

# Examples of Recent EPA Regulation of Nanoscale Materials Under the Toxic Substances Control Act

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## ABSTRACT

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This article provides a summary of recent (2008-2009) regulatory efforts by the U.S. Environmental Protection Agency under the Toxic Substances Control Act concerning nanoscale materials. These efforts include entering into two consent orders with a manufacturer of carbon nanotubes; issuing four significant new use rules for two siloxane-based nanoparticles and two carbon nanotubes (and then withdrawing the latter two); intimating that new testing and data collection rules will be implemented for certain nanoscale materials; and proposing and/or requiring acute toxicity rat inhalation testing regimes in certain instances. The authors explain these developments in detail and then provide some initial strategic and legal considerations for businesses attempting to navigate this emerging regulatory thicket.

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## I. Introduction

After several years of speculating whether, when, and how the U.S. Environmental Protection Agency (“EPA”) might choose to specifically regulate certain nanoscale materials under the Toxic Substances Control Act of 1976 (“TSCA”),<sup>1</sup> the nanotechnology industry was provided with several concrete examples in the fall of 2008 and the first half of 2009. Almost contemporaneously with publishing a federal register notice<sup>2</sup> confirming that it considers carbon nanotubes new chemical substances under TSCA, EPA entered into two broad TSCA Section 5(e)<sup>3</sup> consent orders with a carbon nanotube manufacturer.<sup>4</sup> Shortly thereafter, EPA also issued two proposed significant new

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<sup>1</sup> Toxic Substances Control Act of 1976, 53 U.S.C. §§ 2601-92.

<sup>2</sup> EPA Notice, 73 Fed. Reg. 64946 (Oct. 31, 2008).

<sup>3</sup> 53 U.S.C. § 2604(e). See generally <http://www.epa.gov/opptintr/newchems/pubs/cnosnurs.htm> (describing EPA Consent Orders).

<sup>4</sup> Office of Pollution Prevention and Toxics, Environmental Protection Agency, Regulation of a New Chemical Substance Pending Development of Information, re: Premanufacture Notice No. P-08-0177, Consent Order and Determinations Supporting Consent Order, available at <http://www.nanolawreport.com/EPA%20Premanufacture%20Notice%20Number%20P-08-0177.pdf> (providing a copy of the first consent order for a multi-walled carbon nanotube). See also Press Release, Thomas Swan Gains Second Carbon Nanotube EPA Approval, <http://www.thomas->

use rules (“SNUR”) under TSCA Section 5(a)(2)<sup>5</sup> covering siloxane modified silica and alumina nanoparticles.<sup>6</sup> Finally, in June 2009, EPA issued two proposed SNURs for multi-walled and single-walled carbon nanotubes which it then withdrew in August 2009.<sup>7</sup> We examine each regulatory action, provide commentary, and make some observations regarding the inhalation testing regime proposed by EPA in conjunction with the consent orders and SNURs.

## II. TSCA Background

TSCA is a complex regulatory scheme that provides EPA with comprehensive authority to regulate virtually all chemical substances.<sup>8</sup> At its core, TSCA Section 8 establishes an inventory of all existing chemical substances manufactured, used, processed, or imported into the U.S. If a chemical substance is listed on the inventory, TSCA Section 6 provides EPA with full authority to prohibit, limit its manufacture, or restrict processing or distribution if the chemical substance is found to present an unreasonable risk of injury to health or the environment. If, on the other hand, a chemical substance is not listed on the TSCA inventory, it is considered a “new chemical substance” and TSCA Section 5 requires premanufacturing notice (“PMN”) and approval at least ninety days in advance of its production or import. Upon reviewing the PMN, EPA may limit or ban production of the new chemical substance if it finds it poses an unreasonable risk to human health or the environment. Additionally, if the chemical substance is considered a “significant new use” of an existing chemical substance already on the TSCA inventory, special notice and approval is also required under Section 5, and a significant new use rule may be promulgated for the chemical substance. Finally, EPA has broad authority under TSCA to require health and safety testing of new chemical substances or significant new uses of existing chemical substances when it believes that it has insufficient data or information necessary to evaluate the substance’s safety.

Over the past few years, there has been a significant debate regarding whether nanoscale materials should be treated as existing chemical substances, new chemical substances, or significant new uses of existing chemical substances for purposes of the TSCA inventory and any subsequent regulation. A core issue in this debate has been whether—because of their small size and sometimes unique properties—EPA should treat all nanoscale materials as “new” chemicals under TSCA and subject them to TSCA’s premanufacturing notice and approval requirements even if their bulk counterparts are already on the inventory (and thus presumed safe under specified conditions). Some argue this is the most conservative, precautionary approach given the current environmental, health, and safety (“EHS”) uncertainty surrounding exposure to certain nanoscale materials in some circumstances. An important sibling issue is whether the use of nanoscale

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*swan.co.uk/ASP/News\_Events/News\_Events.asp?Type=News&ID=187&Arc=&DLT=Thomas%20Swan%20Gains%20Second%20Carbon%20Nanotube%20EPA%20Approval* (last visited July 15, 2009).

