

# Nano-Torts on the Horizon: A Jack and Jill Story

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#### **Abstract**

To date, there has been little litigation surrounding nanotechnology generally, or nanosilver in particular. However, increasing criticism about the current state of scientific understanding of the potential health and environmental impacts of nanotechnology, combined with an emerging regulatory framework, raise the specter of litigation in the near term. In all likelihood, traditional principles of tort law will be used to frame and resolve disputes involving nanotechnology, meaning that consumer or other "no-injury" class actions are likely to emerge first. Although it is fair to say that most "nanotorts" are unlikely to proceed until a deeper understanding of nanotechnology and its potential risks to human health and the environment emerges, manufacturers of products incorporating nanotechnology should at least begin to anticipate litigation and take proactive steps to mitigate their legal exposure and understand their likely defenses, so that if and when litigation does emerge they are left holding more than just a proverbial "pail of water."

### I. Introduction

Nanotechnology has been hyped as "the next big thing" across industries—from clothing to consumer products to medical drugs and devices.<sup>1</sup> Simply defined, nanotechnology is the understand-

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<sup>&</sup>lt;sup>1</sup> Jordan Paradise et al., Developing Oversight Approaches to Nanobiotechnology: The Lessons of History, 37 J. L. MED & ETHICS, 543 (2009); Brian Wilhelmi, Analyzing the Laws, Regulations, and Policies Affecting FDA-Regulated Products: Nanosilver: A Test for Nanotech Regulation, 63 FOOD DRUG L. J. 89, 89 (2008); A.D. Maynard, Nanotechonology: The Next Big Things, or Much Ado About Nothing?, 51 Annals of Occupational Hygiene 1-12 (2006).

ing and control of matter at dimensions between approximately 1 and 100 nanometers, where unique physical properties enable novel applications of existing materials.<sup>2</sup> The potential for such novel applications has generated considerable excitement among scientists and manufacturers alike and, as a result, products incorporating nanotechnology have become increasingly common in our lives.<sup>3</sup>

Despite this wide and growing use of nanotechnology, or perhaps because of it, nanotechnology also has been hyped as "the next asbestos" in certain circles. Critics of nanotechnology have noted that the rapid proliferation of products containing nanomaterials, which are now widely sold to the public and disposed of in the environment,<sup>4</sup> has not kept up with the science that ensures its safety.<sup>5</sup> These same critics have raised red flags about the potential human health and environmental impacts of unfettered use of nanotechnology in our modern world.

One particular nanomaterial, silver nanoparticles, recently has come under scrutiny as potentially harmful to human health and the environment as a result of widespread exposure through consumer products.<sup>6</sup> Because of their enhanced physicochemical properties and biological activities, silver nanoparticles have significant potential for use in a variety of applications, including as an antimicrobial agent in medical devices and supplies.<sup>7</sup> Using silver nanoparticles as an antimicrobial agent is of particular interest to manufacturers of medical devices and supplies because microorganisms continue adapting to manufactured drugs, becoming resistant.<sup>8</sup> Yet while the use of silver compounds and ions as anti-infection agents predates penicillin,<sup>9</sup> the scientific and medical communities still do not have a complete understanding of how these particles behave at the nanoscale.<sup>10</sup>

Particularly because of the potential widespread use of this material, many scientists, regulators, and advocacy groups have noted that more research needs to be done to understand the safety

<sup>&</sup>lt;sup>2</sup> NATIONAL NANOTECHNOLOGY INITIATIVE ("NNI"), http://www.nano.gov/ (last visited Jun. 29, 2012).

<sup>&</sup>lt;sup>3</sup> James W. Mizgala & Michael Lisak, *Nanotechnology Manufacturer's Duty to Warn and potential Affirmative Defenses*, 2011 PROD. SAFETY & LIAB. REP. April 11 (2011); by 2008 there were over 500 nano-enabled products already in the market. Linda K. Breggin & John A. Pedergrass, *End of life regulation of nanotechnology*, (project on Emerging Nanotechnologies) (2008); Anil K. Suresh, et al., *Cytotoxicity Induced by Engineered Silver Nanocrystallites Is Dependent on Surface Coatings and Cell Types*, 28 LANGMUIR 2727, 2727 (2012).

<sup>&</sup>lt;sup>4</sup> International Center for Technology Assessment, *Citizen Petition for Rulemaking to the United States Environmental Protection Agency*, (hereinafter "petition") at 2, *available at* http://nanotech.law.asu.edu/Documents/2009/07/CTA\_nanosilver%20petition\_final\_5\_1\_08\_149\_4551.pdf.

<sup>&</sup>lt;sup>5</sup> See generally, Thabet M. Tolaymat et al., An Evidence-based environmental perspective of manufactured silver nanoparticle in syntheses and applications: A systematic review and critical appraisal of peer-reviewed scientific papers, 408 SCIENCE OF THE TOTAL ENVIRONMENT 999 (2010).

<sup>&</sup>lt;sup>6</sup> Suresh, *supra* note 3, at 2727.

