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## The EPA's HPV Challenge Program: A Tort Liability Trap?

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# The EPA's HPV Challenge Program: A Tort Liability Trap?

David W. Case\*

*The result of all this is that the good Samaritan who tries to help may find himself mulcted in damages, while the priest and the Levite who pass by on the other side go on their cheerful way rejoicing.*

W. Page Keeton  
*Prosser and Keeton on Torts*

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### I. Introduction: Environmental Information and Regulatory Policy

Ideas to improve the effectiveness of this country's environmental regulatory system are ubiquitous in the scholarly literature. Such ideas range from relatively modest tinkering at the margins of the existing system to calls for radical evolutionary reform.<sup>1</sup> A critical obstacle to any ability to correct regulatory failures in the environmental protection arena is, however, the absence of necessary information.<sup>2</sup> Information is considered the "*sine qua non*" of an efficacious environmental regulatory system.<sup>3</sup> This is especially true in such areas as pollution control, natural resources management, and regulation of toxic substances.<sup>4</sup> However, "a dearth of information of all kinds" undermines our ability to regulate coherently areas of environmental concern.<sup>5</sup>

1. See generally THINKING ECOLOGICALLY: THE NEXT GENERATION OF ENVIRONMENTAL POLICY (Marian R. Chertow & Daniel C. Esty eds., 1997) (discussing ideas to shift American environmental regulatory policy to "next generation" models); Debra S. Knopman, *Easier to be Green: The Second Generation of Environmental Action*, in BUILDING THE BRIDGE: 10 BIG IDEAS TO TRANSFORM AMERICA 163, 164 (Will Marshall ed., 1997) (discussing ideas for a "second generation" environmental strategy); Michael P. Vandenberg, *An Alternative to Ready, Fire, Aim: A New Framework to Link Environmental Targets in Environmental Law*, 85 KY. L.J. 803 (1997) (offering a "utopian" perspective for radical environmental regulatory reform).

2. See Daniel C. Esty, *Environmental Protection in the Information Age*, 79 N.Y.U. L. REV. 115, 117–18 (2004) ("In recent years, . . . disappointment has arisen over regulatory failures—often traceable to information gaps—that remain pervasive despite numerous regulatory reform initiatives."); Karl Hausker, *Reinventing Environmental Regulation: The Only Path to a Sustainable Future*, 29 ENVTL. L. REP. 10,148, 10,153 (1999) ("Next generation authors recognize that the information and data systems that have served the bedrock regulatory system of the last decades are not up to the task of addressing the environmental problems that lie ahead.").

3. See J. CLARENCE DAVIES & JAN MAZUREK, *POLLUTION CONTROL IN THE UNITED STATES: EVALUATING THE SYSTEM* 53 (1998) (discussing the "data deficit regarding environmental pollution"); John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control*, 91 COLUM. L. REV. 261, 261 (1991) (stating that "[i]nformation remains the *sine qua non* of the rational development of specific regulatory commands regarding hazardous chemicals").

4. See Applegate, *supra* note 3, at 262–63 (stating that information particularly is needed to regulate toxic substances); Esty, *supra* note 2, at 140–41 (outlining the pervasive information gaps that plague environmental decisionmaking).

5. See DAVIES & MAZUREK, *supra* note 3, at 269 (noting that this "dearth of information" makes it impossible to tell whether environmental conditions are improving, to determine the causes of problems, and to tell whether solutions are working). These authors note that "[t]he current [regulatory] system lacks all kinds of necessary information—scientific and economic information, information about actual environmental conditions (monitoring data), and information about whether programs are working (program evaluation)." *Id.* at 289; see also John S. Applegate, *Worst Things First: Risk, Information, and Regulatory Structure in Toxic Substances Control*, 9 YALE J. ON REG. 277, 280–86 (1992) (discussing "scarcity of information" affecting the regulation of toxic substances); Rena I. Steinzor, *Devolution and the Public*

Among the costs of such information deficiencies are pervasive uncertainty and inefficiency in the environmental regulatory process.<sup>6</sup>

Information deficiencies are "unusually great" in the regulation of toxic substances.<sup>7</sup> Recognizing the danger to the public and to the environment from exposure to hazardous chemicals,<sup>8</sup> Congress enacted the Toxic Substances Control Act (TSCA) in 1976.<sup>9</sup> Largely intended to close the information gap in

*Health*, 24 HARV. ENVTL. L. REV. 351, 366–67 (2000) [hereinafter Steinzor, *Devolution*] (discussing the "dearth of information" afflicting regulatory efforts in achieving actual quality improvements in the environment); Rena I. Steinzor, *Reinventing Environmental Regulation: The Dangerous Journey from Command to Self-Control*, 22 HARV. ENVTL. L. REV. 103, 191–92 (1998) [hereinafter Steinzor, *Reinventing Environmental Regulation*] (arguing that gaps in scientific information hobble environmental regulation by undermining the government's ability to establish health-based standards); Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 CORNELL L. REV. 773, 774 (1997) (assessing responsibility for "lack of toxicity information" on perverse incentives of common law tort liability system).

6. See Applegate, *supra* note 3, at 265 (explaining the causes and consequences of uncertainty in the regulatory process). As Professor Applegate emphasizes:

The regulatory effect of uncertainty is, as in market transactions, inefficiency. The agency simply does not know where to allocate resources or how much to allocate. Lacking necessary information, the regulator cannot be certain what the problems are, which problems are most pressing, what regulatory goals to set, how best to achieve them, or even when they have been achieved.

*Id.*; see also U.S. GEN. ACCOUNTING OFFICE, MAJOR MANAGEMENT CHALLENGES AND PROGRAM RISKS: ENVIRONMENTAL PROTECTION AGENCY, GAO-99-17, at 17–18 (Jan. 1999) (outlining the problems a lack of information creates), available at <http://www.gao.gov/pas/cg99017.pdf> (on file with the Washington and Lee Law Review). The author goes on to say:

[The] EPA needs comprehensive information on environmental conditions and changes over time to identify problem areas that are emerging or that need additional regulatory action or other attention . . . . Absent this information, it is difficult for EPA to set priorities, evaluate the success of its programs and activities, and report on its accomplishments in a most credible and informed way.

*Id.*; see also Esty, *supra* note 2, at 140–41 ("[I]nformation problems represent a fundamental issue holding society back from better results in pollution control and natural resource management."); Mary L. Lyndon, *Information Economics and Chemical Toxicity: Designing Laws to Produce and Use Data*, 87 MICH. L. REV. 1795, 1796 (1989) ("The lack of data has . . . profoundly affected the law's attempt to deter and to compensate for chemical harms."); Steinzor, *Devolution*, *supra* note 5, at 367 ("These yawning data gaps undermine all of our efforts to establish priorities, assess risk, and achieve results.").

7. See Applegate, *supra* note 5, at 352 (commenting on the unusual degree to which information is lacking for regulating toxic substances).

8. See 15 U.S.C. § 2601(a) (2000) (finding that human beings and the environment are endangered by both current and developing chemicals and that effective regulation of interstate commerce in these chemicals requires regulation of intrastate commerce in the same); see also S. REP. NO. 94-698, at 3 (1976), reprinted in 1976 U.S.C.A.N. 4491, 4493 (stating that TSCA evolved into "a comprehensive measure to protect the public and the environment from exposure to hazardous chemicals").

9. Toxic Substances Control Act, 15 U.S.C. §§ 2601–92 (2000).

the area of toxic substances, TSCA allowed the acquisition of existing data from chemical producers and processors and the creation of new data when necessary.<sup>10</sup> TSCA mandates that the Environmental Protection Agency (EPA) issue a rule requiring testing to develop data on the health and environmental effects of chemical substances once the agency makes certain findings.<sup>11</sup> First, the EPA must find *either* the existence of an "unreasonable risk of injury" to health or the environment *or* that a chemical produced in "substantial quantities" may reasonably be expected to enter the environment in such quantities or to result in significant human exposure.<sup>12</sup> Second, the agency must find that insufficient data exist to reasonably determine the effect of a chemical substance on health or the environment.<sup>13</sup> And, third, the agency must find that testing this substance is necessary to develop sufficient data to make such a determination.<sup>14</sup>

As a policy tool designed to correct information deficiencies in chemical toxicity data, TSCA has been a substantial disappointment.<sup>15</sup> Almost two decades after its enactment, commentators note that "only a handful of test rules

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10. See Applegate, *supra* note 3, at 318 (stating that TSCA was designed to increase information, to collect existing data, and to allow the creation of new data).

11. See 15 U.S.C. § 2603(a) (2000) (stating that, upon making the required findings, "the Administrator shall by rule require that testing be conducted") (emphasis added); see also Applegate, *supra* note 3, at 315 (stating that promulgation of a "test rule" is done through the informal rulemaking procedures of the Administrative Procedure Act).

12. See 15 U.S.C. §§ 2603(a)(1)(A)(i), (B)(i) (2000) (listing the alternative findings the Administrator must make, which are referred to as "A" or "B" findings); Holly E. Pettit, *Shifting the Experiment to the Lab: Does EPA Have a Mandatory Duty to Require Chemical Testing for Endocrine Disruption Effects Under the Toxic Substances Control Act?*, 30 ENVTL. L. 413, 424-25 (2000) (listing the required findings under Section 4 of the TSCA). These include:

[S]pecifically, EPA must find that 1) either the chemical may present an unreasonable risk to health or to the environment (an "A" finding) or it is produced with substantial quantities (a "B" finding); 2) there is insufficient data to understand the effects of the chemical; and 3) testing is necessary to develop such data.

*Id.*

13. See 15 U.S.C. §§ 2603(a)(1)(A)(ii), (B)(ii) (2000) (describing the second set of alternative findings the Administrator must make).

14. See *id.* §§ 2603(a)(1)(A)(iii), (B)(iii) (describing the third set of alternative findings the Administrator must make).

15. See ENVTL. DEF. FUND, TOXIC IGNORANCE 23 (1997) (discussing TSCA's "fundamental failure" to provide safety assurances on thousands of widely used chemicals), available at [http://www.environmentaldefense.org/documents/243\\_toxicignorance.pdf](http://www.environmentaldefense.org/documents/243_toxicignorance.pdf) (on file with the Washington and Lee Law Review); Alyson C. Flournoy, *Legislating Inaction: Asking the Wrong Questions in Protective Environmental Decisionmaking*, 15 HARV. ENVTL. L. REV. 327, 330 (1991) (noting "relatively modest" action taken under TSCA); Lyndon, *supra* note 6, at 1805 (observing that TSCA has failed to produce data at a satisfactory rate).

have been promulgated under TSCA."<sup>16</sup> By October 2003, the EPA only issued "approximately thirty-one test rules under the statute, 'covering approximately 114 chemical substances and mixtures.'"<sup>17</sup> One explanation for EPA inaction under TSCA is "the elaborate procedural barriers that confine the test rules" combined with a "relatively strict" evidentiary standard the agency must meet to support such rules against judicial challenge.<sup>18</sup> These "procedural hurdles" render promulgation of TSCA test rules "a time consuming and expensive process."<sup>19</sup> Such costs, combined with the ease by which industry can judicially challenge TSCA test rules, are primary factors contributing to agency inaction.<sup>20</sup>

Professor Wendy Wagner observes that, in addition to such regulatory failures, common law tort liability rules also contribute to the dearth of toxicity information on commercial chemicals.<sup>21</sup> In order to recover for harm caused by exposure to potentially toxic products, the common law requires plaintiffs to demonstrate a cause-and-effect relationship between the product and the injury.<sup>22</sup> Toxicity research revealing long-term risks of specific chemical

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16. Applegate, *supra* note 3, at 318–19; *see also* ENVTL. DEF. FUND, *supra* note 15, at 28 (stating that in twenty years, the EPA has used its Section 6 power to proceed against unreasonably dangerous chemicals five times); Flournoy, *supra* note 15, at 330 (noting that the EPA has restrictively regulated five chemicals under Section 6 of the TSCA, and by 1984, more than 80% of the 48,000 generally used chemicals lacked toxicity information).

17. Physicians Comm. for Responsible Med. v. Horinko, 285 F. Supp. 2d 430, 437 (S.D.N.Y. 2003).

18. Applegate, *supra* note 3, at 319; *see also* ENVTL. DEF. FUND, *supra* note 15, at 29–30 n.15 ("Two appellate courts noted that EPA bears a higher burden of justifying regulatory action under TSCA than under the traditional 'arbitrary and capricious' standard that applies to federal agency actions generally." (citing *Shell Chem. v. EPA*, 826 F.2d 295, 297 (5th Cir. 1987) and *Auismont U.S.A. Co. v. EPA*, 838 F.2d 93, 96 (3d Cir. 1988))).

19. Applegate, *supra* note 3, at 319.

20. *See* ENVTL. DEF. FUND, *supra* note 15, at 29 n.15 ("Throughout TSCA's history, chemical manufacturers have used the weaknesses of the law to sue EPA and delay its efforts to require chemical testing."); DAVID M. O'BRIEN, WHAT PROCESS IS DUE? COURTS AND SCIENCE-POLICY DISPUTES 129–30, 146–49 (1987) (explaining how the threat of litigation creates a kind of "regulatory blackmail" as well as delay and inefficiency in promulgating regulations or collecting data, especially regarding carcinogenic substances); Flournoy, *supra* note 15, at 362–63 (noting how judicial challenges to findings and decisions impedes action and increases costs); Pettit, *supra* note 12, at 425–26 (observing that the EPA seeks to avoid promulgation of Section 4 test rules in part because of the burdensome nature of the requisite evidentiary standard); *see also* Flournoy, *supra* note 15, at 363 n.127 (stating that another factor to which commentators attribute agency inaction includes the potential for "severe regulatory consequences" should action actually be taken, which causes the agency to await a higher degree of certainty before acting).

21. *See* Wagner, *supra* note 5, at 774 (noting that the common law tort system contributes to the lack of toxicity information).

22. *See id.* (noting that the common law tort system requires the victims to produce

substances, if available, would greatly assist plaintiffs in this effort. Therefore, manufacturers are disinclined to conduct such research voluntarily in order to minimize exposure to lawsuits and "potentially catastrophic liability."<sup>23</sup> By thus rewarding the failure to conduct voluntary toxicity research, the common law system encourages manufacturers to make the economically rational choice of "remaining ignorant about the latent health risks of potentially toxic products."<sup>24</sup>

Numerous studies have attempted to quantify the lack of toxicity information on chemical substances used commercially in the United States. In 1984, the National Research Council of the National Academy of Sciences reported that no toxicity information existed for 80% of the more than 48,000 unregulated chemical substances then in commercial use.<sup>25</sup> In 1997, an environmental advocacy group, the Environmental Defense Fund (now Environmental Defense), issued the *Toxic Ignorance* report "suggest[ing] that more than 70% of highest-volume industrial chemicals in U.S. commerce lacked sufficient data . . . to conduct basic hazard assessments."<sup>26</sup> High-volume chemicals are defined as those produced or imported in amounts of one million pounds per year and are known as "high production volume" (HPV)

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scientific research to show a cause-and-effect relationship between the chemical and their injuries).

23. See *id.* at 775 (noting the self-incriminatory nature of voluntary safety research and how this discourages companies from doing this research).

24. See *id.* (noting that manufacturers face no penalties for ignorance and risk enormous liability if they learn of long-term dangers). Professor Applegate similarly observes that:

The emerging field of toxic torts is characterized by its lack of information for decision making, and not by its ability to generate data. Again, the industrial defendant is typically in the best position to create the necessary data, but its incentives are the reverse. In the absence of dramatic changes to encourage defendants to generate and disclose potentially inculpatory toxicity evidence, tort law is unlikely to be a major factor in creating toxics data.

Applegate, *supra* note 3, at 299–300; see also Thomas O. McGarity, *MTBE: A Precautionary Tale*, 28 HARV. ENVTL. L. REV. 281, 331 (2004) ("[E]xisting liability and regulatory laws create perverse incentives on the part of externality-producing actors to conceal the information that they do possess and 'to actively discredit and obfuscate damaging information' produced by others.").

25. See Flournoy, *supra* note 15, at 330 (summarizing the Council's study that more than 80% of chemicals lack toxicity information); Wagner, *supra* note 5, at 782 (noting the lack of toxicity information for the majority of chemicals). Both authors cite NAT'L RESEARCH COUNCIL, TOXICITY TESTING: STRATEGIES TO DETERMINE NEEDS AND PRIORITIES (1984).

26. RICHARD A. DENISON, ENVTL. DEF., ORPHAN CHEMICALS IN THE HPV CHALLENGE: A STATUS REPORT ii (2004), available at [http://www.environmentaldefense.org/documents/3810\\_HPVOorphansReport\\_062004.pdf](http://www.environmentaldefense.org/documents/3810_HPVOorphansReport_062004.pdf) (on file with the Washington and Lee Law Review); see ENVTL. DEF. FUND, *supra* note 15, at 7 (stating that almost 75% of the top volume chemicals lack basic toxicity test results).

chemicals.<sup>27</sup> *Toxic Ignorance* prompted the EPA and the chemical industry through the Chemical Manufacturers Association (now the American Chemistry Council) to undertake more extensive studies.<sup>28</sup> Both studies confirmed that basic hazard-screening information was inadequate or completely unavailable in the public record for more than 90% of domestic HPV chemicals.<sup>29</sup>

Spurred by these findings, Environmental Defense, the American Chemistry Council, and the EPA engaged in discussions regarding the need to generate data on HPV chemicals.<sup>30</sup> These discussions led to the announcement on Earth Day, April 21, 1998, by Vice President Al Gore and EPA Administrator Carol Browner of the "Chemical-Right-to-Know" initiative.<sup>31</sup> The fundamental purpose for the initiative is to "assure that adequate information is available to the public to assess risks for chemicals that are present in the local environments."<sup>32</sup> The EPA further emphasizes:

Through the [Chemical Right-to-Know] Initiative, EPA intends to collect health and environmental information to ensure that basic screening data are available on all HPV chemicals. The data will provide the basis for better and faster decisions on which chemicals present risks and how to

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27. See Physicians Comm. for Responsible Med. v. Horinko, 285 F. Supp. 2d 430, 432 (S.D.N.Y. 2003) (defining HPV chemicals); DENISON, *supra* note 26, at ii (offering a definition of HPV chemicals).

28. See DENISON, *supra* note 26, at ii (describing further studies that *Toxic Ignorance* motivated).

29. See *id.* at iii ("[M]ore than 90% of HPV chemicals lacked some or all screening-level data at the outset of the HPV Challenge Program."); OFFICE OF POLLUTION PREVENTION & TOXICS, EPA, CHEMICAL HAZARD DATA AVAILABILITY STUDY: WHAT DO WE REALLY KNOW ABOUT THE SAFETY OF HIGH PRODUCTION VOLUME CHEMICALS? 7 (1998) (stating that only 9% of HPV chemicals met the data availability requirements for human health hazard screening), available at <http://www.epa.opptintr/chemtest/hazchem.pdf> (on file with the Washington and Lee Law Review). See generally ICF KAISER INT'L, PUBLIC AVAILABILITY OF SIDS-RELATED TESTING DATA FOR U.S. HIGH PRODUCTION VOLUME CHEMICALS (1998).

30. See *Physicians Comm.*, 285 F. Supp. 2d at 433 (describing discussions between Environmental Defense, the American Chemistry Council, and the EPA on the need for more data).

31. See *id.* (describing Vice President Gore's announcement on Earth Day); High Production Volume (HPV) Chemical Initiative, Periodic Update Meetings, 64 Fed. Reg. 24,151, 24,152 (May 5, 1999) (describing the announcement of the HPV Challenge Program as a part of the Chemical Right-to-Know initiative).