<sup>5</sup> 53 U.S.C. § 2604(a)(2). See generally *http://www.epa.gov/opptintr/newchems/pubs/cnosnurs.htm* (describing EPA Significant New Use Rules).

<sup>6</sup> EPA Notice, 73 Fed. Reg. 65751-52 (Nov. 5, 2008), PMN Number P-05-673 and PMN Number P-05-687.

<sup>7</sup> Significant New Use Rules on Certain Chemical Substances, 40 C.F.R. §§ 721.10154-55 (2009).

<sup>8</sup> Certain substances regulated under other statutes are generally excluded from TSCA, including, among others, food, drugs, cosmetics and pesticides. Summary of the Toxic Substances Control Act, *http://www.epa.gov/lawsregs/laws/tsc.html* (last visited Nov., 2008). TSCA also provides exceptions/exemptions for chemical substances produced in low volumes or for research and development purposes, 53 U.S.C. § 2604(h)(3).

materials constitutes a “significant new use” of an existing chemical substance which also triggers TSCA’s premanufacturing notice and approval requirements.<sup>9</sup>

### III. Carbon Nanotube Federal Register Notice

In early 2008, EPA took a large step towards clarifying its approach to these issues by publishing a paper explaining its treatment of nanoscale substances under TSCA as “new” versus “existing” chemicals.<sup>10</sup> EPA’s position was consistent with many predictions: EPA did not consider nanoscale materials “new” substances just because of their diminutive size—they must have a distinct molecular identity that is not shared with any other chemical on TSCA’s existing chemical substance inventory before they are considered “new.”<sup>11</sup> In reaching its position, EPA explained that the term “chemical substance” is defined as “any organic or inorganic substance of a particular molecular identity,” and that a “molecule” is defined as the smallest amount of matter retaining all of its same chemical properties.<sup>12</sup> Therefore, EPA reasoned that if a nanoscale material has the same molecular identity as its bulk counterpart, it is an “existing,” not “new,” chemical substance.<sup>13</sup>

Formalizing its position in October 2008, EPA published its *Federal Register* Notice, “Toxic Substances Control Act Inventory Status of Carbon Nanotubes.”<sup>14</sup> The crux of the Notice is that “EPA generally considers CNTs to be chemical substances distinct from graphite or other allotropes of carbon listed on the TSCA inventory. Many CNTs may therefore be new chemicals under TSCA section 5.”<sup>15</sup> Again, this should not be surprising given EPA’s prior statements. EPA, however, also took the unusual step of untangling some of the confusion it had created around the issue by explaining that:

Some [prior] misunderstanding may be the result of an EPA communication to a chemical manufacturer a number of years ago pertaining to a substance the Agency now considers to be a carbon nanotube material. EPA’s initial response, which was specific to that inquiry and based upon the information presented at the time, was that the material was already on the TSCA Inventory. EPA has since notified that manufacturer that a PMN is required for that carbon nanotube material. Nonetheless, the Agency understands that the earlier communication may have been misunderstood by some companies as possible indication that all CNTs may be equivalent to other allotropes of carbon for purposes of the TSCA Inventory.<sup>16</sup>

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<sup>9</sup> Under the applicable statute, relevant factors in this consideration are: (i) the projected volume of manufacturing and processing of a chemical substance, (ii) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance, (iii) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and (iv) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance, 15 U.S.C. § 2604(a)(2).

<sup>10</sup> TSCA Inventory Status of Nanoscale Substances — General Approach Jan. 23, 2008, <http://www.epa.gov/oppt/nano/nmsp-inventorypaper2008.pdf>.

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

<sup>14</sup> EPA Notice, 73 Fed. Reg. 64946 (Oct. 31, 2008).

<sup>15</sup> *Id.*

<sup>16</sup> *Id.*

Finally, EPA indicated that it was only giving manufacturers a few months to come into compliance and file PMNs for carbon nanotubes: “[s]ome time after March 1, 2009, EPA anticipates focusing its compliance monitoring efforts to determine if companies are complying with TSCA section 5 requirements for carbon nanotubes.”<sup>17</sup>