<sup>&</sup>lt;sup>7</sup> Wilfred V. Espulgar & Gil Nanato C. Santos, *Antimicrobial Silver Nanomaterials Synthesized by HVPCG Technique*, 2 International Journal of Scientific & Engineering Research 1 (2011).

<sup>&</sup>lt;sup>8</sup> Espulgar, *supra* note 7, at 1.

<sup>&</sup>lt;sup>9</sup> Tolaymat, *supra* note 5, at 1000.

<sup>&</sup>lt;sup>10</sup> Rick Weiss, *Effects of Nanotubes May Lead to Cancer, Study Says*, WASH. POST, May 21, 2008, http://www.washingtonpost.com/wp-dyn/content/article/2008/05/20/AR2008052001331.html?hp (last visited June 28, 2012).

of silver nanotechnology.<sup>11</sup> Those who advocate for the discontinuance of this technology pending a better and more complete understanding cite previous "revolutionary" materials, such as asbestos, as to why we should proceed carefully, if at all.

Against this backdrop of innovation and criticism, this article considers the potential for litigation related to the use of silver nanoparticles. Part II of this Article provides a basic overview of the use of nanoparticles, particularly the use of silver nanoparticles in the medical field, and the debate that has emerged regarding the potential human health and environmental impacts of nanotechnology. Part III of this Article presents a case study as the basis for a discussion of the possible claims and defenses that could arise in litigation through theories of toxic tort and products liability. We conclude that most tort claims are unlikely to proceed until a deeper understanding of silver nanotechnology and its potential risks to human health and the environment emerges, but the growing general resistance to nanotechnology and the increasing regulatory attention should cause manufacturers of products incorporating nanotechnology at least to begin anticipating litigation and taking proactive steps to mitigate their legal exposure.

## II. Background

Nanotechnology encompasses science, engineering, and technology, and involves imaging, measuring, modeling, and manipulating matter at the nanoscale. Nanoparticles are not new to either nature or science; in fact, they are present in natural form in the environment and have been manipulated by humans for centuries. However, advances in other areas, such as microscopy, have recently provided scientists with the tools to understand and take advantage of materials at the nanoscale. These developments are potentially revolutionary, as it is well-established that the physical-chemical properties of a material—such as such as electrical conductivity, magnetic permeability, and chemical reactivity—change significantly at the nanoscale level.

One material that appears well-positioned for nanoscale innovation is silver. Although the traditional use of silver in the medical field for antimicrobial and antibacterial purposes has largely given way to antibiotics,<sup>17</sup> silver has re-emerged in nanoscale form as a material or coating for medical devices such as bladder catheters and prosthetic heart valve sewing rings.<sup>18</sup> The idea of using silver nanoparticles in medical devices stems from the desire to render the surface of such products

<sup>&</sup>lt;sup>11</sup> See, e.g., The Project on Emerging Nanotechnologies, Mission, http://www.nanotechproject.org/about/mission/ (last visited June 27, 2012).

<sup>&</sup>lt;sup>12</sup> NANOTECHNOLOGY Now, NANOTECHNOLOGY BASICS, http://www.nanotech-now.com/basics.htm (last visited June 29, 2012).

<sup>&</sup>lt;sup>13</sup> UNITED STATES NATIONAL NANOTECHNOLOGY INITIATIVE ("NNI"), http://www.nano.gov/nanotech-101/special (last visited June 28, 2012); *Nanoparticles - What are Nanoparticles?*, NEWS MEDICAL, http://www.news-medical.net/health/Nanoparticles-What-are-Nanoparticles.aspx (last visited June 28, 2012).

<sup>&</sup>lt;sup>14</sup> Nanoparticles - What are Nanoparticles?, NEWS MEDICAL, http://www.news-medical.net/health/Nanoparticles-What-are-Nanoparticles.aspx (last visited June 28, 2012).

<sup>&</sup>lt;sup>15</sup> NNI, *supra* note13.

<sup>&</sup>lt;sup>16</sup>Id.; See also U.S. FOOD AND DRUG ADMINISTRATION, NANOTECHNOLOGY TASK FORCE, NANOTECHNOLOGY at 10, (2007).

<sup>&</sup>lt;sup>17</sup> Wilhelmi, Analyzing the Laws, Regulations, and Policies Affecting FDA-Regulated Products: Nanosilver: A Test for Nanotech Regulation, supra note2, at 91.