32. OFFICE OF POLLUTION PREVENTION & TOXICS, EPA, *Chemical Right-to-Know Program Frequently Asked Questions*, 1, at <http://www.epa.gov/chemrtk/rtkfaqs.pdf> (last modified Aug. 21, 2004) (on file with the Washington and Lee Law Review); see also Data Collection and Development on High Production Volume (HPV) Chemicals, 65 Fed. Reg. 81,686, 81,687 (Dec. 26, 2000) ("EPA's Chemical Right-to-Know (ChemRTK) initiative is being designed in such a way as to make certain basic information about HPV chemicals available to the public.").



eliminate or manage these risks. It is EPA's goal to assure that the public has access to health and environmental effects data for chemicals which are present in their environment. Improving EPA's and the public's understanding of the hazards of chemicals most commonly used in this country is a priority of this program.<sup>33</sup>

Following the launch of the Chemical Right-to-Know initiative, the EPA, Environmental Defense, and the American Chemistry Council continued joint discussions.<sup>34</sup> These discussions eventually led to joint development of a framework agreement for a key element of the initiative (the HPV Challenge Program), which was publicly announced on October 9, 1998.<sup>35</sup> This program intends to narrow the public toxicity information gap by challenging the chemical industry to perform certain testing voluntarily to generate previously unavailable baseline health and environmental effects data for HPV chemicals.<sup>36</sup> Consistent with the overarching Right-to-Know initiative, "[t]he data generated through this program will be made available to the public" by way of the Internet no later than 2005.<sup>37</sup> Companies that manufacture or import the chemicals included in the program were requested to take responsibility for their testing voluntarily.<sup>38</sup> Following a specified period for

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33. OFFICE OF POLLUTION PREVENTION & TOXICS, *supra* note 32, at 2.

34. See Physicians Comm. for Responsible Med. v. Horinko, 285 F. Supp. 2d 430, 433 (S.D.N.Y. 2003) (stating that these three organizations continued to dialogue regarding the need to generate test data on HPV chemicals).

35. See *id.* (describing the formation of the HPV Challenge Program by the three organizations and its October announcement); Data Collection, 65 Fed. Reg. at 81,692 (describing the HPV Challenge Program); RICHARD A. DENISON & KAREN FLORINI, ENVTL. DEF., FACING THE CHALLENGE: A STATUS REPORT ON THE U.S. HPV CHALLENGE PROGRAM 1 (2003) (explaining the formation of the HPV Challenge Program), available at [http://www.environmentaldefense.org/documents/2682\\_FacingtheChallengefinal.pdf](http://www.environmentaldefense.org/documents/2682_FacingtheChallengefinal.pdf) (on file with the Washington and Lee Law Review); see also EPA's High Production Volume (HPV) Chemical Testing Program: Hearing Before the House Subcomm. on Energy and Env't of the Comm. on Science, 106th Cong. 119-20 (1999) (Joint Announcement of a Cooperative Program for High Production Volume U.S. Industrial Chemicals (Oct. 9, 1998)) [hereinafter Joint Announcement] (announcing the formation of a joint testing program for HPV chemicals in a document jointly executed by the American Chemistry Council, Environmental Defense, and the EPA).

36. See Physicians Comm., 285 F. Supp. 2d at 433 (stating that the goal of the HPV Challenge Program is to challenge the industry to collect data on 2800 HPV chemicals voluntarily); Data Collection, 65 Fed. Reg. at 81,692 (outlining the goals of the voluntary testing under the HPV Challenge Program).

37. OFFICE OF POLLUTION PREVENTION & TOXICS, *supra* note 32, at 2-3 (stating that the information will be made public); see also Data Collection, 65 Fed. Reg. at 81,692 (stating that results will be available via the Internet); DENISON, *supra* note 26, at ii (stating that the data will be available publicly in 2005).

38. See Joint Announcement, *supra* note 35, at 120 (inviting companies to participate in the testing voluntarily).

companies to volunteer, the framework agreement emphasized that the EPA would use its rulemaking authority under Section 4 of TSCA "to compel testing for [HPV] chemicals not 'volunteered.'"<sup>39</sup> As an incentive to participate in the voluntary program, the framework agreement states that a higher "degree of testing flexibility" would apply to voluntary testing than for testing under a regulatory test rule.<sup>40</sup> Further, "[v]oluntary testing will not trigger the usual TSCA reporting obligations imposed under a Section 4 program."<sup>41</sup>

The HPV Challenge Program is an example of a collaborative approach to environmental policymaking that found significant favor within the Clinton-era EPA during the 1990s. During the latter half of the 1990s, collaborative programs were at the heart of numerous EPA "reinvention" initiatives designed to experiment with alternative approaches to traditional environmental regulation.<sup>42</sup> Collaborative approaches to environmental protection policy

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39. U.S. ENVTL. PROTECTION AGENCY, *Framework for Voluntary Testing of High Production Volume (HPV) Chemicals*, at [www.americanchemistry.com](http://www.americanchemistry.com) (July 25, 2000) [hereinafter *Framework for Voluntary Testing*] (on file with the Washington and Lee Law Review); see also *Physicians Comm. for Responsible Med. v. Horinko*, 285 F. Supp. 2d 430, 434 (S.D.N.Y. 2003) (stating that the EPA would require testing of chemicals not tested voluntarily); *Testing of Certain High Production Volume Chemicals*, 65 Fed. Reg. 81,658, 81,662–64 (Dec. 26, 2000) (referring to proposed test rule under Section 4 of TSCA for thirty-seven HPV chemicals for which the data needs are unmet).

40. *Framework for Voluntary Testing*, *supra* note 39.

41. *Id.* On December 26, 2000, the EPA announced another voluntary challenge program—the Voluntary Children's Chemical Evaluation Program (VCCEP)—that is also a component of the Chemical Right-to-Know initiative. See *Voluntary Children's Chemical Evaluation Program*, 65 Fed. Reg. 81,700, 81,715 (2000) (stating that VCCEP is an EPA challenge to industry to volunteer to sponsor testing and evaluation of twenty-three chemicals deemed to pose a high risk of likely exposure to children and prospective parents and that information generated through this voluntary program, similar to the related HPV Challenge Program, eventually will be made publicly available by the EPA); OFFICE OF POLLUTION PREVENTION & TOXICS, EPA, VOLUNTARY CHILDREN'S CHEMICAL EVALUATION PROGRAM (VCCEP), <http://www.epa.gov/chemtrk/vccep/index.htm> (last modified Sept. 28, 2004) ("Thirty-five companies and ten consortia . . . volunteered to sponsor 20 chemicals.") (on file with the Washington and Lee Law Review). Although this Article focuses primarily on the HPV Challenge Program, much of its analysis is equally applicable to the EPA's VCCEP as well.

42. For discussions of various EPA-initiated "reinvention" experiments aimed at reform of the traditional environmental regulatory system, see David W. Case, *The EPA's Environmental Stewardship Initiative: Attempting to Revitalize a Floundering Regulatory Reform Agenda*, 50 EMORY L.J. 1, 39–89 (2001) (discussing "reinvention" and the EPA's Environmental Stewardship Initiative); Elizabeth Glass Geltman & Andrew E. Skroback, *Reinventing the EPA to Conform with the New American Environmentality*, 23 COLUM. J. ENVTL. L. 1, 15–25 (1998) (outlining the EPA's "reinvention" and streamlining efforts during the Clinton administration); David B. Spence & Lekha Gopalakrishnan, *Bargaining Theory and Regulatory Reform: The Political Logic of Inefficient Regulation*, 53 VAND. L. REV. 599, 613–19 (2000) (giving four examples of "bargaining experiments" at the EPA, none of which fulfilled its expectations).

encompass a wide variety of mechanisms, "from more flexible enforcement of regulations to voluntary agreements, with much in between."<sup>43</sup> Voluntary agreements can take the form of legally binding contracts, although many, such as the HPV Challenge Program, take the form of nonbinding "gentlemen's agreements."<sup>44</sup> Nonetheless, voluntary agreements "are characterized by strong expectations on the part of government that industry will comply," and, like the HPV Challenge Program, "are typically accompanied by an explicit or implied threat of regulation or other mandatory instruments should voluntary measures fail."<sup>45</sup> Some voluntary challenge programs are less coercive in that there are no threats of regulation or penalties for nonparticipation.<sup>46</sup> A well-known prior example of this type of program is the EPA's 33/50 program, a pollution prevention initiative of the early 1990s to reduce releases of seventeen key toxic chemicals reported in the Toxics Release Inventory.<sup>47</sup>

Potential benefits to the government from the HPV Challenge Program are obvious. The government's attempts to develop this information directly require substantial, indeed, cost-prohibitive taxpayer sums.<sup>48</sup> Through the voluntary challenge program, the private sector—those companies sponsoring various HPV chemicals for testing—will primarily bear the costs of generating

43. Kathryn Harrison, *Talking with the Donkey: Cooperative Approaches to Environmental Protection*, 2 J. INDUS. ECOLOGY 51, 52 (1998). For additional discussion of public-private "partnerships" as a "collaborative redefinition of existing regulatory arrangements," see EDWARD P. WEBER, *PLURALISM BY THE RULES: CONFLICT AND COOPERATION IN ENVIRONMENTAL REGULATION* 9–12 (1998).

44. Harrison, *supra* note 43, at 56. The framework agreement underlying the HPV Challenge Program states explicitly:

This document represents a framework under which companies agreeing to voluntarily test HPV chemicals may do so consistent with EPA's Chemical Right to Know initiative, and avoid a test rule. Because success will require extraordinary cooperation and coordination among stakeholders, the framework itself is not an enforceable agreement or contract.

*Framework for Voluntary Testing*, *supra* note 39.

45. Harrison, *supra* note 43, at 56.

46. *See id.* (noting that voluntary challenges involve few, if any, threats of regulations or penalties).

47. *See id.* (listing the EPA's 33/50 program as an example of a voluntary challenge program); *see also* Seema Arora & Timothy Cason, *An Experiment in Voluntary Environmental Regulation: Participation in EPA's 33/50 Program*, 28 J. ENVTL. ECON. & MGMT. 271, 271 (1995) (noting that this program encourages firms voluntarily to reduce the release of seventeen chemicals).

48. *See* Applegate, *supra* note 3, at 307 ("[G]iven the expense of this [toxicological testing] research, the number of substances that can be investigated is extremely limited. There will never be enough money in a federal or state budget to fill the existing data gaps on a chemical-by-chemical basis."); Wagner, *supra* note 5, at 789–90 (discussing resource constraints limiting government's ability to generate vital information by testing chemicals).

the requisite information.<sup>49</sup> Indeed, the framework agreement emphasizes that "[u]nder this program, industry will voluntarily spend several hundred million dollars creating valuable data in a few short years."<sup>50</sup> Moreover, were industry required to generate this information through a regulatory scheme such as TSCA, substantial monitoring and enforcement costs would accrue, including responding to the legal challenges that coercive regulatory approaches typically produce.<sup>51</sup> Other benefits from utilizing a voluntary challenge program include the ability to generate, utilize, and provide the public with critical toxicology information sooner than would otherwise be the case. In turn, industry participants in the program benefit from public recognition as socially responsible corporate citizens and from development of more favorable program parameters than would have been the case with a program developed exclusively by regulatory means.<sup>52</sup> In this specific instance, participating volunteers avoid having to perform such testing under the less flexible requirements of a TSCA test rule.<sup>53</sup>

Notwithstanding the substantial benefits underlying the effort, the HPV Challenge Program is subject, as are essentially all regulatory efforts, to the law of unintended consequences. The concept of unintended consequences reveals

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49. See Applegate, *supra* note 3, at 299 (observing that "industries that produce and use chemicals ordinarily are in the best position to provide or obtain toxicity and exposure data most cheaply and accurately").

50. *Framework for Voluntary Testing*, *supra* note 39.

51. See Harrison, *supra* note 43, at 58 ("Voluntary approaches are less costly than regulation from government's perspective because industry bears the costs of monitoring and shares the costs of standards development.").

52. In its written descriptions of the program, the EPA emphasizes:

Signing up for the Challenge Program provides an opportunity for recognition as an industry leader on an issue of importance to the public. In the spirit of this right-to-know initiative, the Agency would like to publicly recognize those companies participating in the HPV Challenge Program on its Web Site <http://www.epa.gov/opptintr/chemrtk>.

OFFICE OF POLLUTION PREVENTION & TOXICS, EPA, *HPV Challenge Program Frequently Asked Questions*, 15, at <http://www.epa.gov/chemrtk/hpvfaqs.pdf> (last modified Apr. 21, 2004) (describing public relations benefits for companies) (on file with the Washington and Lee Law Review).

53. Specifically, the EPA states:

[T]he voluntary program allows the use of chemical category approaches which provide some flexibility in the tests to be conducted on each chemical in the category; the test rule will not allow that flexibility. Additionally, the outputs of the voluntary program will be detailed study summaries; the test rule will require submission of entire studies for each of the SIDS test needed for each chemical.

the often "perverse unanticipated effects of legislation and regulation."<sup>54</sup> A general example of an unintended consequence is a regulatory requirement to clean up a water source causing an unforeseen increase in air pollution as a result of the method chosen to clean up the water. A more complex example occurs when a statutory provision is given an interpretation and application by either regulatory agencies or the courts not intended by the legislature.<sup>55</sup> Such unintended consequences can have negative repercussions that seriously undermine the originally intended goals by use of the regulatory mechanism in question. This Article explores such an unintended consequence unforeseen by the parties to the HPV Challenge Program framework agreement. The implications of this unintended consequence have the potential to adversely affect the EPA's future ability to utilize successfully voluntary programs as a policy tool of choice.

This Article argues that voluntary sponsors of chemical testing under the HPV Challenge Program are exposed to significant potential common law tort liability. Specifically, such liability exposure arises under Section 324A of the Restatement (Second) of Torts, an offshoot of the "Good Samaritan" doctrine that holds "volunteers" liable for negligent performance of an undertaking causing injury to third parties.<sup>56</sup> As detailed in Part III, in the 1998 decision of *Dow Chemical Co. v. Mahlum*,<sup>57</sup> the Nevada Supreme Court upheld liability imposed on a parent chemical company that voluntarily had undertaken safety

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54. Rob Norton, *Unintended Consequences*, in THE CONCISE ENCYCLOPEDIA OF ECONOMICS (David R. Henderson ed., Liberty Fund, Inc. 2002), <http://www.econlib.org/library/Enc/UnintendedConsequences.html> (on file with the Washington and Lee Law Review); see also James L. Huffman, *The Impact of Regulation on Small and Emerging Businesses*, 4 J. SMALL & EMERGING BUS. L. 307, 316 (2000) (discussing the impact of the "unintended consequences" of governmental regulation). The author went on to say:

The rule of unintended consequences will forever plague our regulatory efforts. In this regard, the government is no different than private actors, except that the unintended consequences of government action tend to be much more widespread, and the processes for adjustment to those unintended consequences are generally less facile than the day-to-day workings of the marketplace. Our lives are complex beyond our understanding, which means that our decisions, both public and private, will always have consequences we do not anticipate and often do not want.

*Id.*

55. See, e.g., Rena I. Steinzor, *The Legislation of Unintended Consequences*, 9 DUKE ENVTL. L. & POL'Y F. 95, 95 (1998) (discussing application of Superfund liability to "disposal of ordinary garbage" as an example of an "unintended consequence" that undermines Congress's intended goals).

56. See *infra* notes 83–99 (comparing the Good Samaritan doctrine with Restatement Section 324A).

57. *Dow Chem. Co. v. Mahlum*, 970 P.2d 98 (Nev. 1998), *overruled in part by* *GES, Inc. v. Corbitt*, 21 P.3d 11 (Nev. 2001).

testing on chemical substances for a subsidiary manufacturing company.<sup>58</sup> The court found the performance of this voluntary undertaking negligent.<sup>59</sup> Accordingly, a third-party purchaser of the subsidiary's products could recover against the parent chemical company for injuries suffered through use of those products solely on the basis of the voluntary, yet negligently performed, chemical testing.<sup>60</sup>

Similar tort liability may attach to companies voluntarily undertaking chemical testing through the HPV Challenge Program. Among others, individuals in a position to claim injury by decisions made in reliance on information disclosed through the program may have a cognizable cause of action. Importantly, the EPA's stated intention for the HPV Challenge Program is to provide the public with access to the information generated so that citizens can utilize the information to make basic decisions regarding their daily lives. In the EPA's own words, a primary purpose for pursuing information on HPV chemicals is "to empower citizens with knowledge about . . . chemicals that people may be exposed to in the places where they live, work, study, and play," as well as those "found in their environment" and in "the products that they buy."<sup>61</sup> Third-party reliance upon the information generated by the HPV Challenge Program is a basic purpose of the program pursuant to the philosophy of the Chemical Right-to-Know initiative.<sup>62</sup>

Part II of this Article outlines the pertinent components of the HPV Challenge Program. Part III analyzes common law tort liability for "negligent" chemical testing under the Good Samaritan doctrine and the precedent of the *Mahlum* decision. Part IV argues that voluntarily testing specific chemicals through the HPV Challenge Program exposes companies to such potential tort liability. Part V concludes with a discussion of the policy implications for the EPA as a result of this unintended consequence. This discussion considers the potentially adverse effect of this unintended consequence on future use of collaborative policy tools by the EPA. This Article concludes that such

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58. See *id.* at 104–07 (outlining the various tests and upholding liability for "negligent performance of an undertaking").

59. *Id.* at 107, 113–21; see also *infra* Part III.B (discussing *Mahlum*).

60. See *Mahlum*, 970 P.2d at 121 (upholding parent company's liability for negligent testing); see also *infra* Part III.B (discussing *Mahlum*).

61. See Data Collection and Development on High Production Volume (HPV) Chemicals, 65 Fed. Reg. 81,686, 81,687 (Dec. 26, 2000) (stating that the EPA wants to give citizens information on chemicals in these various locations).

62. See *id.* (stating that the program is designed so people can assess the risks associated with these chemicals).

considerations may justify EPA efforts to secure immunity from such liability for voluntary program participants.

## II. The HPV Challenge Program

Concurrent with the formal program announcement on October 9, 1998, the EPA invited approximately 900 chemical companies to participate in the HPV Challenge Program.<sup>63</sup> To participate, sponsors—a company or a consortium of companies working together—were asked to provide three items: (1) a letter committing to sponsor specific chemicals from the EPA's 1990 list of more than 2800 American HPV chemicals; (2) test plans either identifying adequate existing Screening Information Data Set (SIDS) test data on sponsored chemicals or proposing new testing deemed necessary to fulfill complete SIDS testing requirements; and (3) a "robust summary" . . . for each existing and new study.<sup>64</sup> Two "commitment" phases of the program—collectively the "voluntary phase"—permitted companies until March 15, 1999, and December 1, 1999, respectively, to volunteer to sponsor certain chemicals.<sup>65</sup> During this period, commitments were made by "469 companies,

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63. See Carol M. Browner, EPA, *Letter to Manufacturers/Importers, Oct. 9, 1998*, at <http://www.epa.gov/chemrtk/ceoltr1.htm> (last modified Aug. 14, 2002) (inviting companies to participate voluntarily in the Challenge Program) (on file with the Washington and Lee Law Review). This letter states, in pertinent part:

This Challenge Program represents a powerful new direction in environmental protection, one that offers the opportunity for EPA, the chemical industry, and the environmental community to work together toward common goals. The citizens of this country deserve to have basic health and environmental information about the chemicals they come in contact with on a daily basis. For this reason, we need to move quickly to close information gaps on the 2800 high production chemicals identified today. We hope that, with the leadership of companies like yours, we can accomplish this goal voluntarily and collaboratively.

*Id.*

64. Data Collection, 65 Fed. Reg. at 81,687, 81,692, 81,694 (stating that the chemicals to be tested were on the 1990 list and the requirements for participating in the HPV Challenge Program).