#### IV. Carbon Nanotube Consent Orders

Once a PMN is submitted to EPA as required under TSCA, several outcomes are possible. One outcome may be the negotiation of a TSCA Section 5(e) consent order between EPA and the submitter.<sup>18</sup> Section 5(e) “provides the EPA with the authority to regulate new substances pending development of health and environmental effects data based on either the potential risk presented by the substance . . . or the potential for substantial production volume and substantial or significant human exposure or substantial environmental release.”<sup>19</sup> EPA can determine that use under certain specific conditions and with agreed precautions would not pose an unreasonable risk, but that use under other conditions may do so.<sup>20</sup> In such cases, EPA may develop a consent order based on a finding of potential unreasonable risk or substantial exposure.<sup>21</sup> These findings may be based either on information about the chemical substance itself, or its close “analogs” showing that it can pose problems, or on inadequacy of the information available to EPA.<sup>22</sup> Risk-based consent orders typically contain requirements regarding toxicity or environmental fate testing by a certain production volume, worker personal protective equipment, new chemical exposure limits, hazard communication, distribution, release to water, other disposal options, and record keeping.<sup>23</sup>

In September 2008, Thomas Swan & Co. (“Swan”) entered into a consent order with EPA for one of Swan’s multi-walled carbon nanotube (“MWCNT”) products.<sup>24</sup> Shortly thereafter, Swan and EPA entered into a second consent order regarding one of Swan’s single-walled carbon nanotube (“SWCNT”) products. The MWCNT consent order is the first known pertaining to nanomaterials and was distributed in redacted form by EPA. The SWCNT was not publicly circulated, but appears to contain the same terms as the MWCNT order.

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<sup>17</sup> *Id.*

<sup>18</sup> Consent Orders and Significant New Use Rules (SNURS), <http://www.epa.gov/opptintr/newchems/pubs/cnosnurs.htm> (last visited Nov., 2008).

<sup>19</sup> TSCA 5(e) Exposure-Based Policy: Criteria, <http://www.epa.gov/oppt/newchems/pubs/expbased.htm> (last visited Nov., 2008).

<sup>20</sup> Consent Orders, *supra* note 19; *see also* Making a Finding on Unreasonableness of Risk, <http://www.epa.gov/opptintr/newchems/pubs/unrerisk.htm> (last visited Nov., 2008) (“The term “unreasonable risk” is not defined in the . . . TSCA. The legislative history, however, indicates that unreasonable risk involves the balancing of the probability that harm will occur and the magnitude and severity of that harm against the effect of a proposed regulatory action on the availability to society of the expected benefits of the chemical substance. In the context of the New Chemicals Program, EPA considers unreasonableness of risk both in the context of individual chemical substances and in considering whether to exempt categories of chemical substances.”).

<sup>21</sup> Consent Orders, *supra* note 19.

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*

<sup>24</sup> EPA, Consent Order and Determinations Supporting Consent Order, (redacted version) available at <http://www.nanolawreport.com/EPA%20Premanufacture%20Notice%20Number%20P-08-0177.pdf>.

The basis for the Swan consent order is set out in its “risk assessment”<sup>25</sup> and “conclusions of law”<sup>26</sup> sections. EPA begins by outlining its risk assessment “predictions” regarding the “probable” toxicity, human exposure and environmental release of nanotubes, based on the currently available information.<sup>27</sup> Although absorption of nanotubes is expected to be “poor” via all routes of exposure, EPA expressed toxicological concern for their health effects based on “analogy” to respirable, poorly soluble particulates and other carbon materials. Concern for lung irritation caused by the nanotubes based on particle size was also a factor. Based upon these concerns, EPA found that a health risk exists to workers exposed to the nanotubes via both inhalation and dermal routes. EPA further found a potential risk to the general population from water, landfill, or incineration releases.<sup>28</sup>

Next, EPA explained the legal basis for the Swan Consent Order:

EPA is unable to determine the potential for human health effects from exposure to the PMN substance [nanotubes]. EPA therefore concludes . . . that the information available to the Agency is insufficient to permit a reasoned evaluation of the human health effects of the PMN substance.

In light of the potential risk to human health posed by the uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance, EPA has concluded . . . that uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance may present an unreasonable risk of injury to human health.<sup>29</sup>

Combined, the above series of factual and legal findings permit EPA to assert control over the manufacture, import, processing, distribution, use, and disposal of the subject carbon nanotubes under TSCA. Distilled to its essence, EPA is regulating the use of these (and most likely all) carbon nanotubes based upon its lack of knowledge concerning their health effects on humans coupled with its knowledge of tests conducted on “analogous” substances.

## V. Siloxane Modified Nanoparticle Significant New Use Rules

The Carbon Nanotube *Federal Register* Notice and the Swan Consent Orders were closely followed by EPA’s issuance of two separate proposed SNURs on November 8, 2008 for other types of nanomaterials which are used as additives in products: siloxane modified silica nanoparticles<sup>30</sup> and siloxane modified alumina nanoparticles.<sup>31</sup> Each chemical substance had been the subject of a prior PMN.<sup>32</sup>

In its *Federal Register* Notice, EPA stated that dermal and inhalation exposures of the substances were not expected under the uses outlined in the PMNs, and declined to determine whether the substances actually posed unreasonable risks. On the other hand, EPA found that “[b]ased on test data on analogous respirable, poorly soluble, particulates, EPA has concerns for lung effects for the

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<sup>25</sup> *Id.* at Section IV.