<sup>&</sup>lt;sup>18</sup> *Id*.

impervious to germs.  $^{19}$  Achieving this in a safe manner potentially means saving thousands of lives and preventing millions of medical complications as the result of infection.  $^{20}$ 

Despite its potential life-saving benefits, the use of nanosilver particles in medical devices has not gone unnoticed or uncriticized, particularly in the wake of two high-profile studies that draw a potential link between exposure to nanoparticles and human health risks. The first of these studies, published in 2008, suggested that exposure to carbon nanotubes could cause mesothelioma—the same form of lung cancer that has been linked to asbestos exposure—in rodents.<sup>21</sup> The second study, which was published in the European Respiratory Journal in 2009, reported a relationship between exposure to nanoparticles and pleural effusions, pulmonary fibrosis, and granuloma in Chinese workers.<sup>22</sup>

The general resistance to nanotechnology from certain corners also has been fueled by growing regulatory attention. Developing a regulatory system to oversee nanotechnology generally, or specific nanotechnologies such as silver nanotechnology, is complicated because the potential scope of the technology is so broad and the range of products and processes to which it could be applied is expansive.<sup>23</sup> While government agencies have taken an increased interest in regulating nanotechnology, many have questioned whether the established regulatory methods for assessing the safety of materials are adequate for properly addressing the novel issues that nanotechnology poses.<sup>24</sup> For example, environmental agencies throughout the world are examining whether existing regulations can be applied to nanotechnology.<sup>25</sup> Proponents of nanotechnology contend that the existing regulations are adequate to ensure the safety of the technology and that the current use of nanotechnology is already is compliance with these regulations.<sup>26</sup> On the other hand, opponents express the concern that there is too much uncertainty in the ability of existing environmental protections to manage the challenges posed by a growing use of nanotechnology in various applications.<sup>27</sup>

Given the attention that nanotechnology is receiving, and the emerging regulatory framework, manufacturers and suppliers of products that incorporate nanotechnology should be thinking proactively about minimizing future litigation risk. References to the potential link between carbon nanotubes and lung cancer already are appearing on plaintiffs' lawyer websites.<sup>28</sup> While nanotechnology

<sup>&</sup>lt;sup>19</sup> Jack Rubinger, *Halting the Medical device to infection connection*, MANAGING INFECTION CONTROL 102, Jul. 2006.

<sup>&</sup>lt;sup>20</sup> This number only reflects the hospital acquired infections. Jack Rubinger, *supra* note 19.

<sup>&</sup>lt;sup>21</sup> James W. Mizgala & Michael Lisak, *Nanotechnology Manufacturer's Duty to Warn and potential Affirmative Defenses*, 2011 PROD. SAFETY & LIAB. REP. April 11 (2011); Asbestos is the common name for any variety of silicate materials that are fibrous in structure and are more resistant to acid and fire than other materials. The most common forms of asbestos disease are pleural plaques, asbestosis, lung cancer, and mesothelioma. Asbestosis is a chronic, prolonged lung disease that is caused by continuous inhalation of asbestos particles, ASBESTOS RECOURSE CENTER, http://www.asbestosresource.com/disease/ (last visited Jun. 29, 2012).

<sup>&</sup>lt;sup>22</sup> Y. Song, X. Li & X. Du, *Exposure to nanoparticles is related to pleural effusion, pulmonary fibrosis and granuloma,* 34 Eur. Respir. J.559 (2009), *available at* http://erj.ersjournals.com/content/34/3/559.full.pdf+html.

<sup>&</sup>lt;sup>23</sup> Paradise, Developing Oversight Approaches to Nanobiotechnology, supra note 1, at 543.

<sup>&</sup>lt;sup>24</sup> U.S. Food and Drug Administration, Nanotechnology Task Force, Nanotechnology at 13.

<sup>25</sup> Id. at16-21.

<sup>&</sup>lt;sup>26</sup> *Id*.

<sup>&</sup>lt;sup>27</sup> *Id*.

<sup>&</sup>lt;sup>28</sup> Orlyn "Skip" Lockard III, Nanotechnology litigation: winning the war before it starts, Nano Werk, http://www.nanowerk.com/spotlight/spotid=8676.php (last visited Jun. 29, 2012); Rick Weiss, Effects of Nanotubes May Lead to Cancer, Study Says, Wash. Post, May 21, 2008, http://www.washingtonpost.com/wp-dyn/content/article/2008/05/20/AR2008052001331.html?hp (last visited June 28, 2012); Lawyers and

nology presents novel issues, familiar principles of toxic tort, products liability, and environmental law likely will guide any resulting litigation.<sup>29</sup> Likewise, existing case law on familiar issues such as preemption in the drug and device arena is likely to come into play specifically in any litigation arising from the use of nanotechnology in the medical field.<sup>30</sup>

## **III. Case Studies and Analysis**

It remains unclear whether nanotechnology generally, or silver nanotechnology in medical applications specifically, ultimately will be shown to pose an increased risk to human health or the environment. But when there are possible health and safety concerns and regulatory activity, litigation is not far behind. Claims involving silver nanoparticles are likely to cover the full range of tort litigation. The risk of exposure extends both to the workplace, through direct inhalation or dermal contact, and to the general population, through consumer products and/or the environment.<sup>31</sup> This section first outlines possible claims and defenses that could arise in litigation from a toxic tort and products liability perspective. Second, it examines the possible claims and defenses that could arise from exposure of this product to the environment.

