal Plant Pest Act¹⁰⁷ and regulates animal biologics under the Virus-Serum-Toxin Act.¹⁰⁸ EPA regulates and registers genetically altered microbes having pesticidal functions under FIFRA and directs the "new chemical" review program under TSCA.¹⁰⁹ Except to the extent that discharges into land, air, or water are, or may be, caught up under regulations enacted pursuant to EPA's authority over discharges of pollutants¹¹⁰ and medical waste,¹¹¹ hazardous air pollutants,¹¹² or the generation, transport, treatment, storage, and disposal of hazardous waste,¹¹³ there is no direct regulatory approach in place to deal with off-spec, spent or other living product, or the ultimate disposal of process waste, which includes living material.¹¹⁴

In light of our organic chemical experience, a new strategy is necessary to replace this current patchwork approach.

107. See generally 7 U.S.C. § 150aa-150jj (1988).

108. 21 U.S.C. § 151 (1988).

109. See generally THE BNA SPECIAL REPORT SERIES ON BIOTECHNOLOGY, U.S. BIOTECHNOLOGY: A LEGISLATIVE AND REGULATORY ROADMAP, SPECIAL REPORT #2 (August 1989); Edward Kowek, *Towards Understanding the United States Biotechnology Regulatory Framework*, August 29, 1988, in BIOTECHNOLOGY: NEW DEVELOPMENTS IN FEDERAL POLICIES AND REGULATIONS, at 7 (PLI Pat., Copyrights, Trademarks & Literary Prop. Course Handbook Series No. 256, 1988) [hereinafter PLI 1988]. A White House coordinating committee with no regulatory authority was chartered in 1985 (Biotechnology Science Coordinating Committee). *Id.* at 17, 18.

110. CWA §§ 112(12), 301(a), 33 U.S.C. §§ 1262(12), 1311(a) (1988).

111. CWA §§ 502(20), 301(f), 33 U.S.C. §§ 1362(20), 1311(f) (1988).

112. CAA § 112(a)(6), (b)(1)-(2), (c), 42 U.S.C. § 7412(a)(6), (b)(1)-(2), (c) (source categories). The "initial list" of hazardous air pollutants contains no biological products. 42 U.S.C. § 7412(b)(1).

113. See generally RCRA §§ 1002, 1004(5), 42 U.S.C. §§ 6901, 6903(5) (1988). (The term "hazardous waste" means a solid waste, or combination of solid wastes, which because of its quantity, concentration, or physical, chemical, or infectious characteristics may . . .). RCRA § 3001(a), 42 U.S.C. § 6921(a) (1988) (criteria for identifying and listing hazardous waste include toxicity, persistence and degradability in nature). The term "infectious" is not defined in the statute. The 1980 implementing regulations did not contain a category for "infectious" waste. See *supra* note 22.

114. See also Patricia Shanks, *General Environmental and Health and Safety Laws in the Context of Biotechnology Operations*, in BIOTECHNOLOGY: NEW DEVELOPMENTS IN FEDERAL POLICIES AND REGULATIONS, at 55 (PLI Pat., Copyrights, Trademarks & Literary Prop. Course Handbook Series No. 256, 1988).

Such an effort would provide incentives for a fresh and creative look at the issues. It would necessitate calling upon persons with appropriate and necessary expertise, obviating extra-agency turf battles, and looking at the big picture. While organic chemical regulation was necessarily limited in scope because it was developed in a backward-looking way to deal with existing environmental problems, in biotechnology the harms do not exist yet and thus the regulatory approach could be truly forward-looking. Trying to utilize old statutes to develop a forward-looking regulatory approach would present serious risks. Whole classes of activity could be ignored. Sanitary engineers or other staff already in place would be called upon to deal with increasingly complex biological questions. The old statutes would retain a fragmented system with jurisdiction split up among a number of federal agencies and provide no mechanism to simultaneously address other pressing issues including judicial guidance and ethical concerns.

B. Individual Harms and a Private Right of Action

In light of our experience with organic chemicals, three questions need to be addressed early in the biotechnology process: (1) Should a private right of action be established in federal law for personal injury and property damage?; and if so, (2) What constitutes actionable "harm"?; and (3) What relationship, if any, should the regulatory standards have to proofs or defenses in actions for personal redress? Our organic chemical history confirms that a right of action must be made explicit in any biotechnology regulatory scheme.

The nation's response to the impacts of organic chemical technology has not only failed to make any provision for redress of private harms, it paradoxically, in some circumstances, has made it more difficult for private parties to be "made whole." The solution to this problem is threefold. First, as discussed above, regulation should begin early in the process, so that it can be truly forward-looking and not perceived by courts as an after-developed "fix" having no relevance to appropriate standards of care. Second, statutory attention to the concepts of risk and foreseeability is needed to

insure that archaic tort concepts do not preclude private recovery for harms arising from a technology whose proponents are well aware of its potential lack of foreseeability, and its inherent risks. Third, to avoid pre-emption of issues and endless wrangling in litigation in diverse courts, statutory provision for private redress should be made and Congress should articulate the appropriate relationship between regulatory approvals, prohibitions, and standards and the *prima facie* elements of tort liability.

Courts have been baffled by these organic chemical technology issues, which by comparison to biotechnology, is essentially simple. Without guidance from the legislative bodies, the complexities inherent in the biological processes of biotechnology will make the current situation even worse. Finally, courts are ill-equipped to be the arbiters of social policy.¹¹⁵ This is the most persuasive reason for legislative action in the biotechnology field, a field which is already highly charged with passion and fraught with danger.