<sup>26</sup> *Id.* at Section V.

<sup>27</sup> *Id.* at Section IV.

<sup>28</sup> *Id.*

<sup>29</sup> *Id.* at Section V.

<sup>30</sup> 40 CFR 721.10119. *See also* EPA Notice, 73 Fed. Reg. 65751, 65763 (referencing PMN Number P-05-673).

<sup>31</sup> 40 CFR 721.10120. *See also* EPA Notice, 73 Fed. Reg. 65752, 65763 (referencing PMN Number P-05-687).

<sup>32</sup> Numbers P-05-673 & 687, respectively.

PMN substance[s]. Based on physical properties, EPA has concerns for potential systemic effects from dermal exposure to the PMN substance[s].”<sup>33</sup> These concerns and findings were substantially the same as those recited in the Swan Consent Order.

The SNURs also came with two use restrictions: “EPA has determined, however, that use without impervious gloves or a NIOSH-approved respirator with an APF of at least 10; the manufacture, process, or uses of the substance[s] as a powder; or uses of the substance[s] other than described in the PMN may cause serious health effects.”<sup>34</sup> Manufacturers of the chemical substances must ensure their employees wear NIOSH approved respirators and gloves when working with the substances. Thus, in a unique twist, one of the significant new uses being regulated by EPA is not the use of the chemical substances as additives; rather it is their use without appropriate personal protective equipment. While creative, this approach avoids determining the primary issue—are the substances toxic or not for TSCA purposes?

## **VI. Multi-Walled and Single-Walled Carbon Nanotube Significant New Use Rules**

In the June 24, 2009 *Federal Register*, EPA issued two proposed SNURs under Section 5(a) of the Toxic Substances Control Act (TSCA) for multi-walled and single-walled carbon nanotubes.<sup>35</sup> The SNURs followed up on the EPA’s prior September 2008 consent orders entered into with Swan for two of its carbon nanotube products.

Under TSCA, the prior September 2008 consent orders were only binding on Swan. However, they also contained provisions limiting Swan’s distribution of the products to entities which also agree to be bound by the terms of the consent orders. “Consequently, after signing a Section 5(e) Consent Order, EPA generally promulgates a [SNUR] that mimics the Consent Order to bind all other manufacturers and processors to the terms and conditions contained in the Consent Order. The SNUR requires that manufacturers, importers and processors of certain substances notify EPA at least 90 days before beginning any activity that EPA has designated as a “significant new use.” These new use designations are typically those activities prohibited by the Section 5(e) Consent Order.”<sup>36</sup>

Under the terms of the September 2008 consent orders which are incorporated into the new proposed carbon nanotube SNURs, significant new uses of multi-walled and single-walled carbon nanotubes are deemed to occur when employees do not “use gloves impervious to nanoscale particles and chemical protective clothing;” and/or fail to “use a NIOSH-approved full-face respirator with an N-100 cartridge while exposed by inhalation in the work area.” The new proposed SNURs require these same conditions.

At the same time, it should be noted that EPA has been less than clear about exactly what it is attempting to accomplish with its two carbon nanotube SNURs. The SNURs identified the chemical substances affected by the SNURs as “generic” single-walled carbon nanotubes (SWCNTs) and multi-walled carbon nanotubes (MWCNTs). After inquiries by several stakeholders, EPA issued a “clarification” stating that the SNURs only apply to the specific carbon nanotubes that were the

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<sup>33</sup> 73 Fed. Reg. 65751-52.

<sup>34</sup> *Id.*

<sup>35</sup> Significant New Use Rules on Certain Chemical Substances, *supra* note 8.

<sup>36</sup> Environmental Protection Agency, Consent Orders and Significant New Use Rules (SNURs), <http://www.epa.gov/oppt/newchems/pubs/cnosnurs.htm> (last visited July 15, 2009).

subject of the original PMN submissions.<sup>37</sup> These, of course, are only being manufactured by Swan. Because (i) Swan is already bound by the consent orders covering its specific carbon nanotubes, and (ii) any customer of Swan must agree to be bound by the terms of the consent orders, if the SNURs are not intended to bind third-party manufacturers, they are largely superfluous.

Shortly before this article went to print, EPA withdrew the two carbon nanotube SNURs on procedural grounds because an attorney filed a preliminary objection to them on behalf of his unnamed clients. The SNURs were originally promulgated through expedited procedures which require their withdrawal if someone files a notice of intent to submit adverse or critical comment. Accordingly, EPA withdrew the SNURs and may instead publish new proposed SNURs through a lengthier rule making process allowing greater public discussion and comment.<sup>38</sup> This provides EPA with a great opportunity to revisit its thinking and make its position perfectly clear to the public.