65. See *id.* at 81,693 (setting the dates for the commitment phases); see also Physicians Comm. for Responsible Med. v. Horinko, 285 F. Supp. 2d 430, 434 (S.D.N.Y. 2003) (describing the voluntary and regulatory phases of the HPV Challenge Program); Data Collection, 65 Fed. Reg. at 81,687 (outlining the six basic testing endpoints that the Organisation for Economic Cooperation and Development (OECD) adopted as minimal requirements to screen HPV chemicals for toxicity); David Roe, *Ready or Not: The Coming Wave of Toxic Chemicals*, 29 ECOLOGY L.Q. 623, 627 (2002) (noting that the OECD developed the SIDS program in 1990). These six testing endpoints are known as SIDS and include:

Acute toxicity; repeat dose toxicity; developmental and reproductive toxicity; mutagenicity (gene mutation and chromosomal aberration/damage assays);

individually or as part of 187 consortia . . . to sponsor 2,155 chemicals under the voluntary phase of the program.<sup>66</sup> During a subsequent or "regulatory" phase of the program, promulgation of proposed test rules are to occur under Section 4 of TSCA for HPV chemicals not sponsored voluntarily.<sup>67</sup> To date, the EPA has proposed one test rule requiring chemical companies to conduct SIDS testing on thirty-seven HPV chemicals not included in the voluntary portion of the program.<sup>68</sup>

The HPV Challenge Program's stated goals are to:

- (i) Ensure full public availability of [hazard] screening level data of HPV chemicals.
- (ii) Determine the adequacy of existing published and unpublished data to maximize its use for HPV chemicals in order to avoid repeat testing. [and]
- (iii) Conduct needed testing to ensure the availability of [hazard] screening level data on HPV chemicals.<sup>69</sup>

In pursuit of these objectives, all test plans and robust summaries initially submitted by voluntary participants are made available for a 120-day public review and comment period.<sup>70</sup> During this comment period, test plans are evaluated by the EPA as to whether adjustments should be made for necessary

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ecotoxicity (studies in fish, invertebrates, and algae); and environmental fate (including physical chemical properties [melting point, boiling point, vapor pressure, *n*-octanol/water partition coefficient, and water solubility]), photolysis, hydrolysis, transport/distribution, and biodegradation. As conceived by the OECD, the "SIDS battery" of tests can be used by governments to conduct an initial assessment of the hazards and risks posed by HPV chemical substances and prioritize HPV chemicals to identify those in need of additional, more in-depth testing and assessment.

Data Collection, 65 Fed. Reg. at 81,687-88.

66. Data Collection, 65 Fed. Reg. at 81,694.

67. See *Physicians Comm.*, 285 F. Supp. 2d at 434 (stating that the EPA intends to issue rules in the regulatory phase regarding chemicals not tested during the voluntary phase).

68. See *Testing of Certain High Production Volume Chemicals*, 65 Fed. Reg. 81,658, 81,658 (Dec. 26, 2000) (proposing a test rule for thirty-seven chemicals).

69. *Data Collection and Development on High Production Volume (HPV) Chemicals*, 65 Fed. Reg. 81,686, 81,692-93 (Dec. 26, 2000).

70. See *id.* at 81,692 ("The test plans that are submitted by the voluntary participants will be posted 120 days before any testing is initiated, providing an opportunity for interested parties to review and provide comments on the test plans, including technical comments regarding alterations to the proposed test plans."); DENISON & FLORINI, *supra* note 35, at vi (noting that after a test plan and robust summaries have been developed and submitted, they are available for public comment).



additional data development or testing beyond that initially proposed.<sup>71</sup> Subsequently, the sponsor performs additional testing and then "submits a revised, now-complete Robust Summary."<sup>72</sup> At the conclusion of this process, all summarized data generated for each sponsored HPV chemical are made available to the public.<sup>73</sup> The ultimate goal is for all data produced through the voluntary program to be made publicly available by the end of 2005.<sup>74</sup> However, in a 2003 evaluation conducted by Environmental Defense, significant concerns were raised about whether the process is proceeding at a pace to meet this deadline.<sup>75</sup>

Consistent with the "right-to-know" foundation of the program, the public is able to track the progress of the sponsored HPV chemicals on the EPA's Internet site.<sup>76</sup> By the end of 2002, 194 test plans with accompanying robust summaries covering 951 HPV chemicals had been filed.<sup>77</sup> From January 2003 to July 21, 2004, 185 test plans and summary data were added to the online data base.<sup>78</sup> Significantly, the universe of HPV chemicals is a moving target. The original core list of 2782 HPV chemicals derives from the 1990 TSCA Inventory Update list.<sup>79</sup> However, based on the 2002 TSCA Inventory Update, more than 700 new chemicals have since emerged as HPV chemicals that were not domestic HPV chemicals in 1990.<sup>80</sup> Given the Framework Agreement, these new HPV chemicals are "not officially within the scope" of the voluntary program.<sup>81</sup> The EPA anticipates that "over time, the testing of new HPV chemicals will become routine, and companies may wish to test new HPV chemicals as they appear."<sup>82</sup>

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71. See Data Collection, 65 Fed. Reg. at 81,692 (stating that during the 120-day comment period, the EPA will assess the sufficiency of the data submitted).

72. DENISON & FLORINI, *supra* note 35, at vi.

73. *Id.*

74. *Id.* at 4.

75. See *id.* at vii-xii (noting problems and offering recommendations).

76. Data Collection and Development on High Production Volume (HPV) Chemicals, 65 Fed. Reg. 81,686, 81,694 (Dec. 26, 2000).

77. DENISON & FLORINI, *supra* note 35, at vii.

78. See U.S. Envtl. Protection Agency, *High Production Volume (HPV) Challenge Program: Robust Summaries and Test Plans*, at <http://www.epa.gov/chemrtk/viewsrch.htm> (last visited Oct. 18, 2004) (listing submissions by date posted) (on file with the Washington and Lee Law Review).

79. DENISON, *supra* note 26, at iv n.8.

80. *Id.* at v.

81. *Id.* See generally *Framework for Voluntary Testing*, *supra* note 39.

82. U.S. Envtl. Protection Agency, *High Production Volume (HPV) Challenge Program: The HPV Voluntary Challenge Chemical List*, at <http://epa.gov/chemrtk/hpvchmlt.htm> (last modified Aug. 26, 2004) (on file with the Washington and Lee Law Review).

### III. Tort Liability for Negligent Undertakings

#### A. Restatement (Second) of Torts Section 324A

A fundamental principle of tort law is that a person has no general duty to take affirmative action to protect others from harm.<sup>83</sup> Among the exceptions to this "no-duty-to-act" rule is the Good Samaritan doctrine, which traces its roots back to the seminal 1703 English case, *Coggs v. Bernard*.<sup>84</sup> Common law courts apply the Good Samaritan doctrine to impose liability upon a party that voluntarily performs an undertaking causing injury to another through the volunteer's failure to exercise reasonable care.<sup>85</sup> As Justice Benjamin Cardozo notably emphasized while still a New York jurist, "[i]t is ancient learning that one who assumes to act, even though gratuitously, may thereby become subject to the duty of acting carefully, if he acts at all."<sup>86</sup>

Aspects of the Good Samaritan doctrine are captured in various provisions of the Restatement (Second) of Torts.<sup>87</sup> The Restatement recognizes the

83. See DAN B. DOBBS, *THE LAW OF TORTS* § 314, at 853 (2000) (asserting the general rule that unless a party has assumed a duty or has a special relationship with another, there is no tort liability for a failure to act in a way that would benefit another, even if the party foresees harm).

84. *Coggs v. Bernard*, 92 Eng. Rep. 107 (K.B. 1703); see also Annette T. Crawley, Note, *Environmental Auditing and the "Good Samaritan" Doctrine: Implications for Parent Corporations*, 28 GA. L. REV. 223, 234 (1993) (discussing *Coggs*). In *Coggs*, the defendant voluntarily attempted to move casks of brandy owned by the plaintiff. 92 Eng. Rep. at 107. During this activity, "one of the casks was staved, and a great quantity of brandy . . . was spilt." *Id.* The court held that, although the defendant originally was under no duty to move the casks, upon voluntarily undertaking to do so, the defendant was liable to the extent the undertaking was negligently performed. *Id.*

85. See Lisa L. Dahm, *Restatement (Second) of Torts Section 324A: An Innovative Theory of Recovery for Patients Injured Through Use or Misuse of Health Care Information Systems*, 14 J. MARSHALL J. COMPUTER & INFO. L. 73, 95 (1995) (noting that at common law, the Good Samaritan doctrine imposed liability for a voluntary act that lacked reasonable care, even where the act involved performing the duty owed by another person to a third party); Matthew P. Bonham, Note, *Bujol v. Entergy and The Good Samaritan Doctrine: Workers' Compensation and Safety Regulations, Who Needs Them?*, 63 LA. L. REV. 441, 442 (2003) (asserting that the Good Samaritan doctrine traditionally has been used to find liability where reasonable care was not exercised when performing a duty owed to a third party); see also DOBBS, *supra* note 83, § 319, at 860–61 ("The general rule that undertakings can create a duty of care is often expressed by saying one who voluntarily assumes a duty must then perform that duty with reasonable care.").

86. *Glanzer v. Shepard*, 135 N.E. 275, 276 (N.Y. 1922); see also *Indian Towing Co. v. United States*, 350 U.S. 61, 64–65 (1955) (stating that "it is hornbook tort law" that a "good Samaritan" must perform an undertaking in a "careful manner").

87. See Crawley, *supra* note 84, at 232 n.49 (observing that courts generally draw an analogy between the Good Samaritan doctrine and the relevant sections of the Restatement (Second) of Torts). The successive Restatements of Torts are developed by the American Law Institute, which is comprised of judges, practicing lawyers, and law professors. MARSHALL S.

general principle that voluntary undertakings "can create a duty to act affirmatively and with reasonable care."<sup>88</sup> Section 323 applies to undertakings to provide services to another that an actor "should recognize as necessary for the protection of the other's person or things."<sup>89</sup> Section 324A also applies to undertakings to render services to another but specifically focuses on the actor's liability to third persons arising from the negligent performance of that undertaking.<sup>90</sup> Section 324A provides:

One who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of a third person or his things, is subject to liability to the third person for physical harm resulting from his failure to exercise reasonable care to [perform]<sup>91</sup> his undertaking, if

- (a) his failure to exercise reasonable care increases the risk of such harm, or
- (b) he has undertaken to perform a duty owed by the other to the third person, or
- (c) the harm is suffered because of reliance of the other or the third person upon the undertaking.<sup>92</sup>

In general, Section 324A's standard of liability for voluntary undertakings "subsumes the well-known elements of any negligence action, viz., duty, breach

SHAPO, PRINCIPLES OF TORT LAW ¶ 1.02D, at 5–6 (2d ed. 2003). The Restatements are an attempt to reduce the common law tort principles to "blackletter" rules. *Id.* ¶ 1.02D, at 5. The Restatements are not binding on the courts but are persuasive authority intended to provide courts with guidance in dealing with challenging problems. *Id.* at 6.

88. DOBBS, *supra* note 83, § 319, at 861.

89. RESTATEMENT (SECOND) OF TORTS § 323 cmt. a (1965).

90. *Id.* § 324A cmt. a.

91. The published version of Section 324A used the word "protect" rather than the word "perform." However, the reporter for the Restatement acknowledged that this is a typographical error and that the correct word is "perform." See *Hill v. U.S. Fid. & Guar. Co.*, 428 F.2d 112, 115 n.5 (5th Cir. 1970) (referencing letter from reporter for the Restatement (Second) of Torts advising court of typographical error).

92. RESTATEMENT (SECOND) OF TORTS § 324A (1965). The commentary to Section 324A emphasizes:

[T]his Section applies to any undertaking to render services to another, where the actor's negligent conduct in the manner of performance of his undertaking, or his failure to exercise reasonable care to complete it, or to protect the third person when he discontinues it, results in physical harm to the third person or his things. It applies both to undertakings for consideration, and to those which are gratuitous.

*Id.* § 324A cmt. b.

of duty, proximate cause, and damages."<sup>93</sup> Specifically, a third-party plaintiff asserting a prima facie cause of action under Section 324A must produce sufficient evidence to establish five necessary elements. First, the plaintiff must demonstrate the existence of a specific undertaking "to render services to another."<sup>94</sup> Second, the injured third party must have been reasonably foreseeable to the actor. That is, the plaintiff must establish the actor had reason to foresee that the undertaking was necessary for the protection of third parties.<sup>95</sup> In this regard, the actor does not have to foresee the need for protection of a specific individual; rather, it suffices that the plaintiff falls within a "class of foreseeable third parties."<sup>96</sup> Together, these two elements establish that the actor is under a legal duty to exercise due care in the undertaking.

The third element the plaintiff must prove under Section 324A is that this legal duty was breached by the actor's negligent conduct—that is, by the actor's failure to "exercise reasonable care in the performance of the undertaking."<sup>97</sup> Fourth, the plaintiff must establish that the actor's failure to exercise reasonable care was the cause-in-fact of the plaintiff's physical injuries.<sup>98</sup> And, fifth, the actor's negligent conduct must be demonstrated to be the proximate or legal cause of the plaintiff's injuries through proof that at least one of three conditions is met: *either*, that (a) the actor's negligent conduct "increased the risk of such harm," *or* (b) the actor undertook to perform a duty owed by another to third persons such as the plaintiff, *or* (c) "the harm was suffered because either the other or the third persons relied on the [actor's] undertaking."<sup>99</sup>

93. *Paz v. State*, 994 P.2d 975, 980 (Cal. 2000) (citing *Artiglio v. Corning Inc.*, 957 P.2d 1313 (Cal. 1998)).

94. *Id.*

95. *Id.*

96. *Dahm*, *supra* note 85, at 102.

97. *Paz*, 994 P.2d at 980 (citing *Artiglio v. Corning Inc.*, 957 P.2d 1313 (Cal. 1998)).

98. *Id.* The requirement of "physical harm" in Section 324A means that the plaintiff must demonstrate an injury to his person or property. Purely intangible economic loss is excluded as an element of damages. See *DOBBS*, *supra* note 83, § 319, at 861 n.5 (discussing identical "physical harm" language in Section 323).

99. *Paz*, 994 P.2d at 980; see Ralph G. Wellington & Vance G. Camisa, *The Trade Association and Product Safety Standards: Of Good Samaritans and Liability*, 35 WAYNE L. REV. 37, 45–59 (1988) (discussing the three circumstances under which proximate cause can be found under Section 324A). The term "proximate cause" is an often excoriated term generally intended to separate the tort concept of legal causation—or legal limitations on the ultimate scope of negligence liability—from that of factual causation. See generally Jim Gash, *At the Intersection of Proximate Cause and Terrorism: A Contextual Analysis of the (Proposed) Restatement Third of Torts' Approach to Intervening and Superseding Causes*, 91 KY. L.J. 523,

### B. Dow Chemical Co. v. Mahlum

Courts have applied the Good Samaritan doctrine to a wide variety of voluntary undertakings. Commentators note that the doctrine's principles have been applied "to a landlord making voluntary repairs on leased premises, to air traffic controllers supplying information to pilots, to a private hospital maintaining an emergency ward, and to the United States government maintaining a lighthouse."<sup>100</sup> The doctrine has been further applied to cases involving an insurance company's voluntary inspection of an insured's premises, workplace safety inspections or programs imposed by parent corporations upon subsidiaries, a school athletics association's decision to make safety recommendations to its members, and trade associations undertaking to promulgate safety standards for its members.<sup>101</sup> Of specific importance to this Article, the Good Samaritan doctrine also has been applied in a number of instances to voluntary undertakings to conduct scientific testing of chemical substances.<sup>102</sup>

Of the chemical testing cases, the most expansive in terms of potential liability is the Nevada Supreme Court's 1998 decision in *Dow Chemical Co. v. Mahlum*.<sup>103</sup> In 1985, the plaintiff in *Mahlum* received silicone gel breast implants manufactured by Dow Corning Corporation ("Dow Corning").<sup>104</sup> Five years later she experienced deteriorating health and, in 1993, required surgery to remove a ruptured implant.<sup>105</sup> The surgeon was not able to extract all of the silicon gel, and a portion of it became permanently embedded in the plaintiff's

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528–30 (2002–2003). For an explanation of the fact that although some courts and scholars confusingly use "proximate cause" as an umbrella term covering the elements of both factual and legal causation, many others utilize the term (as does this Article) as a distinct concept incorporating only the latter aspect and as excluding cause-in-fact, see JOSEPH A. PAGE, TORTS: PROXIMATE CAUSE 5 (2003).

100. Crawley, *supra* note 84, at 234–35 (footnotes omitted).

101. See generally *id.*; Kathryn Michele Glegg, Note, *Negligent Inspection: Texas Expressly Adopts the Restatement (Second) of Torts Section 324A in Seay v. Travelers Indemnity Co.*, 41 Sw. L.J. 1041, 1041–42 (1987); Kimberly J. Todd, Note, *Snyder v. American Association of Blood Banks: Expansion of Trade Association Liability—Does It Reach Medical Societies?*, 29 U. Tol. L. Rev. 149, 164–65 (1997); Wellington & Camisa, *supra* note 99, at 38–39.

102. See, e.g., Wellington & Camisa, *supra* note 99, at 39–40 (discussing *Martinez v. Perlite Inst.*, 120 Cal. Rptr. 120 (Cal. Ct. App. 1975)).

103. *Dow Chem. Co. v. Mahlum*, 970 P.2d 98 (Nev. 1998), *overruled in part by* *GES, Inc. v. Corbitt*, 21 P.3d 11, 15 (Nev. 2001) ("To the extent that our holding in *Mahlum* suggests that concert of action requires no more than an agreement along with tortious conduct, it is disfavored.").

104. *Id.* at 106.

105. *Id.*

muscle, tissue, and blood vessels.<sup>106</sup> In September 1993, the plaintiff and her husband filed suit in Nevada state court raising numerous claims against both Dow Corning and its parent corporation, Dow Chemical Company (Dow Chemical), claiming that the rupture of the implant caused the plaintiff to develop "an atypical autoimmune disease."<sup>107</sup> In May 1995, Dow Corning filed for Chapter 11 protection in federal bankruptcy court, leaving the plaintiffs to proceed to trial solely against Dow Chemical.<sup>108</sup>

Although Dow Corning, not Dow Chemical, manufactured and distributed silicone products and materials, the plaintiffs alleged that Dow Chemical was nonetheless directly liable for injuries relating to its subsidiary's products.<sup>109</sup> Specifically, the plaintiffs alleged that Dow Chemical was directly liable in tort:

[F]or fraudulently concealing information about the dangers of silicone, conspiring with Dow Corning to effectuate such fraudulent concealment, aiding and abetting Dow Corning's fraudulent misrepresentations about silicone safety, acting in concert with Dow Corning to effectuate such fraudulent misrepresentation, and negligently performing an undertaking—testing the toxicity of liquid silicone—for Dow Corning.<sup>110</sup>

At trial, the jury ruled in favor of the plaintiffs on all of these claims except for the conspiracy allegation.<sup>111</sup> The trial court entered judgment against Dow Chemical for more than \$4.1 million in compensatory damages and \$10 million in punitive damages.<sup>112</sup> Dow Chemical subsequently appealed to the Nevada Supreme Court.<sup>113</sup>

106. *Id.*

107. *Id.* Dow Corning was formed in 1943 by Dow Chemical and Corning Incorporated for "the express purpose of developing commercial and industrial uses for silicone technology." *Id.* at 103. Dow Chemical and Corning Incorporated each own 50% of Dow Corning. *Id.* The plaintiff raised claims against a number of defendants other than Dow Corning and Dow Chemical, but all such claims were eventually dismissed. *Id.* at 106.

108. *Id.*; see Evan Caplan, Note, 'Milking the Dow': *Compensating the Victims of Silicone Gel Breast Implants at the Expense of the Parent Corporation*, 29 RUTGERS L.J. 121, 126 (1997) (noting Dow Corning's Chapter 11 filings in federal court in 1995). Dow Corning's bankruptcy filing was precipitated by thousands of pending personal injury cases related to silicone gel breast implants. Caplan, *supra*, at 125–26. Because of the automatic stay of claims against the debtor accompanying any bankruptcy petition, the plaintiffs were forced to proceed solely against Dow Chemical. *Id.* at 126–27. See generally 11 U.S.C. § 362(a)(1) (2000).

109. *Dow Chem. Co. v. Mahlum*, 970 P.2d 98, 106 (Nev. 1998), *overruled in part by* *GES, Inc. v. Corbitt*, 21 P.3d 11 (Nev. 2001).

110. *Id.*

111. *Id.*

112. *Id.*

113. *Id.* at 106–07.