As a general matter, tort law requires a plaintiff to prove the existence of a "reasonably close causal connection between the conduct [of the defendant] and the [plaintiff's] injury."<sup>32</sup> While in a traditional tort case, a plaintiff satisfies the causation element by illustrating a cause and effect relationship,<sup>33</sup> in toxic torts cases, the long latency and scientific uncertainty of exposure-related diseases create the opportunity for "intervening causes to obscure any cause and effect relationship."<sup>34</sup> Toxic tort plaintiffs accordingly prove causation by establishing a causal nexus between a disease and a hazardous substance.<sup>35</sup> This is accomplished with scientific data and expert testimony,<sup>36</sup> such as an epidemiological study that analyzes patterns of disease in the human population.<sup>37</sup> An epidemiologist compares the incidence of disease in two groups: those exposed and those not exposed to a toxic substance in order to determine the "excess risk" created by the substance.<sup>38</sup> In the context of nanotechnology, no "signature disease" has been associated with exposure to nanoparti-

Settlements, http://www.lawyersandsettlements.com/lawsuit/nanotubes-asbestos-like-risks.html (last visited Jun. 29, 2012).

- <sup>29</sup> Lockard, *supra* note 28.
- <sup>30</sup> In re Heart Valve Litig. v. St. Jude Med., 2005 Tex. App. LEXIS 5117 (Tex. App. Houston 1st Dist. June 30, 2005).
- <sup>31</sup> Environmental exposures from release can be associated with production, use, and end-of-life processes such as landfilling, incineration, and recycling.
- <sup>32</sup> PROSSER AND KEETON ON THE LAW OF TORTS § 38, at 239 (5th ed. 1984); See also Developments in the Law -- Toxic Waste Litigation, 99 HARV. L. REV. 458, 1630-31 (1986) [hereinafter "Developments in the Law"].
- <sup>33</sup> See David Rosenberg, The Causal Connection in Mass Exposure Cases: A "Public Law" Vision of the Tort System, 97 HARV. L. REV. 851, 851 n.2 (1984); Developments in the Law, supra note 32, at 1630-31; Ann Taylor, Public Health Funds: The Next Step in the Evolution of Tort Law, 21 B.C. ENVTL. AFF. L. REV. 753, 765-66 (1994).
- <sup>34</sup> Taylor, *supra* note 33, at 765-76; Rosenberg, *supra* note 33, at 851 n.2.
- <sup>35</sup> *Developments in the Law, supra* note 32, at 1618.
- <sup>36</sup> Amy B. Blumenberg, *Medical Monitoring Funds: The Periodic Payment of Future Medical Surveillance Expenses in Toxic Exposure Litigation*, 43 HASTINGS L.J. 661, 661 (1992).
- <sup>37</sup> See Developments in the Law, supra note 32, at 1231 (describing epidemiological studies as "the only useful studies having any bearing on causation" questions in toxic exposure cases).
- <sup>38</sup> *Id.*

cles in the way that, for example, mesothelioma is linked to asbestos exposure. This poses a challenge for plaintiffs who may have an injury, but cannot link that injury to a specific nanoparticle exposure.

To illustrate the possible litigation exposure to a manufacturer incorporating nanotechnology in its products, imagine that Jack Nanowitz, an average American, falls down and suffers a gash in his head. Jack goes up the hill to the local pharmacy and, after analyzing his choices, picks up a shiny bandage package manufactured by Acme Corporation, a local manufacturer, which promises superior results due to its incorporation of anti-bacterial nanosilver technology. Jack buys and uses the bandage without noticing any unusual results. Over a year later, Jack is at home watching television and has completely forgotten about his fall. He sees a commercial in which a lawyer claims that silver nanoparticles have been linked to health risks and encourages anyone who has bought a product incorporating silver nanoparticles to call his law office. Although Jack is in good health and has never been told by a physician that he is at any increased risk of disease, Jack calls the number on his screen and speaks with the lawyer, who convinces him to sue Acme as the representative plaintiff in a class action. Jack also tells the girl next door, Jill McNano, about the commercial. Jill, who also had purchased and used Acme Corporation's nanosilver bandages on one occasion, suffers from a condition known as Argyria, in which exposure to silver can cause a person's skin to become blue. Although there is no established connection between exposure to Acme's nanosilver bandages and Argyria, Jill retains her own lawyer to proceed with an individual claim for personal injury.

#### A. Jack's Putative Class Action

#### 1. Consumer Protection Claims

The most likely claim for Jack Nanowitz to advance claims against Acme on behalf of himself and all similarly situated plaintiffs is a claim under one or more state consumer protection acts. Such claims are likely to be brought in the form of a class action because the individual damages to each claimant are usually relatively trivial (*e.g.*, the marginal difference in purchase price of the product at issue).<sup>39</sup> Indeed, consumer class actions typically do not allege any personal injury, but seek only economic damages in the form of a refund of the product purchase price on the basis that, if the consumer had known of the actual risks, he or she would not have purchased the product. In effect, such claims allege that consumers "overpaid" for the product. Seeking only an economic remedy avoids many of the difficulties of proving injury causation,<sup>40</sup> and many state consumer protection statues do not require complex proof of elements such as "actual reliance" that are required to support a claim of fraud.<sup>41</sup> In fact, these claims commonly are referred to as "fraud light" claims.