As noted above, there are already Consent Orders for these two very specific nanotubes which are binding to any successor manufacturer or processor, and the consent orders would also be applicable contractually to any of Swan's customers. Arguably, this should be enough. A better approach for EPA would be to issue a *Federal Register* Notice stating that there are unlikely to be manufacturers or processors of the substance other than the PMN submitter already subject to the Consent Orders and thus no new SNURs are necessary.<sup>39</sup>

## VII. Impending Testing and Data Collection Rules

Eight months after EPA's interim report on industry participation (or lack thereof) in its Nanoscale Materials Stewardship Program, EPA's Toxic Substances Control Act's ("TSCA") Interagency Testing Committee ("ITC") published a report in the August 4, 2009 *Federal Register* mentioning that EPA intends to issue a new mandatory data collection rule for nanoscale materials under TSCA Section 8(a) and new testing ruled under Section 4:

EPA intends to develop a proposed TSCA section 8(a) rule to obtain information on the production, uses, and exposures of existing nanoscale materials. EPA has indicated that it will ensure that the chemicals where there is ITC interest as described in this unit are either included in that action or are otherwise new chemical substances subject to premanufacture notifications (PMN) reporting under TSCA. EPA also intends to develop a proposed TSCA section 4 rule to develop needed environmental, health, and safety data.<sup>40</sup>

Among other things, TSCA Section 8(a) allows EPA to issue a rule requiring the mandatory submission of data regarding:

- (A) The common or trade name, the chemical identity, and the molecular structure of each chemical substance or mixture for which such a report is required.
- (B) The categories or proposed categories of use of each such substance or mixture.
- (C) The total amount of each such substance and mixture manufactured or processed, reasonable estimates of the total amount to be manufactured or

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<sup>37</sup> See EPA Issues Clarification Regarding Carbon Nanotube SNURs, available at <http://www.nanolawreport.com/2009/07/articles/carbon-nanotubes/epa-issues-clarification-regarding-carbon-nanotube-snurs/>.

<sup>38</sup> 74 Fed. Reg. 42177-78.

<sup>39</sup> See 40 C.F.R. 721.160(a)(2).

<sup>40</sup> 74 Fed. Reg. 38880.

processed, the amount manufactured or processed for each of its categories of use, and reasonable estimates of the amount to be manufactured or processed for each of its categories of use or proposed categories of use.

(D) A description of the byproducts resulting from the manufacture, processing, use, or disposal of each such substance or mixture.

(E) All existing data concerning the environmental and health effects of such substance or mixture.

(F) The number of individuals exposed, and reasonable estimates of the number who will be exposed, to such substance or mixture in their places of employment and the duration of such exposure.

(G) . . . the manner or method of its disposal, and in any subsequent report on such substance or mixture, any change in such manner or method.

From the *Federal Register* report, it appears that some of the nanoscale materials prompting ITC's interest appear to be: fullerenes; titanium oxide nanowires; titanium oxide nanoparticles; nano zinc oxide; nanosilver; silica; quartz; cerium oxide; indium tin oxide; dendrimers; single-walled carbon nanotubes; multi-walled carbon nanotubes; carbon nanofibers; Se and Cd quantum dots; nanoceramic particles; and nanoclays.<sup>41</sup> If EPA is true to its *Federal Register* Notice, it will soon begin a mandatory data collection effort concerning some or all of these nanoscale materials.

Regarding the proposed TSCA Section 4 test rule for nanoscale materials mentioned in the August 4 *Federal Register* Notice, that Section of TSCA allows EPA to require testing of any chemical substance or mixture which it believes may present an unreasonable risk of injury to the health or the environment; or that there is insufficient data and experience to determine if the chemical substance that the effects of the environmental can reasonably be determined or predicted; and that "testing of such substance or mixture with respect to such effects is necessary to develop such data." EPA has a large number of potential tests at its disposal. The most likely test EPA might issue for nanoscale materials under TSCA Section 4 is discussed in the following section.

### VIII. Inhalation Testing Regime

Under the TSCA Section 5(e) consent orders, Swan is required to conduct a "90-day inhalation toxicity study on rats with a post-exposure observation period of up to 3 months."<sup>42</sup> The same test<sup>43</sup> is recommended by EPA in the silica and alumina nanomaterial SNURs<sup>44</sup> and the multi-walled and single-walled carbon nanotube SNURs which were withdrawn.<sup>45</sup> The test is to be conducted in accordance with one of two guidelines: one established by EPA's Office of Pollution Prevention and Toxic ("OPPT") and the other by the Organization for Economic Cooperation and

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<sup>41</sup> *Id.*

<sup>42</sup> EPA, Consent Order and Determinations Supporting Consent Order, (redacted version) available at <http://www.nanolawreport.com/EPA%20Premanufacture%20Notice%20Number%20P-08-0177.pdf>, at Section VI. Swan is given the opportunity to use an alternative test designated as OECD 413.