On appeal, the Nevada Supreme Court held that insufficient evidence existed to support the plaintiffs' intentional tort claims.<sup>114</sup> Accordingly, the *Mahlum* court reversed the judgment as to the claims based on allegations of fraudulent conduct and vacated the corresponding punitive damages award.<sup>115</sup> However, the court nonetheless affirmed the \$4.1 million compensatory damages award, finding that substantial evidence supported the verdict against Dow Chemical on the claim of negligent performance of an undertaking.<sup>116</sup>

The Nevada Supreme Court relied on Section 324A of the Restatement (Second) of Torts to analyze the plaintiffs' negligent undertaking claim.<sup>117</sup> Dow Chemical initially argued that the plaintiffs failed to demonstrate that the company had undertaken "a duty with respect to the specific product"—silicone gel breast implants—that caused the harm in question.<sup>118</sup> The court, however, emphasized that Dow Chemical's reading of Section 324A was "too narrow a view of negligent undertaking analysis."<sup>119</sup> Rather, the court observed that "[t]he proper focus of the inquiry [under Section 324A] is whether Dow Chemical undertook to perform services to Dow Corning that Dow Chemical should have recognized were necessary for the protection of third persons."<sup>120</sup> Thus, liability for negligent undertaking does not have to relate to a "specific final product" but "can arise when it is reasonably foreseeable that another will be harmed by the failure to exercise reasonable care in performing . . . an undertaking."<sup>121</sup>

Dow Chemical further argued that the trial court erred in submitting to the jury the question of whether the company owed a duty to the plaintiffs.<sup>122</sup> Dow Chemical argued that such a question was a legal issue that must be resolved by the court rather than the jury.<sup>123</sup> The Nevada Supreme Court rejected this argument based on case law construing Section 324A.<sup>124</sup> Indeed, it is hornbook

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114. *See id.* at 109–13 (finding a lack of evidence to uphold the liability for fraudulent concealment, concerted action to commit fraudulent misrepresentation, and aiding and abetting fraudulent misrepresentation).

115. *Id.* at 113.

116. *Id.* at 113, 124.

117. *Id.* at 113–21.

118. *Id.* at 114.

119. *Id.* (quoting *In re Silicone Gel Prods. Liab. Litig.*, 887 F. Supp. 1455, 1460 (N.D. Ala. 1995)).

120. *Id.*

121. *Id.*

122. *Id.*

123. *Id.*

124. *See id.* at 114–15 (citing several cases, including *Pratt v. Liberty Mutual Ins. Co.*, 952 F.2d 667, 671 (2d Cir. 1992), *Artiglio v. Corning, Inc.*, 957 P.2d 1313, 1318 (Cal.

tort law that whether a defendant in a negligence action owes a plaintiff a duty of care is usually a legal issue for judicial determination.<sup>125</sup> The *Mahlum* court emphasized, however, that in cases under Section 324A, the existence and scope of a duty owed is dependent upon the nature and extent of the defendant's undertaking.<sup>126</sup> The nature and extent of the act undertaken by the defendant is in turn a question of fact, which must be determined by the jury.<sup>127</sup> Thus, the Nevada Supreme Court held that "the jury was required to consider the nature and scope of Dow Chemical's undertaking so that its concomitant duty, if any, could be determined."<sup>128</sup>

The *Mahlum* court ruled that the plaintiffs had introduced substantial evidence from which the jury could determine that Dow Chemical had undertaken to perform services that it should have recognized as necessary for the protection of third persons.<sup>129</sup> Specifically, the evidence reflected that Dow Chemical had undertaken to render services to Dow Corning to test the safety of the liquid silicone eventually used in the Corning breast implants.<sup>130</sup> From 1943 until 1968, Dow Corning lacked its own toxicology laboratory and staff to perform toxicological testing.<sup>131</sup> "From the 1940s until the 1970s, 'every organosilicon compound' made by Dow Corning was sent to Dow Chemical for toxicological testing."<sup>132</sup> Because Dow Corning relied so extensively on Dow Chemical's toxicological facilities and expertise, and based on factors demonstrating the strong relationship between the two companies, the court found that the jury had more than sufficient evidence from which to determine the full nature and extent of Dow Chemical's undertaking.<sup>133</sup>

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1998), and *Smith v. State*, 921 P.2d 632, 634 (Alaska 1996), for support).

125. See generally DOBBS, *supra* note 83, § 226, at 577-78 (discussing the role of judges with regard to the issue of duty).

126. See *Dow Chem. Co. v. Mahlum*, 970 P.2d 98, 114 (Nev. 1998) (referencing *Pratt v. Liberty Mutual Ins. Co.*, 952 F.2d 667, 671 (2d Cir. 1992), *Artiglio v. Corning, Inc.*, 957 P.2d 1313, 1318 (Cal. 1998), and *Smith v. State*, 921 P.2d 632, 634 (Alaska 1996), for support), *overruled in part by* *GES, Inc. v. Corbitt*, 21 P.3d 11 (Nev. 2001).

127. *Id.*

128. *Id.* at 115 (citing *Smith*, 921 P.2d at 635)

129. *Id.*

130. *Id.* at 103.

131. *Id.* at 105.

132. *Id.* at 104.

133. *Id.* at 114-15. Specifically, the court summarized the evidence relating to the nature and extent of Dow Chemical's undertaking as follows:

- (1) Dow Chemical's creation of and fifty percent ownership of Dow Corning,
- (2) Dow Chemical's control of one-third of Dow Corning's board of directors,
- (3) Dow Chemical's undisputed expertise in toxicology, (4) Dow Corning's lack of a toxicology laboratory until 1968 and reliance on Dow Chemical's toxicological



The court also found that the evidence was sufficient for the jury to reasonably "infer that Dow Chemical should have known that the services it rendered," including "its toxicological testing of Dow Corning's liquid silicone, were a necessary step in the protection of third persons who would purchase liquid silicone in the form of breast implants."<sup>134</sup> This included evidence that:

Dow Chemical knew prior to the 1970s that other silicone materials developed for medical purposes were being used as implants, knew that liquid silicone was being developed for medicinal uses, and knew at the time of [certain toxicological] tests that Dow Corning was using liquid silicone in its breast implants. . . .<sup>135</sup>

The court emphasized that it was not necessary for Dow Chemical to foresee that this chemical substance would be specifically used in *breast* implants.<sup>136</sup> Instead, it was enough that Dow Chemical could reasonably foresee that "its testing was being relied upon to develop products that would be implanted in humans" in some form or fashion.<sup>137</sup> Dow Chemical "acted with awareness of the general class of persons" to which the plaintiff, as an eventual recipient of silicone breast implants, belonged.<sup>138</sup> Thus, the Nevada Supreme Court found that Dow Chemical was under a legal duty to such foreseeable third parties to exercise reasonable care in undertaking to perform chemical safety testing for Dow Corning.<sup>139</sup>

The Nevada Supreme Court next looked to Section 324A's commentary for guidance as to the scope of Dow Corning's duty of care. The Court said:

[The commentary] explains that the section "applies to any undertaking to render services to another, where the actor's negligent conduct in the manner of

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expertise, (5) the housing of Dow Chemical's and Dow Corning's toxicology laboratories in a Dow Chemical building from 1968 until 1971, (6) the myriad tests performed by Dow Chemical on silicone compounds and the specific tests relating to silicone fluids, (7) the continuing assistance rendered to Dow Corning by Dow Chemical personnel, and (8) Dow Chemical's 1966 joint development agreement, 1969 information development agreement, and 1975 trademark agreement with Dow Corning.

*Id.* at 114 (footnote omitted).

134. *Id.* at 116.

135. *Id.*

136. *Id.*

137. *Id.* (quoting *In re Silicone Gel Prods. Liab. Litig.*, 887 F. Supp. 1455, 1461 (N.D. Ala. 1995)).

138. *Id.* (quoting *Artiglio v. Corning, Inc.*, 957 P.2d 1313, 1323 (Cal. 1998) (Mosk, J., dissenting)).

139. *Id.* at 116-17.

performance of his undertaking, or his failure to exercise reasonable care to complete it, or to protect the third person when he discontinues it, results in physical harm to the third person."<sup>140</sup>

Based on this language, the court emphasized that "once Dow Chemical undertook to test and advise Dow Corning on the safety of liquid silicone, it was obligated to fully complete this course of conduct."<sup>141</sup> Moreover, if the undertaking were discontinued at some point, Dow Chemical "was required to [act if necessary to] protect Dow Corning's consumers."<sup>142</sup> In light of the evidence presented at trial, the *Mahlum* court held that the jury could reasonably infer that Dow Chemical breached its duty to foreseeable third persons in both of these respects.<sup>143</sup>

First, the *Mahlum* court ruled that evidence adduced at trial rendered the jury free to conclude that Dow Chemical's undertaking—toxicity testing of liquid silicone—had been negligently performed.<sup>144</sup> In this regard, the court indicated that the jury was entitled to credit the testimony of the plaintiffs' expert witness who asserted that Dow Chemical had responded inadequately to initial silicone testing suggesting danger rather than safety.<sup>145</sup> Specifically, the plaintiffs' expert testified that Dow Chemical should have designed and conducted follow up testing sufficient to confirm or reject such initial results or at least should have advised Dow Corning of the need for such studies.<sup>146</sup> Instead, what little follow-up testing Dow Chemical did perform was inadequate, inasmuch as results were misreported and findings were again suggestive of problems rather than safety.<sup>147</sup> Having undertaken to test the safety of Dow Corning's liquid silicone, reasonable care required Dow Chemical "to fully complete this testing until a reliable safety determination was made."<sup>148</sup>

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140. *Id.* at 117–18 (quoting RESTATEMENT (SECOND) OF TORTS § 324A cmt. b (1965)).

141. *Id.* at 118.

142. *Id.*

143. *Id.*

144. *Id.*

145. *See id.* (referring to and quoting from the testimony of the plaintiffs' expert witness).

146. *Id.*

147. *Id.* The court quoted the plaintiffs' expert's testimony:

My opinion is a very clear and forceful one that whatever long term testing they did do was inadequate. The results were misreported. The findings were suggestive of problems rather than safety. And in the aggregate, there was absolutely no basis for assuming long term safety based on the animal testing.

*Id.*

148. *Id.*

Second, the *Mahlum* court ruled that Dow Chemical was additionally negligent "by failing to intervene in the marketing of Dow Corning's breast implants."<sup>149</sup> Specifically, the court held that the evidence supported a finding that Dow Chemical could have, and thus "should have used its influence to halt the marketing of Dow Corning's silicone breast implants until the long-term effect of silicone breast implants on humans was understood and these products were determined to be safe."<sup>150</sup> By failing to completely test the liquid silicone for safety and subsequently compounding that omission by failing to take some action to protect foreseeable third parties thereby placed at risk, the court held that a reasonable jury could conclude that Dow Chemical had negligently performed its undertaking to test liquid silicone.<sup>151</sup>

As further required under Section 324A, the Nevada Supreme Court found that the evidence also supported the jury's conclusion that Dow Chemical's negligence was a cause-in-fact of the plaintiff's physical harm.<sup>152</sup> That is, had Dow Chemical taken action to prevent Dow Corning from marketing its breast implants or had Dow Chemical exercised reasonable care in testing the liquid silicone for safety, the plaintiff would not have suffered injuries from the implants.<sup>153</sup> Significantly, the *Mahlum* court noted that the appreciable length

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149. *Id.*

150. *Id.* The court emphasized that the evidence suggested Dow Chemical had "a significant level of control over Dow Corning and its products. Dow Chemical certainly had the authority to influence Dow Corning and to assert direct pressure on Dow Corning through [their] trademark agreement. Dow Chemical, however, did nothing." *Id.* at 120.

151. *Id.* at 119.

152. *Id.*

153. *Id.* at 119–20. In this regard, the *Mahlum* court's analysis is a straightforward application of the "but-for test" of the cause-in-fact element of the negligence action. That is, "but-for" the negligent conduct of Dow Chemical, the plaintiff would have avoided her injuries. See DOBBS, *supra* note 83, § 168, at 409 (describing the but-for test under which the defendant's conduct must be necessary to cause the plaintiff's injury and, without which, the injury would have been avoided). However, in an earlier portion of its opinion, the *Mahlum* court also ruled that substantial evidence supported the jury's conclusion that the defective breast implants manufactured by Dow Corning were the cause of the plaintiff's physical injuries. Dow Chem. Co. v. Mahlum, 970 P.2d 98, 107–08 (Nev. 1998), *overruled in part by* GES, Inc. v. Corbitt, 21 P.3d 11 (Nev. 2001). This finding was a necessary condition precedent to any finding that Dow Chemical's negligent undertaking—failure to exercise reasonable care in conducting toxicity testing of Dow Corning's chemical substances—was also a cause-in-fact of the plaintiff's physical injuries. *Id.* With respect to this "scientifically controversial component of the plaintiff's case"—whether her injuries were caused by exposure to silicone—the court emphasized as follows:

The Mahlums . . . did not need to wait until the scientific community developed a consensus that breast implants caused her diseases. If she had, it might have been too late to recover, in light of the doctrine of laches and statutes of limitation and repose. The Mahlums' . . . complaint was not tried in the court of scientific

of time between the plaintiff's injuries in the 1990s and the decade's earlier period when Dow Chemical was performing safety testing for Dow Corning did not absolve Dow Chemical of liability.<sup>154</sup> The court emphasized that "[t]he consequences of a negligent defendant's act under Section 324A may come to fruition many years after its undertaking has ended, and still the courts have found that liability may exist."<sup>155</sup>

Finally, the *Mahlum* court found that the plaintiffs presented sufficient evidence to satisfy the proximate cause aspect of Section 324A.<sup>156</sup> As noted above, Section 324A requires the plaintiff to demonstrate that at least one of three conditions is present: (a) that the defendant's negligence increased the risk of harm to the plaintiff, (b) that the defendant undertook a duty owed by another to the plaintiff, or (c) that the harm was suffered because either the other owing the duty or the plaintiff relied on the defendant's undertaking.<sup>157</sup> Based on the evidence presented, the court concluded that the jury could reasonably conclude that conditions under both subsections (b) and (c) of Section 324A were satisfied.<sup>158</sup> Specifically, the court held that "the jury could conclude that Dow Chemical undertook at least part of the duty, owed to the Mahlums by Dow Corning, to reasonably ensure the safety of breast implants."<sup>159</sup> Further, the court also found evidentiary support for the conclusion that Dow Corning relied on Dow Chemical's chemical testing and toxicology expertise in developing the implants that injured the plaintiffs.<sup>160</sup>

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opinion, but before a jury of her peers who considered the evidence and concluded that Dow Corning silicone gel breast implants caused her injuries. The jury in this case was properly instructed to consider the proof by a preponderance of the evidence. There is no evidence that the jury did otherwise. Science may properly require a higher standard of proof before declaring the truth, but that standard did not guide the jury, nor do we use that standard to evaluate the judgment on appeal.

*Id.* at 109.

154. *Id.* at 119 n.15.

155. *Id.* (citing *Deines v. Vermeer Mfg. Co.*, 752 F. Supp. 989 (D. Kan. 1990), *aff'd*, 969 F.2d 977 (10th Cir. 1992)). Similarly, in *Kohr v. Johns-Manville Corp.*, 534 F. Supp. 256, 260 (E.D. Pa. 1982), the court found that the fifty years that elapsed between the defendant's allegedly negligently performed studies of asbestos exposures at the plant at which the plaintiff was employed and the filing of the plaintiff's complaint alleging negligent undertaking liability under Section 324A did not "break the causal chain" between the defendant's negligent conduct and the plaintiff's claim of disease with an incubation period of many years.

156. *Mahlum*, 970 P.2d at 121.

157. See *supra* note 99 and accompanying text (discussing issues of causation).

158. *Mahlum*, 970 P.2d at 121.

159. *Id.*

160. See *id.* (noting that Dow Corning lacked a toxicology department for the first six years in which the company marketed its breast implants).

Thus finding all required elements for negligent undertaking liability under Section 324A satisfied, the *Mahlum* court affirmed the jury's verdict against Dow Chemical as to that claim.<sup>161</sup>

The *Mahlum* court's analysis of Dow Chemical's liability under Section 324A is by no means the subject of universal consensus. Indeed, a dissenting opinion filed in *Mahlum* cites decisions from other jurisdictions in favor of Dow Chemical as to essentially identical negligent undertaking claims involving Dow Corning.<sup>162</sup> For example, approximately six months prior to *Mahlum*, the California Supreme Court rejected a Section 324A-based negligent undertaking claim against Dow Chemical in *Artiglio v. Corning Inc.*<sup>163</sup> The *Artiglio* court held that plaintiffs allegedly injured by defective silicone breast implants manufactured by Dow Corning had failed to establish the duty element of the Section 324A cause of action.<sup>164</sup> Specifically, the court concluded that Dow Chemical's silicone toxicology research on behalf of Dow Corning was not "an undertaking of such breadth and magnitude as to create a duty on the part of Dow Chemical to ensure the safety of all of Dow Corning's silicone products."<sup>165</sup> In contrast with the Nevada Supreme Court's diametrically opposing view,<sup>166</sup> the *Artiglio* court emphasized that the many years elapsing between such research activity and the alleged injuries belied any claim that Dow Chemical should have reasonably foreseen that such services were "necessary for the protection of [the] plaintiffs."<sup>167</sup> Accordingly, the court held that no duty of care under Section 324A running to recipients of Dow Corning silicone breast implants arose from Dow Chemical's toxicology research.<sup>168</sup>

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161. *Id.*

162. *See id.* at 132 (Maupin, J., dissenting) (discussing cases).

163. *Artiglio v. Corning Inc.*, 957 P.2d 1313 (Cal. 1998).

164. *Id.* at 1320–21.

165. *Id.* at 1320 (quoting *In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig.*, 113 F.3d 1484, 1495 (8th Cir. 1997)).

166. *See supra* notes 154–55 and accompanying text (discussing the *Mahlum* majority's treatment of the long period that elapsed between the laboratory tests and the plaintiff's injury).

167. *Artiglio*, 957 P.2d at 1320.

168. *Id.* Similar to *Mahlum*, the California Supreme Court's *Artiglio* majority opinion was accompanied by a vigorous dissenting opinion. *See id.* at 1321 (Mosk, J., dissenting) (invoking Cal. Civ. Code Section 1714(a) for the principle that duty extends to "everyone" for injuries resulting from a failure to exercise ordinary care and employing a broader reading of Restatement (Second) of Torts Section 324A to find that a triable issue of fact existed). In fact, the *Mahlum* majority quoted from Justice Mosk's *Artiglio* dissent in support of their ruling. *See Dow Chem. Co. v. Mahlum*, 970 P.2d 98, 116 (Nev. 1998) (quoting Mosk's dissent), *overruled in part by* *GES, Inc. v. Corbitt*, 21 P.3d 11 (Nev. 2001).

Similarly, in a 1997 opinion relied on by both the *Mahlum* dissent<sup>169</sup> and the *Artiglio* majority, the Eighth Circuit rejected Section 324A negligent undertaking claims against Dow Chemical involving silicone temporomandibular joint (TMJ) prosthetic implant devices manufactured by Dow Corning.<sup>170</sup> In accepting an argument rejected by the *Mahlum* court,<sup>171</sup> the Eighth Circuit emphasized that under Section 324A the plaintiffs must demonstrate that Dow Chemical undertook a duty with respect to the specific product—in this case, silicone TMJ implants—that caused the harm at issue.<sup>172</sup> Based on this narrowed view of Section 324A liability, the court asserted that the plaintiffs' contention that "Dow Chemical undertook a duty with respect to all of Dow Corning's silicone products" was insufficient.<sup>173</sup> Instead, for "liability to attach, Dow Chemical must have specifically undertaken the task of ensuring the safety of Dow Corning's TMJ implants or of ensuring the safety of Dow Corning's entire array of silicone products."<sup>174</sup> Because in its view the evidence did not support such findings, the court held that Dow Chemical's toxicological testing of silicone for Dow Corning could not form the basis of a Section 324A undertaking to protect the eventual recipients of the silicone products in question.<sup>175</sup>

Importantly, however, decisions from other courts are also supportive of the *Mahlum* majority's negligent undertaking analysis. The most significant of these decisions came from the U.S. District Court for the Northern District of

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169. The *Mahlum* dissent also relied upon the New York trial court case of *In re New York State Silicone Breast Implant Litigation*, 632 N.Y.S.2d 953 (N.Y. Sup. Ct. 1995). See *Mahlum*, 970 P.2d at 133–34 (Maupin, J., dissenting) (discussing *In re New York State*). *In re New York State* dismissed claims of negligent undertaking against Dow Chemical brought by recipients of Dow Corning manufactured silicone breast implants. 632 N.Y.S.2d at 954. However, the New York Supreme Court for New York County did not analyze the claims under the specific elements of Section 324A of the Restatement, rendering the decision of somewhat limited value as precedent outside of claims specifically raised under New York law.