Each state has consumer protection or deceptive trade practices laws that set out the requirements for maintaining a consumer claim, with slight variations across jurisdictions. Under Illinois law, for example, Jack might allege that Acme's labeling of the bandage was deceptive, that it intended such deception by selling it to consumers, and that Jack did not obtain what he bargained for because he wouldn't have bought the product if he knew the possible (albeit unproven) risks of exposure to silver nanoparticles.<sup>42</sup> In the class context, Jack could assert this claim on behalf of all Il-

<sup>&</sup>lt;sup>39</sup> A class action is a civil court procedure under which one party, or a group of parties, may sue as representatives of a larger class. To proceed, the court must permit the class action. If the class action is certified, members of the class must be given notice, and the opportunity to exclude themselves from the proceeding. Only the class members who opt out are not bound by the judgment in the case.

<sup>&</sup>lt;sup>40</sup> James W. Mizgala & Michael Lisak, *Nanotechnology Manufacturer's Duty to Warn and potential Affirmative Defenses*, 2011 PROD. SAFETY & LIAB. REP. April 11 (2011).

<sup>&</sup>lt;sup>41</sup> *Id.* 

<sup>42 815</sup> ILCS 505/1-11.

linois residents who purchased the Acme nanosilver bandages, claiming that Acme failed to label the product to warn about the possible adverse latent health risk of nanosilver, and thus misrepresented the risk of injury to users of the product.

If Jack succeeded in obtaining certification of a consumer class action, Acme's defense would focus on the risks and benefits of its bandages. Jack is not currently injured, the bandage did what it was intended to do (covered Jack's wound and promoted healing), and Jack did not suffer any infection (whether or not attributable to the use of silver nanoparticles).

Acme also could challenge Jack's "no-injury" consumer class action on the basis that the class members had not suffered any damages. In fact, while Jack may argue on behalf of himself and class members that he would not have bought the nanosilver bandages if he had appreciated the potential risk, he likely would have purchased other bandages at a comparable price to treat his head injury. Thus, Acme could argue that a refund of the purchase price, or at least the full purchase price, would be inappropriate since Jack would have spent the same or a comparable amount even in the absence of Acme's representations about its product.

#### 2. Medical Monitoring

Another approach that Jack may take in the class context is to assert a claim for "medical monitoring." Although plaintiffs attempt to pursue claims for medical monitoring routinely, both in individual cases and in putative class actions, medical monitoring claims are a lightning rod for controversy. A claim for medical monitoring seeks compensation for the costs of periodic medical examination to assess for a disease that is not yet manifest but may occur in the future as the result of an alleged toxic exposure. Typically, a medical monitoring claim requires a plaintiff to show exposure to a toxic substance, resulting in an increased risk of a serious disease, illness, or injury, for which early detection can be achieved through testing and that such testing is beneficial. Many courts have required plaintiffs to demonstrate a physical injury in order to receive medical monitoring damages. A minority of jurisdictions, however, recognize a claim for medical monitoring damages even when no injury is present.

Medical monitoring claims involving silver nanoparticles are most likely to surface in the jurisdictions that do not require a physical injury, because no "signature disease" has been identified in connection with nanosilver exposure. However, while there is little current data to suggest that nanosilver poses any risk to human health, a long latency period has yet to be ruled out. Therefore, even if Jack cannot establish a present physical injury, he may make a claim that he and the other putative class members are at risk of developing an injury in the future.

#### **B.** Jill's Personal Injury Claims

In her personal injury action, Jill McNano is likely to claim that, under common law principles of negligence, Acme owed her a duty to ensure that its product was safe, Acme breached that duty

<sup>&</sup>lt;sup>43</sup> See Merry v. Westinghouse Electric Corp., 684 F. Supp. 847 (M.D. Pa. 1988).

<sup>&</sup>lt;sup>44</sup> See, e.g., Bradley v. Armstrong Rubber Co., 130 F.3d 168, 176 (5th Cir. 1997) ("The requirements of permanent and physical injury to property ensure that this remedy does not open the floodgates of litigation by every property owner who believes that a neighbor's use will injure his property."); Bartleson v. United States, 96 F.3d 1270, 1275 (9th Cir. 1996) ("Damages for diminution in property value due to stigma have been recognized by the California courts in cases of permanent nuisance."); Santa Fe Partnership v. ARCO Products Co., 54 Cal. Rptr. 2d 214, 217 (Ct. App. 1996), review denied, 1996 Cal. LEXIS 5727, at 1 (Cal. Oct. 2, 1996).