<sup>43</sup> In May 2008, EPA also provided notice through the federal Regulatory Information service that it may issue a TSCA Section 4(a) test rule to gather data, "to determine the health effects of multi-walled carbon nanotubes." <http://www.reginfo.gov/pub/do/eAgendaViewRule?pubID=200904&RIN=2070-AJ47> (last visited July 15, 2009). The notice indicates that the potential test rule is a substantive, non-significant, long-term action.

<sup>44</sup> 73 Fed. Reg. 65751-52 (referencing PMN Numbers P-05-673 and P-05-687).

<sup>45</sup> *supra* note 36.

Development (“OECD”).<sup>46</sup> The two guidelines are substantially equivalent. The OECD Guidelines’ stated purpose is “to fully characterize test article toxicity by the inhalation route for a subchronic<sup>47</sup> duration, and to provide robust data for quantitative inhalation risk assessment.”<sup>48</sup> The OPPTS Guideline’s purpose is to explain how to conduct a subchronic inhalation study for the “assessment and evaluation of the toxic characteristics of a gas, volatile substance, or aerosol/particulate.”<sup>49</sup> It is, thus, a somewhat broad attempt to minimize variations among testing procedures that must be performed to meet the data requirements of TSCA.

The protocol for the test is set out in the Swan Consent Order. It clearly states that the test is not capable of determining health effects that have a long latency period such as carcinogenicity. It also cautions that extrapolation of the results of this animal study to humans will be of limited value:<sup>50</sup>

Purpose. In the assessment and evaluation of the toxic characteristics of a gas, volatile substance, or aerosol/particulate, determination of subchronic inhalation toxicity may be carried out after initial information on toxicity has been obtained by acute testing. The subchronic inhalation study has been designed to permit the determination of the no-observed-effect-level (NOEL) and toxic effects associated with continuous or repeated exposure to a test substance for a period of 90 days. This study is not capable of determining those effects that have a long latency period for development (e.g., carcinogenicity and life shortening). Extrapolation from the results of this study to humans is valid only to a limited degree. It can, however, provide useful information on health hazards likely to arise from repeated exposures by the inhalation route over a limited period of time. It will provide information on target organs and the possibilities of accumulation, and can be of use in selecting concentration levels for chronic studies and establishing safety criteria for human exposure. Hazards of inhaled substances are influenced by the inherent toxicity and by physical factors such as volatility and particle size.<sup>51</sup>

## IX. Analysis

### 1. The Causation Issue

Some may attempt to use the results of the tests required by EPA to assert that the substances tested have been shown by the tests to cause disease in humans. However, the risk analysis specified in the OPPTS and OECD guidelines was never intended to establish either scientific or legal causation.

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<sup>46</sup> OPPTS 870.3465 or OECD 413. Consent Order, Section II (d)(1).

<sup>47</sup> Medline defines “chronic” as follows: “marked by long duration, by frequent recurrence over a long time, and often by slowly progressing seriousness . . . having a slow progressive course of indefinite duration—used especially of degenerative invasive diseases, some infections, psychoses, and inflammations <chronic heart disease> <chronic arthritis> <chronic tuberculosis> . . . ,” <http://www2.merriam-webster.com/cgi-bin/mwmednlm?book=Medical&va=chronic>.

<sup>48</sup> Summary, OECD Guidelines, available at <http://www.oecd.org/dataoecd/37/24/40277898.doc>.

<sup>49</sup> Section 1(b), Purpose, OPPTS Guidelines, available at [http://www.epa.gov/opptsfrs/publications/OPPTS\\_Harmonized/870\\_Health\\_Effects\\_Test\\_Guidelines/Series/870-3465.pdf](http://www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/870_Health_Effects_Test_Guidelines/Series/870-3465.pdf).

<sup>50</sup> The Study will use specified mice as its subjects.

<sup>51</sup> OPPTS Guidelines, *supra* note 50.

It is important to distinguish “legal” from “scientific” causation. Science uses a probabilistic method to determine causation whereas the law requires proof by a preponderance of the evidence: it is “more likely than not” that the substance caused the disease. Although the law is frequently more conservative than scientists in finding that causation has been established, neither science nor the courts require that the actual “mechanism of disease” be shown before causation can be deemed established. Thus, it is both scientifically and legally possible to establish causation without showing how the disease occurred. A scientist is able to say with confidence that a substance causes cancer without knowing how the cancer is caused because the scientist’s conclusion is based on probabilistic reasoning, not on a conclusive understanding of the mechanism of disease. This probabilistic reasoning often uses the mathematical devices of statistics and epidemiology to prove general causation, that the substance in question is capable of causing a certain type of disease, for example, that cigarette smoking causes lung cancer. However, it is generally recognized that these mathematical devices are incapable of proving specific causation, i.e., that cigarette smoking caused this specific plaintiff’s lung cancer. Something more than statistics and epidemiology is needed to satisfy the law. A physician or other scientist must testify that they are of the opinion that the substance caused this specific disease in this specific plaintiff. This will no doubt be based on personal examination of the plaintiff, tissue samples, or at least a pathological report written by a respected pathologist.