170. See *In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig.*, 113 F.3d 1484, 1494–95 (8th Cir. 1997) (holding that Dow Chemical's trademark agreements with, and silicone research performed for, Dow Corning were insufficient as a matter of law to create a duty to "ensure the safety of Dow Corning's silicone products").

171. See *supra* notes 118–21 and accompanying text (discussing the analysis by the *Mahlum* majority on Section 324A liability).

172. See *In re TMJ Implants*, 113 F.3d at 1494 (emphasizing that the standard for imposing Section 324A liability requires the defendant to "specifically undertake[]" the duty to ensure safety).

173. *Id.*

174. *Id.*

175. See *id.* at 1494–95 (finding that Dow Chemical's trademark agreement with Dow Corning allowing inspections and its silicone tests outside the medical arena were insufficient to meet the duty threshold).

Alabama in *In re Silicone Gel Breast Implants Products Liability Litigation*.<sup>176</sup> This case involved a federal multidistrict proceeding involving breast implant litigation against Dow Chemical and Corning, Inc. from diversity jurisdiction cases then pending "in 90 out of 94 [federal court] districts."<sup>177</sup> As in the cases

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176. *In re Silicone Gel Prods. Liab. Litig.*, 887 F. Supp. 1455 (N.D. Ala. 1995). In addition to *In re Silicone Gel*, other cases involving scientific testing of chemical substances are also supportive of the result reached in *Mahlum*, although their analyses are less in depth than in *Mahlum*. For example, *Arnstein v. Manufacturing Chemists Ass'n*, 414 F. Supp. 12 (E.D. Pa. 1976), involved a wrongful death claim brought against a nonprofit trade association and five chemical companies which employed the decedent. The complaint alleged that the decedent's death was caused by long term exposure to vinyl chloride during the course of his employment with the chemical companies. *Id.* at 13. The trade association, arguing that it owed no duty to the plaintiff and there was no causal connection between its conduct and the decedent's death, moved for dismissal under Federal Rule of Civil Procedure 12(b)(6). *Id.* at 14. The *Arnstein* court denied the motion, finding that the plaintiff stated a cognizable cause of action against the chemical industry trade association under Restatement (Second) of Torts Section 324A. *See id.* at 14–15 (citing Section 324A erroneously as "section 324"). The complaint revealed that the trade association had conducted testing of vinyl chloride on behalf of its members and "had recommended a safe exposure level which was allegedly inadequate." *Klein v. Council of Chem. Ass'ns*, 587 F. Supp. 213, 224–25 (E.D. Pa. 1984) (discussing assertions of the complaint in *Arnstein* that were made part of the record in *Klien*). On the basis of this pleading, the *Arnstein* court held that the plaintiff was not precluded from pursuing a negligent undertaking claim against the trade association for the wrongful death of the third party decedent employee. *Arnstein*, 414 F. Supp. at 15.

Another case supporting *Mahlum* is *Martinez v. Perlite Institute, Inc.*, 120 Cal. Rptr. 120 (Cal. App. 1975). Although the decision deals primarily with a jurisdictional issue, the *Martinez* court recognized the existence of a cognizable third party negligent undertaking cause of action based on a claim of negligent toxicity testing. *See id.* at 125–26 (finding it "not unreasonable" for a jury to conclude that the Perlite Institute may have committed a tort causing injuries in California, either intentionally or with reasonable foreseeability, thus making personal jurisdiction over the Institute valid). In *Martinez*, a trade association was held to have undertaken a duty of care when it agreed to test a member company's perlite ores for dangerous toxic substances. *Id.* at 125. The court found that it was reasonable for the association to believe that its members would rely on such testing. *Id.* The court suggested, therefore, that if this testing undertaking was negligently performed, employees of the association member could possibly suffer an injury that was proximately caused by the negligence of the trade association. *Id.* at 125–26.

Another case arguably supportive of *Mahlum* is *Klein v. Council of Chemical Ass'ns*, 587 F. Supp. 213 (E.D. Pa. 1984). In *Klein*, the court dismissed a Section 324A negligent undertaking claim against a chemical industry trade association brought by a printing industry worker employed by certain manufacturers of printing chemicals. *Id.* at 224–25. However, the dismissal was based upon the plaintiff's failure to identify a specific chemical to which he was exposed and which caused his injury. *Id.* at 224. Nevertheless, the *Klein* court implied, favorably citing the example of *Arnstein* and the plaintiff's identification of vinyl chloride as the injury causing chemical in that case, that a cognizable cause of action under Section 324A would have been stated had a specific chemical been identified by the plaintiff. *See id.* at 224–25 ("The failure to identify the product and consequently the defendant's conduct with regard to it required granting the motion to dismiss.").

177. *In re Silicone Gel Prods. Liab. Litig.*, 887 F. Supp. 1455, 1457 (N.D. Ala. 1995).

discussed above, the plaintiffs alleged that Dow Chemical should be held liable under Section 324A of the Restatement "for negligently testing and researching [Dow Corning] silicones for toxicity, biological activity, and safety."<sup>178</sup> The district court's lengthy analysis of the plaintiffs' Section 324A negligent undertaking claims was cited subsequently in support of the *Mahlum* court's majority opinion.<sup>179</sup>

As in *Mahlum*, Dow Chemical asserted in *In re Silicone Gel* that because its "research and testing was not specifically performed on breast implants," it assumed no duty to eventual Dow Corning breast implant recipients.<sup>180</sup> The district court, emphasizing instead that Dow Chemical's duty "is measured in terms of reasonable foreseeability," rejected this "restrictive" view of Section 324A.<sup>181</sup> Further, according to the court, the fact that the testing activity in question occurred prior to Dow Corning's introduction of breast implants did not prevent Dow Chemical's liability for negligent undertaking.<sup>182</sup> The court emphasized:

Evidence exists upon which a jury could determine that Dow Chemical knew that its research would be and was being used to market additional products for human implantation, that the research would be relied upon by Dow Corning and implant recipients or their physicians, that the research was necessary for the protection of recipients of Dow Corning medical devices, and that harm could result if that research was improperly conducted or reported.<sup>183</sup>

#### *IV. Negligent Undertaking Liability Exposure for HPV Challenge Program Participants*

Is the Nevada Supreme Court's *Mahlum* decision a portent of future negligent undertaking liability for HPV Challenge Program volunteers? A definitive answer to this question necessarily would require an injured party and causal connection to specific allegations of negligent conduct on the part of a specific actor. Said another way, unless and until such a claim is alleged and

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178. *Id.* at 1460.

179. *Dow Chem. Co. v. Mahlum*, 970 P.2d 98, 114 (Nev. 1998), *overruled in part by* *GES, Inc. v. Corbitt*, 21 P.3d 11 (Nev. 2001).

180. *In re Silicone Gel*, 887 F. Supp. at 1460.

181. *Id.* at 1460-61.

182. *See id.* at 1460 (emphasizing Dow Chemical's awareness of the issue no later than 1973 due to transfers of key personnel and the close business arrangement).

183. *Id.* at 1461.



litigated to judicial resolution, we cannot know for certain. However, whether participants in the HPV Challenge Program potentially are exposed to such liability is a question that can be explored in the present. The following analysis asserts that the undertaking assumed by program participants subjects each of them to an appreciable risk of future liability under the principles of Section 324A of the Restatement (Second) of Torts.

### A. Threshold Undertaking

As discussed above, the threshold element of Good Samaritan liability under Section 324A is a specific undertaking to perform a certain task.<sup>184</sup> Without an actual assumption of a specific undertaking "there can be no correlative duty to perform that undertaking carefully."<sup>185</sup> In this regard, HPV Challenge Program volunteers unequivocally undertake to perform certain specific, well-defined tasks for specific, well-defined purposes. The commitments undertaken by participants to perform specific toxicology testing on specific chemicals are set forth in exhaustive detail in the initial framework agreement,<sup>186</sup> the respective Federal Register notices detailing the requirements of the program,<sup>187</sup> the various test plans identifying and describing the actual chemical testing to be performed,<sup>188</sup> and in other EPA program-related documents.<sup>189</sup> Thus, because the precise nature and extent of the participants' actual undertakings are well documented, the potential existence and scope of the participants' concomitant legal duty under Section 324A can be readily examined.<sup>190</sup>

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184. See *supra* note 94 and accompanying text (discussing the first element of Good Samaritan liability).

185. *Artiglio v. Corning Inc.*, 957 P.2d 1313, 1318 (Cal. 1998) (quoting *Blessing v. United States*, 447 F. Supp. 1160, 1188-89 (E.D. Pa. 1978)).

186. See generally *Framework for Voluntary Testing*, *supra* note 39.

187. See generally *Data Collection and Development on High Production Volume (HPV) Chemicals*, 65 Fed. Reg. 81,686, 81,687 (Dec. 26, 2000); *Testing of Certain High Production Volume Chemicals*, 65 Fed. Reg. 81,658 (Dec. 26, 2000).

188. See *supra* notes 64, 77-78, and accompanying text (discussing the scope of HPV testing).

189. See generally *OFFICE OF POLLUTION PREVENTION & TOXICS*, *supra* note 32; *OFFICE OF POLLUTION PREVENTION & TOXICS*, *supra* note 52.

190. See *In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig.*, 113 F.3d 1484, 1493 (8th Cir. 1997) (holding documented contractual relationships and research performed to be insufficient to establish a duty to breast implant recipients).

The HPV Challenge Program's fundamental purpose is to address the fact that "there is little or no publicly available information regarding the potential hazards associated with most HPV chemicals."<sup>191</sup> As the EPA explains:

This lack of available hazard data compromises EPA's and others' ability to determine whether these HPV chemicals pose potential risks to human health or the environment, as well as the public's right-to-know about the hazards of chemicals that are found in their environment, their homes, their workplaces, and the products that they buy . . . . EPA believes that for most of the HPV chemicals, insufficient data are readily available to reasonably determine or predict the effects on health or the environment from the manufacture (including importation), distribution in commerce, processing, use, or disposal of the chemicals, or any combination of these activities. EPA has concluded that a program to collect and, where needed, develop basic screening level toxicity data is necessary and appropriate to provide information in order to assess the potential hazards/risks that may be posed by exposure to HPV chemicals.<sup>192</sup>

Thus, the HPV Challenge Program seeks to assemble basic data about the potential hazards associated with HPV chemicals to allow the EPA and the public to "evaluate and prioritize [their] potential health and environmental effects."<sup>193</sup>

To achieve these purposes, the primary task of participants in the challenge program is to test various HPV chemicals for toxicity by utilizing internationally recognized testing endpoints: the Organisation for Economic Co-operation and Development's SIDS.<sup>194</sup> As the framework agreement bluntly states, "[w]hen a sponsor signs up to test a chemical or group of chemicals, the sponsor commits to do all of the testing or provide all of the information that would be required under SIDS."<sup>195</sup> The EPA's Federal Register notice describing the HPV Challenge Program reflects that this undertaking is the program's critical aspect. As the EPA emphasizes:

If no data are available for a SIDS testing endpoint, there cannot be sufficient data to characterize the potential hazards/risks associated with [an HPV] chemical . . . . As a result, EPA and others cannot reasonably determine or predict the human health and environmental effects resulting from manufacturing, processing, and use of these chemical substances.<sup>196</sup>

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191. Data Collection, 65 Fed. Reg. at 81,686.

192. *Id.* at 81,687.

193. *Id.* at 81,686.

194. *Id.* at 81,687.

195. *Framework for Voluntary Testing*, *supra* note 39.

196. Data Collection and Development on High Production Volume (HPV) Chemicals, 65

### B. Standard of Care for Program Participants

Whether such an undertaking gives rise to a legally actionable duty of care depends, in the language of Section 324A, upon whether the actor "should recognize" such services "as necessary for the protection" of third parties.<sup>197</sup> Or, as emphasized in *Mahlum*, a duty is imposed when "it is reasonably foreseeable that another will be harmed by the failure to exercise reasonable care in performing" the undertaking.<sup>198</sup> By its very nature, the principal purpose of the undertaking—toxicology research, which is the subject of the HPV Challenge Program—is the protection of third parties. The EPA stresses repeatedly in the written materials describing the program that this research is needed to evaluate "whether these HPV chemicals pose potential risks to human health."<sup>199</sup> The EPA further seeks to empower citizens with knowledge of whether HPV chemicals "found in their environment, their homes, their workplaces, and the products that they buy" constitute potential health hazards.<sup>200</sup> Indeed, the urgency-inspiring creation of this voluntary challenge program by the EPA, Environmental Defense, and the American Chemistry Council is essentially the same as that ostensibly underlying the creation of TSCA by Congress—protection of the public from exposure to hazardous chemicals.<sup>201</sup>

Does this mean that the undertaking for which HPV Challenge Program participants have volunteered creates a potential legal duty to every member of the general public? The concept of "reasonable foreseeability" acts as a constraint on the duty element of the negligence cause of action for the very purpose of avoiding such potentially limitless liability.<sup>202</sup> If a particular risk of harm is "too bizarre, remote, or extreme," then the requirement that such harm be reasonably foreseeable is not met, and in the negligence lexicon, no duty of care is imposed.<sup>203</sup> Nonetheless, the concept of foreseeability as a limitation on

Fed. Reg. 81,686, 81,688 (Dec. 26, 2000).

197. RESTATEMENT (SECOND) OF TORTS § 324A (1965).

198. *Dow Chem. Co. v. Mahlum*, 970 P.2d 98, 114 (Nev. 1998) (quoting *In re Silicone Gel Prods. Liab. Litig.* 857 F. Supp. 1455, 1460 (N.D. Ala. 1995)), *overruled in part by* *GES, Inc. v. Corbitt*, 21 P.3d 11 (Nev. 2001).

199. Data Collection, 65 Fed. Reg. at 81,687.

200. *Id.*

201. See *supra* note 8 and accompanying text (quoting TSCA legislative history).

202. See DOBBS, *supra* note 83, § 143, at 334 (limiting risks to those that can be foreseen by a reasonable person); Stuart Madden, *Risk/Utility Analysis*, 10 KAN. J.L. & PUB. POL'Y 146, 147 (2000) (noting the importance of the duty element of negligence to the weighing of costs and benefits).

203. See Madden, *supra* note 202, at 147 (observing that duty is owed to those subjected to

duty is, at best, unevenly applied by the courts.<sup>204</sup> Torts scholars observe that "[w]hat one court finds unforeseeable as a matter of law, another court will find foreseeable as a matter of law."<sup>205</sup> One need look no further than the Dow Chemical negligent undertaking cases for a representative sampling of such uncertainty. As discussed above, the Nevada Supreme Court and the Northern District of Alabama found the existence of foreseeable harm to third parties on essentially identical facts that the California Supreme Court and the Eighth Circuit rejected as supporting such a finding.<sup>206</sup>

Moreover, from the defendant's standpoint, and despite its role as a limitation on liability, foreseeability is nonetheless an expansive concept in negligence analysis. For example, defendants are not required to foresee the specific harm that later befalls a plaintiff in order to impose a legal duty of care. It is enough that a defendant could have foreseen broad categories of potential risks and harms, rather than the actual specific harm.<sup>207</sup> Similarly, a defendant does not have to foresee that her actions are necessary to protect a specific third party. A duty is owed if the plaintiff falls within a class of third parties "whose rights were foreseeably affected by the defendant's unreasonable creation of risk."<sup>208</sup> In this regard, cases under Section 324A have demonstrated that a class of foreseeable third parties "can be quite large and quite remote."<sup>209</sup> For example, in *Long v. District of Columbia*, the District of Columbia Circuit held that an electric company contracting with the District of Columbia to maintain traffic signals had assumed a duty to the "traveling public" as foreseeable third

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unreasonable risk of harm when the actor "proceed[s] with an absence of ordinary care").

204. See John C.P. Goldberg & Benjamin C. Zipursky, *The Moral of Macpherson*, 146 U. PA. L. REV. 1733, 1776 (1998) (noting that some courts view foreseeability as a jury issue of breach or proximate cause).

205. *Id.* Similarly, contributing to the confusion that often surrounds the concept of foreseeability in negligence law is the fact that "[s]ometimes courts stretch for foreseeability and sometimes they are narrow or hard-nosed." John C.P. Goldberg & Benjamin C. Zipursky, *The Restatement (Third) and the Place of Duty in Negligence Law*, 54 VAND. L. REV. 657, 727 (2001).

206. See *supra* notes 168–83 and accompanying text (discussing *Mahlum* and *In re Silicone Gel*).

207. See DOBBS, *supra* note 83, § 143, at 335 (noting that the defendant's failure to foresee specific harm will not relieve him of liability).

208. Ernest J. Weinrib, *The Passing of Palsgraf?*, 54 VAND. L. REV. 803, 808 (2001); see also Goldberg & Zipursky, *supra* note 205, at 685 (stating that "a plaintiff cannot prevail merely by establishing that the actor's conduct constituted the breach of a duty of care owed to someone, but must instead show that the breach was a breach of duty owed to the plaintiff, or to a class of persons including the plaintiff").

209. Dahm, *supra* note 85, at 102.

party plaintiffs.<sup>210</sup> That is, under Section 324A, any negligent performance of the company's undertaking to maintain the traffic signals resulting in injury to any member of the public traveling through the district would allow that person to sue the company in tort.<sup>211</sup> In theory, every man, woman, and child in the United States or even the world could conceivably fall within this class of foreseeable plaintiffs. Indeed, even in the *Mahlum* case, the class of foreseeable plaintiffs—any person who might eventually purchase a silicone implant product from the manufacturer, Dow Corning—was remarkably broad and remote.<sup>212</sup>

A helpful construct in examining specific issues of foreseeability relative to HPV Challenge Program participants is the "relational conception of duty" advocated by Professors John Goldberg and Benjamin Zipursky.<sup>213</sup> According to this conception of duty, an actor owes a duty of care to another because "that other person figures (or should figure) in [that actor's] deliberation in a certain way."<sup>214</sup> To avoid "casting the duty net too wide," this construct inquires "as to which types of [actors] are obligated to be vigilant to avoid causing certain types of harm to certain others."<sup>215</sup> In this regard, "[t]he ease or difficulty for persons in the defendant's category to anticipate those harms is relevant to whether it makes sense for such [actors] to be said to have a duty to be vigilant against causing them."<sup>216</sup> Thus, "the decision that certain defendants are particularly well-situated to foresee the sort of harm that befell the plaintiff" is "relevant to whether a category of defendant may properly be declared to owe a duty of due care to a category of plaintiff."<sup>217</sup> Or, said another way, in certain

210. See *Long v. District of Columbia*, 820 F.2d 409, 418 (D.C. Cir. 1987) (finding duty in light of electric company's "contract to perform services within its field of expertise").

211. See *id.* at 418–19 (citing a number of other cases with similar facts that had taken similar positions recognizing such an extremely broad class of foreseeable third party plaintiffs); see also *David v. Broadway Maint. Corp.*, 451 F. Supp. 877, 882 (E.D. Pa. 1978) (finding that foreseeable plaintiffs were class of "pedestrians" injured by company's negligent maintenance of street lights); *Fink v. Kasler Corp.*, 649 P.2d 1173, 1175 (Haw. 1982) (finding that company contracting with state to maintain stop signs could reasonably foresee class of plaintiffs including traveling public); *Schmeck v. City of Shawnee*, 651 P.2d 585, 597–98 (Kan. 1982) (finding that power company undertaking to install traffic lights on behalf of city owes a duty to "automobile passengers" to do so with reasonable care). The ruling in *Schmeck* has been superseded by the Kansas Tort Claims Act, KAN. STAT. ANN. §§ 75-6101 to 6115 (2003).