<sup>&</sup>lt;sup>45</sup> See, e.g., Hansen v. Mountain Fuel Supply Co., 858 P.2d 970. 977-78 (Utah 1993); Abuan v. General Elec. Co., 3 F.3d 329, 334 (9th Cir. 1993); Cook v. Rockwell Int'l Corp., 755 F. Supp. 1468, 1477 (D. Colo. 1991); In re Paoli Railroad Yard PCB Litigation, 35 F.3d 717 (3d Cir. 1994).

through some negligent act or omission, and such breach was the proximate cause of Jill's Argyria.<sup>46</sup> Jill's case will turn on whether she is able to show that Acme's alleged breach of duty was the result of its failure to adequately test its product in the face of known potential harms. Because some existing research suggests that silver nanoparticles may be toxic under certain circumstances,<sup>47</sup> Jill would likely use the information from these existing studies to create a theme in which she portrays Acme as a malicious corporation that used a vulnerable population as guinea pigs, and that even though Acme did not fully understand how its product would behave,<sup>48</sup> it prioritized profits over safety.<sup>49</sup>

Jill also is likely to assert a claim against Acme for strict products liability. Much like negligence, a claim for strict products liability will require Jill to prove that Acme had a duty to supply a safe product and that it breached that duty causing Jill to develop Argyria, entitling her to recover damages. However, in contrast to a negligence claim, under a strict products liability theory, Jill does not need to show that Acme's alleged breach of duty is the result of any negligent action. <sup>50</sup> Evidence that the product was dangerous or defective—due to a defect in its manufacture, design, and/or warnings—and that defect caused an injury is enough to establish liability.

In our hypothesized personal injury action, Jill may find the most traction in a strict liability failure to warn claim. Although a product is designed, manufactured, and assembled to specification, a manufacturer or seller may be liable if the product has a potential for injury that is not readily apparent to the user and carries no warnings of the risk, or it lacks appropriate instructions. Broadly speaking, manufacturers of a product may be liable for defects if they failed to use reasonable care in warning potential users of risks that the that they are unlikely to appreciate on their own. Manufacturers may also be exposed to liability when the foreseeable risks of harm caused by the product could have been reduced or avoided through reasonable warnings. In this type of case, the main questions to resolve are whether there was a duty to warn, and if the manufacturer appropriately discharged any alleged duty to warn end-users. Here, Jill would argue that Acme knew, or should have known based on the attention that has been given to nanotechnology, of the potential risks of silver nanoparticles, triggering a duty to adequately warn unsuspecting end-users of those risks.

With respect to both her negligence and strict products liability claims, Jill will have the most difficulty proving that Acme's product caused her condition. Accurate product identification will be

<sup>&</sup>lt;sup>46</sup> Squires v. Luckey Farmers, Inc., 2004 Ohio 4919, P27 (Ohio Ct. App., 2004) elements of negligence; MEDSCAPE REFERENCE, http://emedicine.medscape.com/article/1069121-overview (last visited Jun. 19, 2012).

<sup>&</sup>lt;sup>47</sup> Scott DeVries et al., *Forestalling Nanotechnology Litigation*, 31 GENETIC ENGINEERING & BIOTECHNOLOGY NEWS, Jan. 1, 2011.

<sup>&</sup>lt;sup>48</sup> Because of how particles behave at the nano level, it is uncertain at what level, if any, they become toxic.

<sup>49</sup> Since Acme is most likely to be purchasing its silver nanoparticles from a third-party supplier, Jill also may name that third-party supplier as a defendant. Under the bulk supplier doctrine, however, the third-party supplier will have fulfilled its duty to warn if it conveyed to Acme sufficient information concerning any pertinent risks of silver nanoparticles. The bulk supplier doctrine allows a supplier of raw materials to satisfy its duty to warn where the supplier has reasonably relied on an intermediary to transmit warnings to the end user. The logic behind this theory is that the intermediary is better positioned to assess the risks posed by the product it ultimately places on the market.

<sup>&</sup>lt;sup>50</sup> Restatement § 402A provides for strict liability in tort for anyone "who sells a product in a defective condition unreasonably dangerous to the user or consumer or his property." RESTATEMENT THIRD OF TORTS §§ 3-6 (2005).

<sup>&</sup>lt;sup>51</sup> James W. Mizgala & Michael Lisak, *Nanotechnology Manufacturer's Duty to Warn and potential Affirmative Defenses*, 2011 PROD. SAFETY & LIAB. REP., April 11.

<sup>&</sup>lt;sup>52</sup> *Id.* 

her first hurdle: unless she can prove a single use or unwavering brand loyalty, Jill may not be able to pinpoint the exact manufacturer of the nanosilver bandages that allegedly caused her injury. Depending on the jurisdiction, failure of product identification can be dispositive, or at the very least a significant factor in a manufacturer's defense. In some states such as Ohio, where theories of market share and alternative liability are not accepted,<sup>53</sup> legal liability cannot attach absent a proven connection between the defendant's specific product or act and the plaintiff's injury.<sup>54</sup>

If Jill can establish product identification, she also will need to prove that Acme's product was capable of causing her alleged injury (general causation) and actually did cause her injury (specific causation). In defense, Acme will need to present studies and experts to dispute the claim that silver nanoparticles in general can cause Argyria. If Acme is unable to challenge general causation, it still can challenge specific causation by arguing that exposure to its product alone was insufficient to cause Jill's injuries—i.e., that exposure to its product was not a substantial factor in causing Jill's injuries—and/or that Jill's injury was caused by exposure to another substance or a product manufactured by someone else.