The stated purpose of the test in the OPPTS Guidelines is to provide useful information on “health hazards” likely to arise from repeated inhalation over a “limited” period of time, to provide information on target organs and the possibilities of accumulation, and to be of use in selecting concentration levels for chronic studies and establishing safety criteria for human exposure.<sup>52</sup> The silica and alumina SNURs both justify the test by stating that it would “help characterize the human health effects of the PMN substance.”<sup>53</sup> Thus, both by design and purpose, the test was never intended sufficient to establish scientifically, much less legally, that these or any nanomaterials cause disease. The risk assessment criteria used by EPA are mandated by TSCA and are based on the precautionary principle,<sup>54</sup> not causation. In this regard, the criteria merely speak in terms of “predictions,” “probable toxicity,” and toxicological concern for health effects based on “analogy” to other particulates.

Based upon these rather indistinct findings, EPA concludes that it is unable to determine the potential for human health effects and, therefore, further concludes that the information available is insufficient to permit a reasoned evaluation of the human health effects of the nanotubes. Still, both the Consent Order and SNURs were issued due to the potential risk to human health posed by the uncontrolled manufacture, import, processing, distribution, use, and disposal of nanomaterials which may present an unreasonable risk of injury to human health. Thus, EPA efforts to regulate the use of nanotubes is first based on “predicted” and “probable” facts, not on knowledge of the human health consequences of actual exposure. EPA readily admits, and in fact TSCA requires, that it is unable to determine the potential for human health effects from exposure. However, EPA still expresses “concern,” as it must under TSCA, for the health effects of the nanomaterials premised on

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<sup>52</sup> *Id.*

<sup>53</sup> “Recommended testing,” EPA Notice, 73 Fed. Reg. 65751-52 (Nov. 5, 2008).

<sup>54</sup> The precautionary principle implies a willingness to take action in advance of scientific proof on the grounds that further delay will prove injurious to society. The February 2, 2000 European Commission Communication on the Precautionary Principle states that the principle applies where scientific evidence is insufficient, inconclusive or uncertain and preliminary scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen by the EU, available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2000:0001:FIN:EN:PDF>.

its knowledge of data pertaining to “analogous” substances and the possibility of lung irritation due to particle size.

## **2. Effect of the Four SNURs**

EPA has issued a SNUR for each of the four nanomaterials: the multi-walled and single-walled carbon nanotubes (which were withdrawn)<sup>55</sup> and the silica and alumina nanoparticles. These SNURs compel anyone who intends to manufacture, import or process any of the subject nanomaterials for a significant new use to notify EPA at least ninety days before beginning to do so. This notice will permit EPA to evaluate the intended use and, if necessary, issue an order that prohibits or limits the use. Failure or refusal to file a PMN or to comply with the EPA’s resulting orders may have severe consequences. This is also true of any potential failure by Swan or its successors or customers to comply with the consent orders.

### **A. Civil and Criminal Liability**

Section 15 of TSCA<sup>56</sup> makes it unlawful for any person to do any of the following: fail or refuse to comply with any rule promulgated or order issued under TSCA; use for commercial purposes a chemical substance or mixture which the person knew or had reason to know was manufactured, processed, or distributed in commerce in violation of rules or orders of TSCA; fail or refuse to establish or maintain records, submit reports, notices, or other information, or permit access to or copying of records, as required by a rule or regulation of TSCA; or, fail or refuse to permit entry or inspection as required by TSCA.

These prohibitions would encompass any potential failure by Swan to comply with the consent orders or anyone’s failure to comply with one of the four SNURs.

### **B. Conduct Subject To Review**

Violations that are specifically enumerated in the Rule granting EPA authority to levy criminal and civil sanctions include the following: manufacturing or importing a new chemical substance before a PMN is submitted and the notice review period expires;<sup>57</sup> using for commercial purposes a chemical substance or mixture which the user knew or had reason to know was manufactured, processed, or distributed in commerce in violation of TSCA;<sup>58</sup> failure or refusal to establish and maintain records or to permit access to or copying of records;<sup>59</sup> and, failure or refusal to permit entry or inspection of premises.<sup>60</sup> Other violations of Rule 720.1 that are not specifically enumerated can also give rise to penalties. Additionally, persons who submit materially misleading or false information may be subject to penalties calculated as if they never filed a PMN.<sup>61</sup> Violators

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<sup>55</sup> 40 C.F.R. 721.10155-56 (referencing Swan’s MWCNT and SWCNT under PMN P-08-177 and PMN P-08-328, respectively, *see also* 74 Fed. Reg. 29982-98, *especially* 29991, 29998 (June 24, 2009)).