212. See *supra* notes 134–39 and accompanying text (explaining *Mahlum*'s finding that Dow Chemical was under duty to exercise reasonable care in testing for chemical safety).

213. Goldberg & Zipursky, *supra* note 204, at 1838.

214. *Id.*

215. *Id.*

216. *Id.*

217. *Id.* at 1838–39.

cases, "the courts predicate their recognition of a duty of care in part on the ground that the defendants as a class are uniquely well positioned to foresee the risk of injury to members of the plaintiff class."<sup>218</sup>

In applying this relational conception of duty to HPV Challenge Program participants, the first step is to identify the general class of actors to which these participants belong. Participants in the program are companies that manufacture or import certain "industrial chemicals for which aggregate [domestic] production/importation volumes meet or exceed" one million pounds annually.<sup>219</sup> Participants commit, either individually or as a consortium of companies working together, to sponsor testing of specific HPV chemicals manufactured or imported by that company or companies.<sup>220</sup> Thus, the class of actors to which these theoretical defendants belong generally can be characterized as commercial chemical companies sponsoring toxicity testing of chemical substances in which they possess specific commercial interests.

The next step is to consider what classes of persons that this class of actors might be "uniquely well positioned" to foresee why their actions could cause certain types of harm. Such well-positioned actors owe members of these classes of persons a duty to take reasonable care to avoid causing such types of harm.<sup>221</sup> Significantly, the EPA's Challenge Program-related documents shed considerable light on this question. As emphasized above, the fundamental purpose of the activity engaged in by HPV Challenge Program participants is to develop data for use in assessing potential hazards to human health from exposure to specific chemicals.<sup>222</sup> The EPA's written program description indicates that such exposures could occur through such activities as "the manufacture (including importation), distribution in commerce, processing, use, or disposal of the chemicals, or any combination of these activities."<sup>223</sup> Further, the EPA's program materials indicate that such exposures could occur "where [citizens] live, work, study, and play" and from "the products that they buy."<sup>224</sup>

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218. Goldberg & Zipursky, *supra* note 205, at 727.

219. Data Collection and Development on High Production Volume (HPV) Chemicals, 65 Fed. Reg. 81,686, 81,686 (Dec. 26, 2000).

220. See Browner, *supra* note 63 (inviting chemical manufacturers or importers to join HPV Challenge Program).

221. See Goldberg & Zipursky, *supra* note 204, at 1838 (explaining that "the foreseeability of the particular plaintiff's injury to the defendant is relevant to the factual issue of whether the duty so interpreted has been breached").

222. See *supra* notes 191-93 (discussing the fundamental purpose of the Program).

223. *Data Collection*, 65 Fed. Reg. at 81,687.

224. *Id.*

Given the fundamental purpose of the HPV Challenge Program—to develop data for use in efforts to determine whether such exposures are potentially harmful—actors in the category of program participants appear particularly well situated to foresee the sorts of harm that might befall such persons should their undertaking be performed negligently. Indeed, as the facts of *Mahlum* intimate, a failure to exercise reasonable care in the research and testing required to develop this data conceivably could create situations involving harm from chemical exposure that might have otherwise been avoided. It thus "makes sense for such [program participants] to be said to have a duty to be vigilant against causing" such harms by negligence in performing their program-related undertakings.<sup>225</sup>

*Mahlum* aptly illustrates application of the relational conception of duty to an undertaking analogous to that involved in the HPV Challenge Program. As discussed above, the Nevada Supreme Court found that a jury could reasonably infer that Dow Chemical should have foreseen that its toxicological testing of silicone was "a necessary step in the protection of third persons who would purchase liquid silicone in the form of breast implants."<sup>226</sup> Although not framed in such terms, the court clearly viewed Dow Chemical as within a category of defendants well positioned to foresee a risk of injury to "the general class of persons" to which the plaintiff belonged.<sup>227</sup> As emphasized by California Supreme Court Justice Mosk in his *Artiglio* dissent (cited favorably by the *Mahlum* majority), "the general class of persons for whose 'protection' the actor [performing human toxicological research on substances for biomedical applications] should recognize his 'services' are 'necessary' . . . embraces all those who are subsequently exposed to any such substances, including plaintiffs who were recipients of Dow Corning silicone breast implants."<sup>228</sup> Thus, the court considered it proper that a category of defendants—entities undertaking toxicological research, including Dow Chemical—be declared to owe a duty of due care to a category of plaintiffs—all those subsequently exposed to the substance that was the subject of such research, which included the injured plaintiff in *Mahlum*.

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225. Goldberg & Zipursky, *supra* note 204, at 1838.

226. Dow Chem. Co. v. Mahlum, 970 P.2d 98, 116 (Nev. 1998), *overruled in part* by GES, Inc. v. Corbitt, 21 P.3d 11 (Nev. 2001).

227. *Id.*

228. *Artiglio v. Corning, Inc.*, 957 P.2d 1313, 1322 (Cal. 1998) (Mosk, J., dissenting).

### C. Breach of Duty

Assuming the duty element is satisfied, the next element in the Section 324A cause of action is breach of that legal duty by a defendant's failure to exercise reasonable care in performing the undertaking. In the language of negligence, a defendant breaches a duty of care owed to a plaintiff by engaging in conduct that creates an unreasonable risk of harm.<sup>229</sup> As with all elements in a negligence case, the issue of breach—essentially an evaluation of the reasonableness of the defendant's conduct—is broad and general.<sup>230</sup> Evaluation of breach is fact specific, and whether the plaintiff can meet her burdens of proof and persuasion necessarily must be decided on a case-by-case basis. Of considerable concern to HPV Challenge Program participants should be *Mahlum's* creation of judicial precedent for the proposition that toxicological research may be conducted in a manner deemed to breach a legal duty of care owed to foreseeable third parties. As discussed above, the *Mahlum* court ruled that a reasonable jury could conclude that Dow Chemical breached its duty to act with reasonable care based on evidence including that: (1) certain testing was inadequately performed, (2) testing results were misreported, (3) assumptions regarding long term chemical safety were based on animal testing not supporting such suppositions, (4) needed follow up testing to confirm or reject negative results was not performed, (5) Dow Chemical failed to advise Dow Corning of the need for such follow up studies.<sup>231</sup>

Any determination that HPV Challenge Program volunteers have failed to exercise due care in performing specific research and testing obligations must, as emphasized at the beginning of this Part, await specific allegations of negligent conduct on the part of a specific actor. Nevertheless, warning signs indicate such occurrences are, at the very least, possible and perhaps even probable. Groups such as Physicians Committee for Responsible Medicine (PCRM), People for the Ethical Treatment of Animals, American Anti-Vivisection Society, and Alternatives Research and Development Foundation harshly criticize the HPV Challenge Program. These groups and others sued

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229. See DOBBS, *supra* note 83, § 115, at 270–71 (noting that defining negligence as "unreasonable risk" reduces ambiguity related to duty).

230. *Id.* § 114, at 269.

231. See *Mahlum*, 970 P.2d at 118 (concluding that Dow Chemical "was required to fully complete . . . testing until a reliable safety determination was made"); see also *In re Silicone Gel Prods. Liab. Litig.*, 887 F. Supp. 1455, 1460 (N.D. Ala. 1995) (denying summary judgment against claim that Dow Corning failed to exercise reasonable care in performing toxicological testing and research, thus affirming that the plaintiff produced sufficient evidence to create a jury question).



the EPA in 2002 seeking to enjoin the agency from continuing to implement the program.<sup>232</sup> Of primary concern by these groups was the amount of animal testing that would occur in generating the toxicity data required by the HPV Challenge Program.<sup>233</sup> This objection was based not only on animal welfare concerns but also on concerns about the accuracy of animal testing as a predictor of human risk.<sup>234</sup> Although the EPA agreed to make changes to minimize the overall amount of animal testing, animal testing remains a substantial part of the testing protocol under the program.<sup>235</sup>

Studies based on experiments on laboratory animals often are utilized in assessing human health risks posed by potentially toxic chemical substances.<sup>236</sup> However, use of animal studies as a predictor of toxicological risks to humans, even on the level of basic hazard screening, receives harsh criticism and may be of questionable value.<sup>237</sup> The HPV Challenge Program is condemned

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232. See *Physicians Comm. for Responsible Med. v. Horinko*, 285 F. Supp. 2d 430, 431 (S.D.N.Y. 2003) (denying the plaintiff's motion for summary judgment on all claims while granting in part and denying in part the defendant's motion for summary judgment).

233. *Id.* at 434.

234. *Id.* at 434–35; see also Neil Barnard, *Editorial: Challenge EPA Toxicity Tests—An Urgent Call*, PHYSICIANS COMM. FOR RESPONSIBLE MED., Winter 1999 (inviting readers to contact Vice President Gore), available at <http://www.pcrm.org/magazine/GM99Winter/GM99Winter8.html> (on file with the Washington and Lee Law Review).

235. See *Physicians Comm.*, 285 F. Supp. 2d at 435 ("Plaintiffs dispute whether HPV Challenge Program was changed at all to minimize the amount of animal testing performed."); PHYSICIANS COMM. FOR RESPONSIBLE MED., ANALYSIS OF THE HIGH PRODUCTION VOLUME CHALLENGE: INDUSTRY VIOLATIONS AND EPA NEGLIGENCE 3–5, 7–8 (2001) (describing agreement and the EPA's reluctance to enforce the agreement), available at [http://www.pcrm.org/resch/anexp/hpv\\_report0801.htm](http://www.pcrm.org/resch/anexp/hpv_report0801.htm) (on file with the Washington and Lee Law Review). The changes to the program relating to animal testing were negotiated between the animal protection community and the creators of the HPV Challenge Program (EPA, Environmental Defense, and the American Chemistry Council). Andrew Nicholson et al., *An Evaluation of the US High Production Volume (HPV) Chemical-Testing Programme: A Study in (Ir)Relevance, Redundancy and Retro Thinking*, 32 ATLA (SUPP. 1) 335, 335–36 (2004). Despite the claims that animal testing is reduced significantly through this agreement, reviews of HPV test plans conducted since that agreement demonstrate that substantial animal testing continues to take place. See *id.* at 339 (noting that calculations are based on an OECD report).

236. Jack L. Landau & W. Hugh O'Riordan, *Of Mice and Men: The Admissibility of Animal Studies to Prove Causation in Toxic Tort Litigation*, 25 IDAHO L. REV. 521, 533 (1989); Mark E. Shere, *The Myth of Meaningful Environmental Risk Assessment*, 19 HARV. ENVTL. L. REV. 409, 433–34 (1995); see also NAT'L RESEARCH COUNCIL, SCIENCE AND JUDGMENT IN RISK ASSESSMENT 119–20 (1994) (explaining that animal experimentation is considered the first step in scientific risk assessment for human toxicity).

237. See Shere, *supra* note 236, at 433 (noting criticism of the "premise that massive dosage studies on animals provide a direct basis for evaluating human risks"); see also M. ALICE OTTOBONI, THE DOSE MAKES THE POISON: A PLAIN-LANGUAGE GUIDE TO TOXICOLOGY 58 (2d ed. 1991) ("The proposition that data obtained from animal experimentation can be applied directly and quantitatively to humans is so obviously flawed that it has had no proponents until

vigorously on this same ground. In testimony before the House Committee on Science, Subcommittee on Energy and the Environment, PCRM President Neal Barnard argued that the HPV Challenge Program was fundamentally flawed because "animal tests are often so inaccurate that they do more harm than good."<sup>238</sup> Dr. Barnard cited a Swedish research trial involving 29 independent laboratories and 50 chemical substances that found that rodent studies were only 65% accurate in predicting human toxicity risk.<sup>239</sup> Because of this significantly high frequency of inaccuracy in animal tests, Dr. Barnard expressed concern that the HPV program could "in fact be used to exonerate toxic chemicals" as potential risks to human health.<sup>240</sup> Dr. Barnard cited as an example early animal studies on tobacco smoke as a carcinogen. Because inhalation studies involving animals failed to indicate any hazardous results, such tests allowed the erroneous interpretation that tobacco inhalation was not dangerous to humans.<sup>241</sup>

There are, indeed, numerous examples of chemical substances later proven to be hazardous to human health but that initially were the subject of animal studies indicating no such risk.<sup>242</sup> Although the industrial solvent benzene was eventually shown to cause leukemia by studies of exposed workers, earlier

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relatively recently."); Christopher H. Buckley, Jr. & Charles H. Haake, *Separating the Scientist's Wheat from the Charlatan's Chaff: Daubert's Role in Toxic Tort Litigation*, 28 ENVTL. L. REP. 10,293, 10,301 (1998) (describing the skepticism of courts regarding "probative force" of animal studies); Landau & O'Riordan, *supra* note 236, at 522 ("Using animal studies to predict human toxicity responses is, at best, a primitive procedure which rests upon assumptions about the nature of toxic reactions and the biological relationship between humans and animal species that have never been reliably confirmed."). Similarly, Judge Jack Weinstein remarked on the limited value of animal studies in the Agent Orange toxic tort case as follows: "The animal studies are not helpful in the instant case because they involve different biological species. They are of so little probative force and are so potentially misleading as to be inadmissible." *In re Agent Orange Prod. Liab. Litig.*, 611 F. Supp. 1223, 1241 (E.D.N.Y. 1985). Notwithstanding such criticism, as Professor Wendy Wagner has observed that "animal studies have proven very enlightening in some cases." Wagner, *supra* note 5, at 779 n.24 (citing DAVID BRUSICK, PRINCIPLES OF GENETIC TOXICOLOGY 109-10 (1980)).

238. *EPA's High Production Volume (HPV) Chemical Testing Program: Hearing Before the House Subcomm. on Energy and Env't of the Comm. on Sci.*, 106th Cong. 38 (1999) [hereinafter *EPA Hearing*] (statement of Neal D. Barnard, M.D., President, Physicians Committee for Responsible Medicine).

239. *Id.* at 38-39 (citing the Multicenter Evaluation of In-Vitro Cytotoxicity (MEIC) trial based in Uppsala, Sweden, conducted by Dr. Bjorn Ekwall and colleagues).

240. *Id.* at 37.

241. *Id.* at 38.

242. *See generally id.* at 103 (statement of Animal Legal Defense Fund, a national organization of lawyers, law professors, law students and paralegals) (asserting that "[f]alse negatives . . . are a serious problem in animal testing, which even the Interagency Coordinating Committee for the Validation of Alternative Methods (ICCVAM) has recognized").

animal studies were unable to demonstrate such a link.<sup>243</sup> Asbestos is a known human carcinogen, but decades of animal studies on asbestos demonstrated no evidence of risk.<sup>244</sup> The chemical betanaphthylamine, linked to a 100% bladder cancer rate in workers exposed to the substance over a five-year period, was not indicated to be a human health risk based on previous animal studies.<sup>245</sup> Arsenic has long been an accepted human carcinogen, but animal studies have never suggested such a risk.<sup>246</sup> Such a checkered history has led to suggestions that attempts to predict human toxicity risks based on animal studies are "something of a crap shoot."<sup>247</sup> Indeed, given assertions that more accurate testing methods are presently available, potential plaintiffs are likely to seize upon program participants' use of testing described as "a grossly inaccurate measure of human risk" to argue that such conduct in and of itself should be deemed to create an unreasonable risk of harm to foreseeable third parties.<sup>248</sup>

In addition, negligent conduct by participants undertaking toxicology research within the HPV Challenge Program is always possible through old-fashioned methods of inadvertence and carelessness. Past investigations by the Food and Drug Administration indicate that animal and clinical toxicity test results submitted by industry sponsors or toxicology laboratories working for such sponsors often contained deficiencies caused by inadvertence, faulty design, inadequate training, improper data handling, and "poor and sloppy" procedures.<sup>249</sup> A 2003 status report on the HPV Challenge Program prepared

243. See Shere, *supra* note 236, at 422–23, 438–39 (citing *Indus. Union Dep't v. API*, 448 U.S. 607, 618 (1980), and *Occupational Exposure to Benzene*, 43 Fed. Reg. 5925, 5932 (1978) as instances where this link was unable to be demonstrated).

244. *Id.* at 439.

245. *Id.*

246. Buckley & Haake, *supra* note 237, at 10,302; Landau & O'Riordan, *supra* note 236, at 544.

247. Landau & O'Riordan, *supra* note 236, at 544; see also *EPA Hearing*, *supra* note 238, at 242 (statement of Neal D. Barnard, M.D., President, Physicians Committee for Responsible Medicine) (responding to Republican Subcommittee members' post-hearing questions and stating that certain type of animal testing method (LD-50) "is grossly inaccurate in predicting human toxicity in more than one-third of cases").

248. See *EPA Hearing*, *supra* note 238, at 38–40 (discussing human cell testing that was shown by the results of the MEIC trial to be approximately 80% accurate as a predictor of human toxicity); see also *id.* at 80–83 (transcript of discussion) (describing existing alternatives to animal testing including methodologies asserted as showing "clear-cut superiority" to certain types of animal tests); *id.* at 104 (quoting Animal Legal Defense Fund that "Congress did not intend whole animal testing to be perpetuated when non-animal testing alternatives exist which are cheaper, more accurate, and more reliable").

249. Sidney A. Shapiro, *Divorcing Profit Motivation from New Drug Research: A Consideration of Proposals to Provide the FDA with Reliable Test Data*, 1978 DUKE L.J. 155, 166–68.

by Environmental Defense offers some disturbing foreshadowing for program participants in this regard. The report sharply criticizes the performance of some individual companies, consortia, or trade associations, asserting that "[t]he quality of test plans and robust summaries submitted to date is decidedly mixed, ranging from excellent to *unacceptable*."<sup>250</sup> Of further concern, deficiencies in toxicology research also are attributed to bias or even outright fraud by industrial researchers.<sup>251</sup> Commentators observe that "industrial researchers have incentives to withhold negative information or to perform poorly designed and executed experiments incapable of revealing negative information."<sup>252</sup> Whether serious flaws in research design or performance were inadvertent or deliberate, either would unquestionably constitute a breach of a duty to exercise reasonable care in the performance of an HPV Challenge Program participant's undertaking.

#### D. Cause-in-Fact

Even if the conduct of HPV Challenge Program participants meets the requisite liability standard, plaintiffs must next prove that such a failure to exercise reasonable care was the cause-in-fact of their physical injuries. As in *Mahlum*, a plaintiff bringing a Section 324A-based cause of action necessarily must address two distinct concerns in this regard. First, the plaintiffs must demonstrate that exposure to the HPV chemical in question was the actual cause of their injuries. Second, the plaintiffs would have to demonstrate that the defendant's negligent conduct in performing its HPV Challenge Program undertaking with respect to that chemical was also an actual cause of their physical injuries.<sup>253</sup> That is, the plaintiffs must be able to further establish that but for the program participant's negligent conduct, the plaintiffs would have avoided their injury.<sup>254</sup>

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250. DENISON & FLORINI, *supra* note 35, at ix (emphasis added).

251. See Robert R. Kuehn, *The Environmental Justice Implications of Quantitative Risk Assessment*, 1996 U. ILL. L. REV. 103, 137 n.169 (stating that toxicological data supplied by regulated industry "may be biased or even outright fraudulent"); Lyndon, *supra* note 6, at 1816 (stating that "deception certainly occurs" with toxicity data produced by industry sources "and is often perceived as widespread").

252. DAVID D. DONIGER, *THE LAW AND POLICY OF TOXIC SUBSTANCES CONTROL* 15 (1978); see Shapiro, *supra* note 249, at 166 (describing FDA investigation revealing "deliberate decisions which seemingly were calculated to minimize the chances of discovering toxicity" in animal testing data submitted by industry researcher to the FDA).

253. See *supra* note 153 and accompanying text (discussing this dual burden for the cause-in-fact element of the plaintiffs' negligent undertaking claim in *Mahlum*).