1. Guidance to Courts: Evidence, Experts and the Burdens of Proof

For similar reasons, the need for legislative guidance to courts extends also to questions of admissibility of evidence, qualifications and scrutiny of experts, and burdens of proof. Where defendants are still permitted to urge that experts in a 50-year old technology are propounding "new," "novel," or "martian" science,¹¹⁶ it is hard to imagine the adjectives which will be offered to discredit scientists in a technology which, at least in terms of commercial or other practical applications, truly is new and novel. Congress should consider, and then articulate, standards for use of government records and proceedings in judicial proceedings, recognizing the expertise of practitioners in the field, and shifting the burden of proof to those who have peculiar or proprietary knowledge of processes or products. Articulating these standards early in the develop-

115. See *supra* part II.D.

116. See *supra* notes 90-92.

ing technology will avoid wasteful litigation and help to ensure fundamental fairness by providing early and timely notice to investors, practitioners, market participants and insurers of the risks associated with biotechnology.

2. Articulating Definitions of Risk and Foreseeability Appropriate for the New Technology

The tort elements of foreseeability, reasonableness and harm should be legislatively re-examined now. Congress or state legislators should determine whether the traditional common laws should be statutorily altered *before* courts are called upon to fashion remedies in individual cases, and before legislative bodies begin to enact extensive packages of statutory/regulatory law. Otherwise, the nascent industry will proceed at the risk of abrupt regulatory changes and financial peril and, as seen when dealing with organic chemicals, the community at large will proceed without the practical protections the common law is thought to provide. At a minimum, it would be appropriate on some principled basis, in this technological area, to expand the legal concept of foreseeability to include a larger, more generically described universe of possibilities. This would recognize the complexities and difficulties of specific end point predictions which appear to be inherent in the developing science. At the same time, such a legislative action early in the regulatory process would place investors and market participants on notice that a wider range of possible outcomes will be deemed "foreseeable" and would allow investment decisions to be made with full notice of potential liability. This in turn would, hopefully, prompt the regulated community to undertake studies of efficacy and safety early in the process and weed out potentially harmful or polluting processes or products before the "sunk cost" prohibits abandonment of the project. Such an approach would maximize safe and worthwhile processes and products by requiring hard, realistic investment-based scrutiny up front. In short, such a legislative pronouncement would induce the market to police itself. Similarly, risk or exposure itself may be appropriately defined as an actionable damage or an en-

forceable event. However, absent legislative direction, courts will once again be forced to chart unexplored territory, with a high likelihood of the same unfortunate results we have seen in the area of organic chemicals. Once again investors, insurers and practitioners of new technologies will be unable to realistically assess their financial risks, and victims of accidents or reckless conduct will be without the protections our common law is thought to afford.

IV. Conclusion

The lesson to be learned from our organic chemical experience and applied to biotechnology is essentially threefold. First, regulation in the field of biotechnology should not wait until a public health or environmental nightmare is detected. It should begin now and grow with the industry, providing incentives for improvements in production, efficacy of products, safety and waste disposal. This will avoid the unfortunate result that regulation of methods and products, which lagged behind and post dated the documentation of harm, hazard or carelessness, are not only held to be inadmissible, but, by virtue of their subsequent enactment, create an inference that whatever the industry saw fit to do earlier was an exercise of due care.¹¹⁷

Second, regulation should focus on the big picture; all aspects of the technological process from cradle to grave, including the potential impacts that it will have on individuals, the general public and society at large. Regulation should not only provide for recovery of natural resource damages, but for individual damages as well. It is a basic premise of this article that it was a mistake to develop a pervasive regulatory rubric for organic chemical technology without making provision for standards for adjudicating private rights and remedies. Not only did the lack of regulation and standards put courts in the anomalous position of laboring to develop social policy, it also called upon them to adjudicate issues of after-discovered pol-

117. Compare *Jones v. Arrow Exterminating Co.*, No. 92-02133, Record on Appeal at 898-906, 524-31, 663-95, 700-19, 898-906, 448-54 (pending N.Y. App. Div., 2d Dep't).

lution and injury, applying the traditional tests of foreseeability, reasonableness and harm. The courts' struggle with these issues has been highlighted above.¹¹⁸ In addition to these basic dilemmas, the regulatory system itself has directly caused some ironic results, specifically in the areas of pre-emption, standards of care and admissibility of evidence. It is a paradox that the very existence of regulations designed to protect health and welfare have served, in some cases, to extinguish private rights, limit the opportunities to prove deviation from reasonable care, and made more onerous the tests for admissibility of evidence.

Third, the role and responsibilities of the regulator and the regulated entity should be grounded in an evaluation of whether a proposed use or process conforms to an articulated acceptable social norm or value. We as a society are poised on the brink of the era of applied biotechnology and we stand to reap the benefits and incur the risks that this technology will bring in the coming years. Using the history of organic technology as a guide, we have the opportunity to investigate the legal, regulatory, and ethical considerations which should govern biotechnology, which is scientifically complex, rich in potential, but fraught with risks. By establishing statutory and regulatory decisions now, we can avoid the legacy of debt ridden waste sites and complex tort litigation that organic chemical technology has left us. At the same time, we can maximize the likelihood that the "Seventh Generation" will enjoy the positive fruits of the new biotechnology.

118. See *supra* part II.D.