Acme also may be able to rely on specific defenses arising from its compliance with certain regulations, such as the FDA's premarket approval process. Under the presented scenario, if Acme was subject to and complied with the FDA's process in releasing its nanosilver bandage to the market, it could assert that such compliance "preempted" Jill's claims.<sup>55</sup>

## C. Environmental and Property Claims

Now assume that Jack and Jill, having failed in bringing their other claims but not yet litigation weary, realize that their neighborhood is situated just downstream from the Acme plant where the nanosilver bandages are manufactured. Jack and Jill contact their friends and neighbors, many of whom report having observed increased numbers of dead or dying fish in the pond at the center of their village that is fed both by groundwater and by the stream that passes by the Acme plant. Jack and Jill organize a citizen action group, which hires a consultant to advise the villagers of the potential environmental impacts of the nanosilver operations at Acme's plant on their village. The consultant hypothesizes that nanosilver from the Acme plant is being released into the water supply while machinery is being cleaned at night and, as a result, the antimicrobial properties of the nanosilver particles have upset the ecosystem in the village pond and elsewhere. Jack and Jill immediately call their lawyers to determine whether they have any environmental or property claims.

#### 1. Trespass and Nuisance

Based on their own observations and the hypothesis of their consultant, Jack, Jill, and their citizen action group are likely to consider claims in the nature of trespass and nuisance. Trespass is generally defined as an interference with the plaintiff's interest in the exclusive possession of property. Traditionally, trespass was reserved for tangible invasions of property. Modern tort law, however, has expanded the theory of trespass to include contamination, pollution, and toxins released into the air and water. 57

<sup>&</sup>lt;sup>53</sup> The Ohio Supreme Court has categorically rejected the application of the market share liability approach in products liability action.

<sup>&</sup>lt;sup>54</sup> See, e.g., Moeller v. Garlock Sealing Techs., LLC, 660 F.3d 950, 953-54 (6th Cir. Ky. 2011).

<sup>&</sup>lt;sup>55</sup> See, e.g., In re Heart Valve Litig. v. St. Jude Med., 2005 Tex. App. LEXIS 5117 (Tex. App. Houston 1st Dist. June 30, 2005) (nothing that the FDA's premarket approval preempts negligence claims).

<sup>&</sup>lt;sup>56</sup> RESTATEMENT (SECOND) OF TORTS § 157, e.g.

<sup>&</sup>lt;sup>57</sup> CATHY J. OKRENT, TORTS AND PERSONAL INJURY LAW 181-87 (4th ed. 2010).

Similar to a trespass, a nuisance is an interference with the use or enjoyment of property.<sup>58</sup> The difference between a nuisance and trespass is that a trespass requires physical invasion of property while nuisance claims need to show only unreasonable and substantial interference with the use of property. In pollution cases, however, it is often difficult to distinguish between the two claims and they are often brought together.<sup>59</sup>

Today's toxic tort trespass and nuisance allegations often involve substances that cannot be seen without a microscope. For example, in the landmark case *Martin v. Reynolds Metals Company*, 60 the defendant operated an aluminum reduction plant that released fluoride particles invisible to the naked eye. 61 The fluoride collected on the plaintiff's property, poisoned cattle, and made the land unsuitable for grazing. 62 Although the intrusion was by microscopic particulate matter, the impact was demonstrable and affected the plaintiff's exclusive possession of the land. 63

Trespass and nuisance claims involving nanosilver likely will follow the paradigm established by *Martin*. Indeed, some critics have posited that the positive effects of using silver nanotechnology may be overshadowed by the potential negative environmental impact. The concern is that the increasing use of silver nanoparticles<sup>64</sup> also increases the risk that this material will be released into sewage lines and wastewater treatment facilities, ultimately ending up in rivers, streams, and lakes where it can put the ecosystem at risk.<sup>65</sup> In our hypothetical case, as in personal injury claims, Acme could challenge causation. In this situation, however, the challenge may be more difficult. While few, if any, epidemiological studies have been able to establish a causal nexus between nanosilver and disease in humans, there is some evidence to suggest that nanosilver's antimicrobial properties could have environmental effects.<sup>66</sup> The defendant will have to be more specific by arguing that the nanosilver could not have caused the particular harm alleged. Moreover, as nanosilver has only been shown to be toxic in high quantities, a causation challenge should argue that the concentration is not high enough to damage the environment.