254. See *supra* note 153 and accompanying text (explaining the but-for portion of the

The first of these causation issues "is the acid test of any toxic tort lawsuit."<sup>255</sup> Toxic tort harm typically arises from "occupational, environmental, or consumer exposures" to hazardous chemicals, products, or wastes.<sup>256</sup> In the context of the link between exposure and injury in a toxic tort case, proof of causation requires that the plaintiff establish two things: "first, that the particular substance involved is capable of causing the type of injury that plaintiff suffered; and second, that exposure to the substance did, in fact, cause plaintiff's injury."<sup>257</sup> However, because of the scientific uncertainties plaguing cause-and-effect issues in toxic tort cases, a myriad of "unique and troublesome" issues render proof of causation an often difficult issue for injured plaintiffs to overcome.<sup>258</sup> Such difficulty, often related to such factors as the lapse of time between exposure and the onset of symptoms demonstrating injury and imperfect knowledge of disease etiology,<sup>259</sup> likely will create significant problems for any potential plaintiffs bringing Section 324A-type claims against HPV Challenge Program participants. However, despite the difficulties associated with causation problems in toxic tort cases, such issues are by no means an impossible barrier to recovery.<sup>260</sup> Indeed, *Mahlum* is itself conclusive corroboration of this fact. Moreover, even in toxic tort cases, the issue of causation is not always problematic and, on occasion, "is quite clear-cut."<sup>261</sup>

### E. Proximate Cause

The final issue for consideration under Section 324A is whether a failure to exercise reasonable care in the undertaking is the proximate cause of a plaintiff's physical harm. Traditional negligence analysis utilizes proximate

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*Mahlum* analysis).

255. Landau & O'Riordan, *supra* note 236, at 521.

256. Wagner, *supra* note 5, at 777.

257. Landau & O'Riordan, *supra* note 236, at 526.

258. *See id.* at 527 (noting that "problems arise out of the current lack of conclusive information about the nature of the human toxic response"). For extended discussions of the typical causation problems in toxic tort cases, see Daniel A. Farber, *Toxic Causation*, 71 MINN. L. REV. 1219, 1226-28 (1987) (discussing problem of linking the defendant to chemical exposure); David Rosenberg, *The Causal Connection in Mass Exposure Cases: A "Public Law" Vision of the Tort System*, 97 HARV. L. REV. 851, 855-59 (1984) (analyzing problem of "alternative possible sources of the plaintiff's injury").

259. GERALD W. BOSTON & M. STUART MADDEN, *LAW OF ENVIRONMENTAL AND TOXIC TORTS: CASES, MATERIALS, AND PROBLEMS* 5 (2d ed. 2001).

260. Farber, *supra* note 258, at 1234.

261. *Id.* at 1251.

cause to limit the scope of a defendant's legal responsibility for harm caused by careless conduct under appropriate circumstances.<sup>262</sup> That is, even if a defendant breaches a duty of care owed to a plaintiff, the injury caused by that carelessness may be too remote or unforeseeable or too far removed from the scope of risk created by the defendant's conduct to merit imposition of liability.<sup>263</sup> Given the considerable disagreement among scholars and courts often arising over the proper approach to proximate cause, this concept can sometimes prove one of the more conceptually difficult negligence elements to resolve.<sup>264</sup>

The Restatement (Second) of Torts, however, simplifies this issue considerably in Section 324A, which sets forth three specific sets of circumstances in which the defendant's breach of duty owed to third parties may be found to be the proximate cause of the plaintiff's physical injury. Unless the plaintiff is able to demonstrate that at least one of these three conditions applies, no liability attaches under Section 324A even if the plaintiff has demonstrated otherwise the existence of legal duty, breach, cause-in-fact, and physical injury. Subsection (b) of Section 324A—when a volunteer undertakes to perform a duty owed to a third party by the entity on whose behalf the specific services are rendered—does not appear to apply to the circumstances of the HPV Challenge Program.<sup>265</sup> However, subsections (a) and (c)—when the volunteer's breach of duty increases the risk of physical harm to a third person or such harm is suffered because of reliance on the undertaking by either the third person or the entity for whom the services are rendered—do appear potentially applicable.

Regarding subsection 324A(a), the Restatement's official commentary states, "[i]f the actor's negligent performance of his undertaking results in increasing the risk of harm to a third person, the fact that he is acting under . . . a gratuitous agreement with another will not prevent his liability to the third person."<sup>266</sup> Thus, where an HPV Challenge Program participant conducts

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262. PAGE, *supra* note 99, at 30.

263. Goldberg & Zipursky, *supra* note 204, at 1837.

264. See PAGE, *supra* note 99, at 2 (observing "a notable lack of consensus" among jurists and scholars on the subject of proximate cause); see also DAVID MELLINKOFF, *THE LANGUAGE OF THE LAW* 382 (1963) (observing as to this issue that "[j]udges not only disagree with judges; and professors with professors and judges; it is a field where a professor may disagree with himself").

265. There appears to be no basis for the contention that the EPA is itself legally obligated to perform toxicity testing on the HPV chemicals that are the subject of the HPV Challenge Program. Thus, the program participants voluntarily performing such testing at the agency's behest are not performing a duty owed by the EPA to third persons.

266. RESTATEMENT (SECOND) OF TORTS § 324A cmt. c (1965).

toxicity testing in a negligent fashion and a member of a foreseeable class of third parties is subsequently injured by exposure to that substance, the participant would be liable if a court deemed the negligent conduct increased the risk of harm to the third party. Although *Mahlum* does not address this specific issue, other courts have applied this aspect of Section 324A's proximate cause standard in analogous circumstances.

For example, in *Hempstead v. General Fire Extinguisher Corp.*,<sup>267</sup> a nonprofit service organization routinely undertook to test products of manufacturers to determine whether such products met certain manufacturing requirements and safety standards.<sup>268</sup> The testing organization periodically listed products it deemed to comply with these standards in publications available to the public and also authorized manufacturers to label such products to convey the same information.<sup>269</sup> An individual, injured as a result of an exploding fire extinguisher previously listed and labeled by the organization, brought this action against the organization.<sup>270</sup> In denying summary judgment for the defendant, the court held that the testing organization could be held liable under Section 324A because "[t]he alleged failure . . . to exercise reasonable care in approving the design of the extinguisher has obviously increased the risk of harm to plaintiff over that which would have existed if reasonable care had been exercised."<sup>271</sup>

In *Kohr v. Johns-Manville Corp.*,<sup>272</sup> an insurance company research group performed a series of studies on asbestos exposure among workers at an asbestos plant.<sup>273</sup> Fifty years later, plant workers suffering asbestos-related health disorders sued the insurance company under Section 324A alleging negligent performance of these studies.<sup>274</sup> In denying the insurance company's motion for summary judgment, the court held that "a jury could infer [from the evidence] that the 'empirical studies' conducted by [the research group] . . . were, in fact, inaccurate and skewed by industry representatives in order to avoid the legal effect of asbestos exposure among workers."<sup>275</sup> The court

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267. *Hempstead v. Gen. Fire Extinguisher Corp.*, 269 F. Supp. 109 (D. Del. 1967).

268. *See id.* at 116 (discussing the nature and purpose of Underwriters' Laboratories, one of the named parties to the suit).

269. *See id.* (noting that companies may attach labels to approved products stating "Underwriters' Laboratories, Inc., Inspected").

270. *Id.* at 110–11.

271. *Id.* at 118.

272. *Kohr v. Johns-Manville Corp.*, 534 F. Supp. 256 (E.D. Pa. 1982).

273. *Id.* at 257–58.

274. *See id.* at 258 (noting acceptance of Section 324A in Pennsylvania courts).

275. *Id.* at 259.

further indicated that the plaintiff had adduced facts tending to show that the defendant, "recognizing the study as necessary to protect [the asbestos plant's] workers, produced it with a lack of reasonable care in drawing its conclusions, thereby increasing risk of harm to plaintiff."<sup>276</sup>

Similarly, *Heinrich v. Goodyear Tire & Rubber Co.*<sup>277</sup> involved a parent company undertaking to provide health and safety information regarding all chemicals used at its subsidiary's manufacturing plant.<sup>278</sup> A plant employee suffering an "occupational disease" (ostensibly due to chemical exposure at the plant) sued the parent company asserting negligent undertaking liability under Section 324A.<sup>279</sup> The *Heinrich* court denied the defendant's motion to dismiss, finding that the alleged facts stated a cognizable claim under Section 324A(a) in that the defendant's negligence resulted in an increased risk of harm to the plaintiff.<sup>280</sup> Cases such as *Hempstead*, *Kohr*, and *Heinrich* suggest that negligently performing an undertaking involving safety or health risks, including as to potentially hazardous chemical exposure, may be seen as increasing the risk of harm to foreseeable plaintiffs. For the same reasons, toxicity research undertaken by HPV Challenge Program participants falls squarely within the scope of Section 324A(a)'s increased risk of harm test for proximate cause.

Alternatively, subsection 324A(c) allows proximate cause to be found if physical harm is suffered because of reliance on the undertaking by either the entity for whom the services are rendered or the injured third party.<sup>281</sup> The official Restatement commentary elaborates that:

This is true whether or not the negligence of the actor has created any new risk or increased an existing one. Where the reliance of the other, or of the third person, has induced him to forgo other remedies or precautions against such a risk, the harm results from the negligence as fully as if the actor had created the risk.<sup>282</sup>

For a plaintiff to establish "reliance" for purposes of subsection 324A(c), courts typically require evidence of some detrimental change in position by the party alleged to have relied on the undertaking.<sup>283</sup> Importantly, the underlying

276. *Id.* at 258.

277. *Heinrich v. Goodyear Tire & Rubber Co.*, 532 F. Supp. 1348 (D. Md. 1982).

278. *Id.* at 1350–51.

279. *Id.* at 1350, 1354.

280. *Id.* at 1355–56.

281. RESTATEMENT (SECOND) OF TORTS § 324A(c) (1965).

282. *Id.* cmt. e.

283. See *Wellington & Camisa*, *supra* note 99, at 55–57 (discussing court interpretations requiring a change in position to constitute reliance).



purposes for the HPV Challenge Program demonstrate that reliance by both the EPA and third parties is a fundamental characteristic of the program.

The EPA, for whom the "services" in question are being rendered, already has expressed unequivocally its intention to rely on the respective undertakings of HPV Challenge Program participants. Throughout the written program materials, the EPA repeatedly emphasizes its objective to rely on the data generated by program participants to evaluate and prioritize potential human health and environmental effects resulting from manufacturing, processing, and use of HPV chemicals.<sup>284</sup> Should the EPA rely on negligently performed testing by HPV Challenge Program participants such that it chooses to forgo further evaluation or heightened prioritization regarding certain chemicals later deemed to have caused physical injury to foreseeable plaintiffs, then the requirement of subsection 324A(c) is met. *Heinrich* illustrates this point regarding an analogous undertaking to provide health and safety information regarding chemicals used at a manufacturing plant. The court emphasized that "liability may be imposed under section 324A(c) if, for example, [the subsidiary] relied upon [the parent's] information and services such that [the subsidiary] lessened, or omitted taking, its own safety measures regarding the chemicals as to which information was supplied by [the parent]."<sup>285</sup>

Furthermore, the intentional design of the HPV Challenge Program provides that third parties may also specifically rely upon the testing and research undertakings of program participants. The EPA's stated goal is to make data generated by program participants available to the public "to empower citizens with knowledge about . . . chemicals [they] may be exposed to in the places where they live, work, study, and play."<sup>286</sup> Indeed, in its 1998 study on the lack of basic toxicity information on domestic HPV chemicals, the EPA emphasized that a fundamental reason for making this type of information publicly available is "so that producers, users, workers, and consumers could be aware and be able to evaluate the hazards and risks posed by the chemicals they encounter in their daily lives."<sup>287</sup> Significantly, the report further emphasizes that "[s]teps to ensure the availability of basic toxicity information on HPV chemicals would be an integral part of meeting" the objective of "improv[ing] the ability of the public to reduce exposure to specific environmental and

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284. See *supra* notes 192–93, 196, and accompanying text (discussing the goals and methodology of the Program).

285. *Heinrich v. Goodyear Tire & Rubber Co.*, 532 F. Supp. 1348, 1356 (D. Md. 1982).

286. Data Collection and Development on High Production Volume (HPV) Chemicals, 65 Fed. Reg. 81,686, 81,687 (Dec. 26, 2000).

287. OFFICE OF POLLUTION PREVENTION & TOXICS, *supra* note 29, at 2.

human health risks."<sup>288</sup> The launch of the HPV Challenge Program a mere six months following release of this report was clearly a deliberate "step" in this direction.<sup>289</sup>

As observed above, the HPV Challenge Program is a central element of the EPA's larger Chemical Right-to-Know initiative.<sup>290</sup> The initiative's basic goal is to "assure that the public has access to health and environmental effects data for chemicals which are present in their environment."<sup>291</sup> Thus, the initiative is a close relative to federal and state right-to-know laws which have proliferated during the last few decades.<sup>292</sup> The underlying premise of right-to-know policy is to allow individuals to make "informed decisions" regarding the presence of hazardous substances in their environments.<sup>293</sup> Thus, "[a]t least in theory, workers can take precautions, bargain with their employers for safety, suggest safer procedures, refuse certain work, or even change jobs."<sup>294</sup> Similarly, "[i]n theory, access to information about environmental contaminants enables individuals and community groups to take appropriate action to minimize adverse health risks."<sup>295</sup> Such action might include avoiding areas where hazardous chemicals are located or minimizing exposure to media or products contaminated by such chemicals.<sup>296</sup> In the case of data generated by HPV Challenge Program participants, however, reliance on negligently produced or reported data may induce individuals to forgo such actions or to otherwise decide against taking precautions against exposure to chemicals in

288. *Id.*

289. The EPA's 1998 Chemical Hazard Data Availability Study was released in April 1998. *Id.* at 1. The HPV Challenge Program was announced on October 9, 1998. Data Collection, 65 Fed. Reg. at 81,692.

290. *Id.* at 81,687.

291. OFFICE OF POLLUTION PREVENTION & TOXICS, *supra* note 32.

292. See Applegate, *supra* note 3, at 294-95 (discussing federal right-to-know laws); Frances L. Edwards, *Worker Right-to-Know Laws: Ineffectiveness of Current Policy-Making and a Proposed Legislative Solution*, 15 B.C. ENVTL. AFF. L. REV. 1, 4-8 (1987) (discussing federal, state, and municipal right-to-know mandates).

293. Edwards, *supra* note 292, at 8; see also Applegate, *supra* note 3, at 297-98 (describing ways in which citizens might use data provided by right-to-know statutes).

294. Applegate, *supra* note 3, at 297; see Edwards, *supra* note 292, at 8 ("The underlying premise is that informing workers of the effects of work-related hazardous chemical exposure will enable 'workers to play a meaningful role in their own health management.'").

295. Robert F. Blomquist, *The Logic and Limits of Public Information Mandates upon Federal Hazardous Waste Law: A Policy Analysis*, 14 VT. L. REV. 559, 562 (1990); see Applegate, *supra* note 3, at 297-98 (stating that "by providing toxicity and exposure information paralleling quantitative risk assessment, the data requirements of the right-to-know laws encourage individuals to undertake their own, informal risk assessments").

296. Blomquist, *supra* note 295, at 562.

their local environments.<sup>297</sup> Or, similar to allegations made in *Mahlum*, injured consumers may assert that reliance on favorable toxicity data induced continued purchases of products containing hazardous HPV chemicals where such purchases would have been otherwise avoided.<sup>298</sup> These and other similar assertions by individuals alleging reliance on an HPV Challenge Program participant's undertaking are sufficient to meet the proximate cause standard of Section 324A(c).

#### V. Conclusion: Policy Implications for the EPA

This Article reveals an unintended consequence of the joint creation of the HPV Challenge Program by the EPA, Environmental Defense, and the American Chemistry Council. Companies and consortia voluntarily sponsoring toxicity testing on specific HPV chemicals are exposed to common law tort liability under the "negligent undertaking" principles of Section 324A of the Restatement (Second) of Torts. Accordingly, liability for latent harms caused by potentially toxic chemicals outside of the traditional product liability context exists for HPV Challenge Program participants. Similar to Dow Chemical in *Mahlum*, the mere act of conducting scientific research on a chemical substance renders program participants potentially answerable in damages for injuries allegedly caused by products that these companies may not manufacture or by other forms of chemical exposure for which they otherwise would not be directly responsible.

This prospect most certainly would have affected the decisionmaking process of industry participants if contemplated contemporaneously with their commitment to the HPV Challenge Program. Indeed, "exposure to lawsuits and potentially catastrophic liability" based on traditional toxic tort theories contributed to the unwillingness of industry to conduct voluntary toxicity research before the inception of this program.<sup>299</sup> Similar industry concerns over

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297. A further complicating factor is the open question of whether individuals have the ability "to make intelligent use" of toxicity information disclosed through such programs in any event. Applegate, *supra* note 3, at 297; see also Wendy Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613, 1653-54, 1672, 1702 (1995) (discussing limitations of the general public to understand scientific information based on deficiencies in science education and training).

298. See *Dow Chem. Co. v. Mahlum*, 970 P.2d 98, 119-20 (Nev. 1998) ("Charlotte Mahlum also testified that had she known of the significant health hazard posed by liquid silicones, she would have refused Dow Corning's breast implants."), *overruled in part by* *GES, Inc. v. Corbitt*, 21 P.3d 11 (Nev. 2001).

299. See Wagner, *supra* note 5, at 775 (describing common law incentives for companies to minimize chemical safety research).

other types of increased liability exposure minimized levels of participation in previous EPA voluntary programs.<sup>300</sup> Significantly, the mere threat of litigation, even if only the prospect of frivolous lawsuits, deterred industry participation in such voluntary programs.<sup>301</sup> A defendant that prevails in a lawsuit of even questionable merit may yet incur enormous litigation costs in the process. For such reasons, the probability that plaintiffs' attorneys will ultimately utilize *Mahlum* and Section 324A as a road map to lawsuits and aggressive pursuit of monetary liability creates substantial negative incentives for continuing or future industry participation in the HPV Challenge Program.<sup>302</sup>

In this regard, a June 2004 status report by Environmental Defense identifies more than 150 chemicals falling within the scope of the existing program that were either never sponsored or had initial sponsorships withdrawn.<sup>303</sup> In addition, more than 600 chemicals emerging as HPV chemicals since commencement, and thus not technically within the scope of the program, also remain unsponsored.<sup>304</sup> Environmental Defense argues that producers or importers should sponsor voluntarily the testing and research called for in the HPV Challenge Program for these and any additional chemicals reaching HPV status in the future.<sup>305</sup> The EPA echoes this call with the optimistic suggestion that such voluntary testing of subsequently emerging HPV chemicals should "become routine."<sup>306</sup> However, such future voluntary

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300. See Case, *supra* note 42, at 54 (noting widespread industry fears of citizen enforcement actions); Steinzor, *Reinventing Environmental Regulation*, *supra* note 5, at 147-49 (discussing the concern of industry regarding the vulnerability of Project XL participants to citizen suits as a deterrent to participation).

301. Case, *supra* note 42, at 54; see also Stephen J. Choi, *Selective Disclosures in the Public Capital Markets*, 35 U.C. DAVIS L. REV. 533, 542 (2002) (suggesting that fear of frivolous lawsuits is a deterrent to voluntary disclosure of information by public companies).

302. Indeed, personal injury lawyers in the toxic tort arena continually seek to evolve new legal theories to expand the number of potentially liable companies for the harmful effects of toxic substances. See Victor E. Schwartz et al., *Congress Should Act to Resolve the National Asbestos Crisis: The Basis in Law and Public Policy for Meaningful Progress*, 44 S. TEX. L. REV. 839, 859-60 (2003) (discussing this phenomenon in relation to liability exposure for asbestos).

303. DENISON, *supra* note 26, at ii. Environmental Defense reports that, as of June 2004, 532 chemicals from the original program list were unsponsored and that as many as 259 of these were "true orphans: chemicals for which their producers and importers have not met their responsibility to sponsor . . . under the program." *Id.* at ii-iv.