#### 2. Property value/stigma damages

Jack, Jill, and their citizen action group also may allege and pursue claims based on alleged diminution in property values or "stigma damages" based on the nanosilver contamination in the village groundwater and pond. In some jurisdictions, courts have recognized a cause of action that allows property owners to recover the diminution in property values resulting from negative perception that accompanies the contamination of their properties.<sup>67</sup> The damages in these cases are often referred to as "stigma damages." As one might imagine, a contaminated property would be less ap-

<sup>&</sup>lt;sup>58</sup> RESTATEMENT (SECOND) OF TORTS § 821D.

<sup>&</sup>lt;sup>59</sup> ROGER E. MEINERS, THE LEGAL ENVIRONMENT OF BUSINESS, 449 (10th ed. 2009)

<sup>&</sup>lt;sup>60</sup> Martin v. Reynolds Metal Co., 342 P.2d 790 (Or. 1959).

<sup>&</sup>lt;sup>61</sup> *Id*.

<sup>62</sup> Id.

<sup>63</sup> Id.

<sup>&</sup>lt;sup>64</sup> Nanoparticles - What are Nanoparticles?, NEWS MEDICAL, http://www.news-medical.net/health/Nanoparticles-What-are-Nanoparticles.aspx (last visited June 28, 2012).

<sup>65</sup> See, e.g., http://www.sciencedaily.com/releases/2008/04/080429135502.htm.

<sup>&</sup>lt;sup>66</sup> See, e.g., Ofek Bar-Ilan et al., Toxicity Assessments of Multisized Gold and Silver Nanoparticles in Zebrafish Embryos, 5 SMALL 1897–1910 (2009).

<sup>&</sup>lt;sup>67</sup> See generally E. Jean Johnson, Environmental Stigma Damages: Speculative Damages in Environmental Tort Cases, 15 UCLA J. ENVTL. L. & POL'Y 185 (1997).

pealing to prospective buyers and thus less valuable to an owner who wants to sell the property. But stigma damages are not based on the harm actually caused by contamination. Instead, stigma damages are determined by what third parties think about the contaminated property, regardless of whether their thoughts are factual.<sup>68</sup> Courts that accept a cause of action for stigma damages have been receptive to the claim when a plaintiff's land has been contaminated causing a long-term negative perception of the property.<sup>69</sup> These damages are available even if there is no substantial physical harm to the land, but the negative perception has caused depreciation or when the damage is only temporary if the negative perception persists.<sup>70</sup>

In Jack and Jill's case, even if the nanosilver had no real harmful effect on their property, they may claim that a perception of contamination has diminished their property values, whether or not their property actually was affected by nanosilver particles. Such claims may be particularly attractive in the context of nanotechnology litigation because, unlike other theories of recovery, they do not necessarily require the plaintiff to establish that the nanosilver has any particularly deleterious effects. A negative perception surrounding nanosilver contamination alone may be enough to recover damages.

Acme's defense to "stigma damages" claims is likely to be fact intensive and involve significant reliance on expert opinions, focusing on whether each plaintiff's property has in fact been contaminated, whether any such contamination has caused permanent or ongoing damage to the property that cannot be easily remediated, and whether the plaintiff has actually suffered any diminution in property values and, if so, whether such diminution can be attributed to the alleged nanosilver contamination.<sup>71</sup>

#### **IV. Conclusion**

To date, there has been little litigation surrounding nanotechnology generally, or nanosilver in particular. However, increasing criticism about the current state of scientific understanding of the potential health and environmental impacts of nanotechnology, combined with an emerging regulatory framework, raise the specter of litigation in the near term. In all likelihood, traditional principles of tort law will be used to frame and resolve disputes involving nanotechnology, meaning that consumer or other "no-injury" class actions are likely to emerge first. Although it is fair to say that most "nanotorts" are unlikely to proceed until a deeper understanding of nanotechnology and its potential risks to human health and the environment emerges, manufacturers of products incorporating nanotechnology should at least begin to anticipate litigation and take proactive steps to mitigate their legal exposure and understand their likely defenses, so that if and when litigation does emerge they are left holding more than just a proverbial "pail of water."

<sup>&</sup>lt;sup>68</sup> *Id*.

<sup>&</sup>lt;sup>69</sup> See, e.g., Adams v. Star Enterprise, 51 F.3d 417, 422-23 (4th Cir. 1995); Rudd v. Electrolux Corp., 982 F. Supp. 355, 369 (M.D.N.C. 1997) (need actual interference [cause] substantial enough to reduce market value [effect]); Miller v. Janiski, 705 S.W.2d 442 (1986) (depreciation in property value standing alone does not make the activity constitute a nuisance which should be abated or which can form the basis of an award of damages; Kan. Gas Serv. Co., 285 Kan. 33, 48 (Kan. 2007).

<sup>&</sup>lt;sup>70</sup> Johnson, *supra* note 67, at 241.

<sup>&</sup>lt;sup>71</sup> See, e.g., John C. McMeekin II and John Ehrmann, Not in My Backyard—Litigating Stigma Damages and Diminution of Property Claims in Environmental Class Actions, DRI Toxic Tort & Environmental Law Newsletter, Volume 1, Issue 4 (July 18, 2012).