304. *Id.* at vi. As of June 2004, 735 new HPV chemicals had emerged since the launch of the HPV Challenge Program, 112 of which were subsequently voluntarily sponsored by program participants. *Id.*

305. *Id.*

306. *Id.* at v (quoting U.S. Env'tl. Protection Agency, *supra* note 82).

collaboration may be seriously, perhaps fatally, compromised by the "negligent undertaking" liability exposure that would accompany any such undertaking. The EPA's ability to initiate future voluntary chemical research and testing programs based on the HPV Challenge Program model similarly is threatened. And, of more immediate concern, belated knowledge that participation in the HPV Challenge Program increases exposure to lawsuits and potential liability may cause current participants to attempt to withdraw existing commitments.

Materialization of such threats to the existing HPV Challenge Program or to future participation in similar efforts would continue a frustrating tradition for the EPA's utilization of collaborative approaches to environmental policymaking. Since the early 1990s, industry participants denigrated high profile EPA voluntary programs such as the 33/50 program, Project XL, and the Common Sense Initiative for low participation rates.<sup>307</sup> Scholars attribute this problem to a combination of insufficient incentives to motivate industry participation and the existence of adverse incentives causing industry to perceive participation as undesirable.<sup>308</sup> Such minimal participation rates are among explanations offered as to why past EPA voluntary programs disappoint both in terms of results and impact.<sup>309</sup> The perception that EPA voluntary programs are largely insignificant and ultimately ineffectual will be furthered should the problem revealed by this Article eventually derail the HPV Challenge Program or similar future collaborative regulatory efforts.

Eventually the EPA must consider what course of action, if any, to take in response to such concerns. Taking no action at all is, of course, one possible

307. Case, *supra* note 42, at 47 n.293, 47–48. Low participation rates by industry in voluntary environmental programs are not limited to EPA programs. For example, the voluntary Eco-Management and Audit Scheme (EMAS) of the European Union, a scheme where companies voluntarily adopt standard procedures for environmental management, auditing, and reporting in exchange for limited regulatory controls, has also suffered from an extremely low participation rate by industrial companies across the European Union. See David W. Case, *Corporate Environmental Reporting as Informational Regulation: A Law and Economics Perspective*, 76 U. COLO. L. REV. (forthcoming 2005) (manuscript at 19, on file with the Washington and Lee Law Review) (reporting participation at less than 1%).

308. Case, *supra* note 42, at 47–48, 54; see also Steinzor, *Reinventing Environmental Regulation*, *supra* note 5, at 124–25, 149–50 (noting criticism of Project XL, particularly the legal uncertainty of some of its provisions).

309. See Case, *supra* note 42, at 46–48 ("As long as participation in reinvention programs continues to be voluntary, failure to develop more compelling incentives to motivate industry participation eventually may render external regulatory reinvention programs at the EPA a pointless exercise."); Eric W. Orts, *Reflexive Environmental Law*, 89 Nw. U. L. REV. 1227, 1286 (1995) ("Without meaningful incentives to impel widespread participation, purely voluntary programs will likely have no more than a marginal impact on basic environmental programs."); Steinzor, *Reinventing Environmental Regulation*, *supra* note 5, at 196 (suggesting use of EPA regulation as a "negative incentive" that may compel industry compliance).

option. That is, the EPA can choose to do nothing and allow the tort system to function as it will with respect to the undertakings of participants in the HPV Challenge Program. As discussed above, however, such an approach is not for the risk averse. Achieving the desired policy objectives of the HPV Challenge Program certainly will be more difficult and perhaps impossible if the program erodes or even collapses from the weight of participant withdrawals. Moreover, ignoring incentives for industry avoidance of voluntary participation in chemical testing efforts threatens the EPA's ability to effectively pursue these policy objectives through collaborative approaches in the future.

Another option is for the EPA to abandon voluntary approaches altogether in seeking to achieve the specific policy objectives at stake—developing and utilizing previously unavailable data on the effect of chemical substances on human health and the environment. Instead, the EPA can seek to obtain such information solely through TSCA, which was ostensibly created by Congress for that purpose. However, as discussed in Part I of this Article, TSCA is widely viewed as a failure in this regard.<sup>310</sup> TSCA's elaborate procedural barriers, burdensome evidentiary standards, and corresponding vulnerability to expensive and time-consuming judicial challenges by industry create strong incentives for the EPA to avoid promulgation of test rules under TSCA.<sup>311</sup> Indeed, these weaknesses of TSCA as a regulatory instrument are among the primary motivations for creation of the HPV Challenge Program in the first place.<sup>312</sup> A decision to simply abandon such collaborative approaches achieves nothing more than a return to the unsatisfactory regulatory status quo that the HPV Challenge Program was intended, at least in part, to rectify.

A final option is for the EPA to seek to reduce the negative incentives for voluntary participation in collaborative chemical research and testing efforts created by *Mahlum* and the negligent undertaking principles of Section 324A. This approach would prove a difficult undertaking, given that alleviating the burdens of such legal liability would require some type of action by Congress. An example of a previous federal program that might inform the EPA's consideration of such a possibility is the National Swine Flu Immunization

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310. See *supra* note 15 and accompanying text (discussing failure of TSCA to achieve its goal of correcting deficiencies in chemical toxicity data).

311. See *supra* notes 18–20 and accompanying text (describing evidentiary burdens placed on the EPA in conjunction with TSCA).

312. See DENISON & FLORINI, *supra* note 35, at 1 (referencing "sporadic" exercise of EPA authority under TSCA as preamble to creation of HPV Challenge Program); see also ENVTL. DEF. FUND, *supra* note 15, at 23, 29 n.15 (criticizing regulatory efforts under TSCA). This report created substantial momentum for the subsequent discussions and eventual agreement with the EPA to create the HPV Challenge Program. DENISON & FLORINI, *supra* note 35, at 1.

Program of 1976.<sup>313</sup> In March 1976, President Ford announced a large scale federal immunization program to stem an expected outbreak of a deadly swine flu virus.<sup>314</sup> Drug manufacturers and public health officials collaborated to develop a vaccine for the program.<sup>315</sup> However, before the distribution phase of the program could commence, manufacturers and distributors of the vaccine expressed reluctance to participate based on concerns about exposure to legal liability for potential injuries associated with the vaccine.<sup>316</sup>

To alleviate these concerns, Congress amended the Federal Tort Claims Act to require claims for injuries caused by the vaccine to be brought directly against the federal government.<sup>317</sup> The relevant provision states:

[T]he liability of the United States arising out of the act or omission of a program participant may be based on any theory of liability that would govern an action against such program participant under the law of the place where the act or omission occurred, including negligence, strict liability in tort, and breach of warranty.<sup>318</sup>

Although accepting liability for injuries resulting from the vaccinations, the government reserved the right to seek indemnity from manufacturers for any finding of negligence on the part of a program participant.<sup>319</sup> Thus, the legislation completely absolved program participants from any claims of strict liability in tort under Section 402A of the Restatement (Second) of Torts but not as to claims based on common law negligence.<sup>320</sup> This provision tended to alleviate the most serious liability concern of the vaccine manufacturers and required that they obtain insurance covering their liability arising from negligence.<sup>321</sup> Notwithstanding the government's right to seek reimbursement

313. National Swine Flu Immunization Program of 1976, Pub. L. No. 380, 90 Stat. 1113 (1976) (codified at 42 U.S.C. §§ 247b(j)–(l) (2000)). For a detailed discussion of the circumstances leading up to this program, see Thomas E. Baynes, Jr., *Liability for Vaccine Related Injuries: Public Health Considerations and Some Reflections on the Swine Flu Experience*, 21 ST. LOUIS U. L.J. 44, 62–69 (1977).

314. H. William Smith III, Note, *Vaccinating Aids Vaccine Manufacturers Against Product Liability*, 42 CASE W. RES. L. REV. 207, 219–20 (1992).

315. *Id.* at 220.

316. *See id.* (discussing unwillingness of manufacturers to bear risks of product liability suits); *see also* Dan M. Berkovitz, *Price-Anderson Act: Model Compensation Legislation?—The Sixty-Three Million Dollar Question*, 13 HARV. ENVTL. L. REV. 1, 55 (1989) (describing manufacturers' refusal to release vaccines without insurance or indemnification).

317. Smith, *supra* note 314, at 220–21.

318. 42 U.S.C. § 247b(k)(2)(A)(i) (2000).

319. Smith, *supra* note 314, at 221.

320. *See* Berkovitz, *supra* note 316, at 55 (detailing how potential liability for faulty vaccines was spread across the public at large, rather than solely to producers or victims).

321. Smith, *supra* note 314, at 221.

of damages from a negligent program participant, no such reimbursement has been sought.<sup>322</sup>

Certainly, an imminent public health crisis made the circumstances surrounding the Swine Flu Program far more exigent than those surrounding the HPV Challenge Program. Moreover, the type of liability concern in the former program—product liability—is altogether different from the liability concern that is the subject of this Article—negligence in performing toxicity testing. Nonetheless, both programs involve important public health concerns and a "challenge" from the federal government for companies to act voluntarily to address such concerns notwithstanding significant exposure to lawsuits and liability accompanying any undertaking to do so. Further, similar to vaccines, toxicity research has the potential to provide tremendous societal benefits.<sup>323</sup> The voluminous literature of the past few decades on the dearth of basic chemical health effects toxicity data and the accompanying adverse effect on government policy and regulation suggest that the policy goals underlying the HPV Challenge Program are of no less public import.<sup>324</sup> Thus, the fact that Congress willingly removed the deterrent of legal liability to participation in the former program at least establishes precedent supporting some form of analogous action in this instance.<sup>325</sup>

Nonetheless, a decision to immunize actors from liability for negligent conduct that causes physical injury to innocent victims runs counter to this country's common law traditions of corrective justice.<sup>326</sup> If an actor's fault

322. John P. Wilson, *The Resolution of Legal Impediments to the Manufacture and Administration of an AIDS Vaccine*, 34 SANTA CLARA L. REV. 495, 552 (1994).

323. See Victor E. Schwartz & Liberty Mahshigian, *National Childhood Vaccine Injury Act of 1986: An Ad Hoc Remedy or a Window for the Future*, 48 OHIO ST. L.J. 387, 388 (1987) (describing the National Childhood Vaccine Injury Act as addressing "a crisis situation that existed for products that provide tremendous societal benefits").

324. See *supra* notes 3–29 and accompanying text (discussing benefits stemming from improved chemical toxicity data).

325. Indeed, Congress is no stranger to utilizing its Commerce Clause power to impact common law tort liability rules to address specific problems affecting national policy concerns. See Schwartz et al., *supra* note 302, at 842–47 (discussing a number of federal statutes that preempted state tort laws). Congress has done so on numerous occasions over the past century. *Id.* at 842–57 (chronicling dozens of statutory schemes enacted by Congress over the past century in this regard).

326. See Gerald J. Postema, *Risks, Wrongs, and Responsibility: Coleman's Liberal Theory of Commutative Justice*, 103 YALE L.J. 861, 871 (1993) (discussing interpretation of tort law including the "central thesis . . . that modern tort law gives legal expression to our informal social practice of corrective justice"); see also DOBBS, *supra* note 83, § 9, at 13–16 (discussing ideals of corrective justice concept of tort law); Margaret Jane Radin, *Compensation and Commensurability*, 43 DUKE L.J. 56, 60–61 (1993) (explaining nature and definition of corrective justice).



causes harm to a specific individual, conceptions of corrective justice require that the wrongdoer compensate the injured party in order to, in theory, "restore [those] persons to the status quo ante."<sup>327</sup> As Professor Jules Coleman emphasizes, "[c]orrective justice imposes a duty to repair wrongful losses on those agents responsible for them."<sup>328</sup>

Under what circumstances, then, would it be fair and equitable to deviate from this conception of corrective justice and in some way assuage the burdens of liability normally imposed upon negligent wrongdoers? One interpretation of corrective justice theory addresses this question, in part, by asserting that "corrective justice does not require a particular mode of rectification."<sup>329</sup> Indeed, "[a]ny way of annulling wrongful . . . losses is permissible provided it does not create other corrective injustices."<sup>330</sup> Under this "annulment thesis," the fundamental concern of corrective justice is making the injured victim whole.<sup>331</sup> Other concerns—"such as holding persons responsible for their actions"—are "secondary and derivative" of this fundamental aim.<sup>332</sup> Thus, "if anyone, wrongdoer or not, compensates the [injured party], corrective justice has been done."<sup>333</sup> Said another way, "[o]nce the loss is redressed, nothing remains for corrective justice to do."<sup>334</sup> Significantly, such secondary concerns as imposing the loss on the party responsible for it "do not survive satisfaction of [corrective justice's] fundamental aim."<sup>335</sup>

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327. Radin, *supra* note 326, at 57. Professor Radin further emphasizes:

[C]orrective justice means to make required changes in an unjustified state of affairs between an injurer and a victim, when the injurer's activity has caused the injustice, so that such changes bring about a just state of affairs between them, and one that is related in a morally appropriate way to the status quo ante. A shorthand way of saying this is that corrective justice restores moral balance between the parties. From this perspective, tort law is an engine for bringing about corrective justice by requiring tortfeasors to make recompense to their victims. This view of tort law is not couched in market rhetoric. Its core concepts are rights and wrongs, not dollars and exchange.

*Id.* at 60.

328. JULES L. COLEMAN, RISKS AND WRONGS 329 (1992).

329. *Id.* at 365.

330. *Id.*

331. *See id.* at 365–66 (distinguishing this "annulment thesis" conception of corrective justice from the "mixed view" that states that holding wrongdoer responsible for repairing wrongful losses is the only way to implement corrective justice); *see also* Postema, *supra* note 326, at 885 (discussing Professor Coleman's view of the fundamental concern of corrective justice).

332. Postema, *supra* note 326, at 885–86.

333. DOBBS, *supra* note 83, § 9, at 15 n.8.

334. Postema, *supra* note 326, at 886.

335. *Id.*

Accordingly, when public policy concerns warrant government action to reduce or eliminate the burdens of liability for a negligent wrongdoer, corrective justice still may be accomplished through such means as legislation (as occurred with the Swine Flu program, for example) or a government mandated insurance program addressing the compensation needs of victims.<sup>336</sup> Thus, a legislative response from Congress reducing or even eliminating the negligent undertaking liability concerns of HPV Challenge Program participants may be consistent with conceptions of corrective justice. This response assumes that appropriate provisions will be made to compensate for physical injury suffered by any victims of such negligence, similar to the scheme established for the Swine Flu program.

If the EPA pursues this track, however, the agency must convince Congress that threats to public-private partnerships such as the HPV Challenge Program implicate policy concerns justifying such legislative action. Indeed, the EPA must demonstrate that a legislative response to the liability exposure concerns at issue is "in the public interest, and not simply . . . a 'bailout' for an alleged wrongdoer."<sup>337</sup> In this regard, the EPA should consider the underlying rationales for the ubiquitous Good Samaritan statutes that exist in every state and at the federal level.<sup>338</sup> The most well known of such statutes provides absolute or qualified immunity to those who voluntarily render emergency medical assistance from liability for injuries caused by the failure to exercise reasonable care in performing such assistance.<sup>339</sup> Similar Good Samaritan statutes have been passed to limit negligence liability for those who cause harm while performing various voluntary services and undertakings.<sup>340</sup> Statutes passed by Congress in this regard include the Volunteer Protection Act of 1997

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336. See DOBBS, *supra* note 83, § 9, at 15 n.8 (noting that under the view that any compensation of a victim constitutes corrective justice, the state or an insurance company could compensate a victim); see also COLEMAN, *supra* note 328, at 364–65 (discussing authority of government to act for reasons grounded both in consideration of corrective justice and other policy concerns).

337. Schwartz et al., *supra* note 302, at 842.

338. Christopher H. White, Note, *No Good Deed Goes Unpunished: The Case for Reform of the Rescue Doctrine*, 97 NW. U. L. REV. 507, 517 (2002) (noting that states recognized the injustice and uselessness of a system that punishes altruistic acts); see also DOBBS, *supra* note 83, § 252, at 663–64 (noting that the original purpose of such statutes was to encourage physicians to provide voluntary assistance in emergencies without fear of liability).

339. Barry Sullivan, *Some Thoughts on the Constitutionality of Good Samaritan Statutes*, 8 AM. J.L. & MED. 27, 28 (1982). Some of these statutes limit coverage solely to physicians or trained medical professionals, while others extend coverage to all persons attempting to render assistance. White, *supra* note 338, at 517.

340. DOBBS, *supra* note 83, § 283, at 765–66.

(VPA),<sup>341</sup> immunizing individuals who undertake volunteer work for nonprofit organizations and governmental entities for harm caused by ordinary negligence in the course of such work,<sup>342</sup> and the Bill Emerson Good Samaritan Food Donation Act,<sup>343</sup> providing limited negligence immunity for harm caused to third parties due to good faith donations of grocery products and food to nonprofit organizations for ultimate distribution to needy individuals.<sup>344</sup>

Each of these statutes reflects legislative determination that application of the common law Good Samaritan doctrine is socially harmful public policy in certain circumstances. In such cases, the legislature recognized that application of this doctrine—which, as emphasized above, encompasses the principles of Section 324A of the Restatement (Second) of Torts<sup>345</sup>—unwisely deters socially beneficial conduct.<sup>346</sup> For example, congressional findings incorporated directly within the VPA emphasize that the willingness of volunteers to participate in nationally important social service programs "is deterred by the potential for liability against them."<sup>347</sup> Further, absent statutory protection, "high liability costs and unwarranted litigation costs" and "legitimate fears . . . about frivolous, arbitrary, or capricious lawsuits" discourage volunteers from providing services.<sup>348</sup> Accordingly, Congress asserts that limiting the liability risk assumed by such volunteers is within the national interest because citizens depend on these programs and the federal government lacks capacity to perform such services otherwise.<sup>349</sup>

In a similar vein, the paucity of available toxicity information on chemical substances commercially used in the United States has been well chronicled.<sup>350</sup>

341. 42 U.S.C. §§ 14,501–05 (2000).

342. *Id.* § 14,503. Immunity does not apply to harm "caused by willful or criminal misconduct, gross negligence, reckless misconduct, or a conscious, flagrant indifference to the rights or safety of the individual harmed by the volunteer." *Id.* § 14,503(a)(3).

343. 42 U.S.C. § 1791 (2000).

344. *Id.* § 1791(c). A donor is not protected for "injury to or death of an ultimate user or recipient of the food or grocery product that results from an act or omission of the person, gleaner, or nonprofit organization, as applicable, constituting gross negligence or intentional misconduct." *Id.* § 1791(c)(3).

345. *See supra* notes 83–99 and accompanying text (comparing the Good Samaritan doctrine with Section 324A).

346. *See White, supra* note 338, at 517 (noting that states recognized the injustice and uselessness of a system that punishes altruistic acts).

347. 42 U.S.C. § 14,501(a)(1) (2000).

348. *Id.* §§ 14,501(a)(6), (a)(7)(A).

349. *Id.* §§ 14,501(a)(7)(B), (C).

350. *See supra* notes 25–29 and accompanying text (describing Environmental Defense Fund and EPA studies that recognized a lack of toxicity information available for chemicals used commercially in the United States).

The adverse effect of these information deficiencies on the national effort to regulate in the critical areas of public health and environmental protection is also well documented.<sup>351</sup> The federal government's capacity and resources to generate this information directly are extremely limited,<sup>352</sup> and its primary regulatory scheme for correction of this problem is considered in some quarters a "fundamental failure."<sup>353</sup> Thus, if the HPV Challenge Program and similar future collaborative efforts can generate such critically needed information efficiently and cost effectively, enormous public policy benefits necessarily will follow. Such benefits place encouragement of voluntary participation in the HPV Challenge Program and similar future efforts squarely within the national interest. Thus, national policymakers should consider a legislative response to the deterring effect of the liability risk assumed by HPV Challenge Program participants under the negligent undertaking principles of Section 324A.

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351. See *supra* notes 3–7 and accompanying text (citing several articles that address uncertainty and inefficiency in the environmental regulatory process due to lack of information).

352. See *supra* notes 48–49 and accompanying text (noting that limited state and federal budgets would constrain necessary toxicological investigations but that the private sector has adequate resources to conduct such investigations).

353. ENVTL. DEF. FUND, *supra* note 15, at 23.