<sup>56</sup> 15 U.S.C. § 2614, *see also* <http://epw.senate.gov/tsca.pdf> (Senate version of TSCA, as amended through Dec. 32, 2002).

<sup>57</sup> 40 C.F.R. § 720.120(b).

<sup>58</sup> 40 C.F.R. § 720.120(c).

<sup>59</sup> 40 C.F.R. § 720.120(d).

<sup>60</sup> 40 C.F.R. § 720.120(e).

<sup>61</sup> 40 C.F.R. § 720.120(f).

may be subject to civil and criminal penalties for each violation.<sup>62</sup> Each day a violation continues constitutes a separate violation.<sup>63</sup>

### **C. Penalties and other TSCA Provisions**

*Civil Penalties:* Violation of TSCA can result in a civil monetary penalty of up to \$25,000 per day per violation.<sup>64</sup> In determining the amount of a civil penalty, EPA considers such things as the nature, circumstances, extent and gravity of the violation, as well as the violator's ability to pay, effect on ability to continue to do business, history of past violations and the degree of culpability.<sup>65</sup>

*Criminal Penalties:* Fines up to \$25,000 per day per violation and/or imprisonment up to one year may be assessed against any person who knowingly or willfully violates TSCA. This is in addition to or in lieu of any civil penalty which may be imposed.<sup>66</sup>

*Injunctive Relief:* EPA has authority to seek court orders for both "specific enforcement" and "seizure."<sup>67</sup> This includes seeking to enjoin the manufacture or processing of the substance and/or seizing the substance if manufactured or processed in violation of or any rule promulgated or order issued under TSCA.<sup>68</sup>

*Inspections:* EPA has the power through appropriate procedures to conduct on site inspections to assure compliance and to verify that information submitted to it is true and correct. This includes conducting an audit of data submitted to it.<sup>69</sup>

*Preemption and State Enforcement:* If EPA has regulated a particular substance under TSCA, states are preempted from imposing additional testing requirements or most other requirements aimed at protecting public health or the environment.<sup>70</sup>

*Citizen Civil Actions and Petitions:* TSCA provides for "citizen civil actions" and "petitions" against any person<sup>71</sup> to restrain violations of TSCA or any rule or order issued under TSCA. This includes testing, notification, manufacturing and use restrictions. Suit may also be brought against EPA to compel the performance of any nondiscretionary act or duty.<sup>72</sup> A private party may also petition EPA to issue a rule regarding a specific chemical<sup>73</sup> and may file suit to compel the rule if EPA denies the petition.<sup>74</sup> The court may award costs of suit and reasonable fees for attorneys and expert

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<sup>62</sup> *Id.*

<sup>63</sup> 15 U.S.C. § 2615(a)(1).

<sup>64</sup> *Id.*

<sup>65</sup> 15 U.S.C. § 2615(a)(2)(B).

<sup>66</sup> 15 U.S.C. § 2615(b).

<sup>67</sup> 15 U.S.C. § 2616(a)-(b).

<sup>68</sup> *Id.*

<sup>69</sup> 15 U.S.C. § 2610.

<sup>70</sup> 15 U.S.C. § 2617.

<sup>71</sup> "Person" includes the United States and any other governmental instrumentality or agency. 15 U.S.C. § 2619(a).

<sup>72</sup> *Id.*

<sup>73</sup> 15 U.S.C. § 2620.

<sup>74</sup> *Id.*

witnesses.<sup>75</sup> These costs and fees would probably be sizeable in light of the complex scientific and medical issues involved and the need for one or more expert witnesses.

### 3. Proposed Joint Testing Program

The consent order provides that Swan will complete a ninety day inhalation toxicity study.<sup>76</sup> However, in seeming recognition of the significant costs involved in conducting such a study under the stringent “Guidelines” specified by EPA, and no doubt in recognition of the advantages of securing a cooperative study sponsored by several industry members located in various countries throughout the world, EPA encouraged Swan to develop additional health effects testing in coordination with other multi-walled carbon nanotube (MWCNT) manufacturers.<sup>77</sup> EPA suggested this might be done either under the in-depth portion of EPA’s Nanoscale Materials Stewardship Program or through independent testing.<sup>78</sup> The example of a consortium of companies committing to testing a representative set of MWCNTs for subchronic mammalian toxicity was specifically advanced by EPA which even offered to facilitate coordination with other ongoing MWCNT studies nationally and internationally.<sup>79</sup> Such a study might be that recently announced by the Natural Environment Research Council.<sup>80</sup> If such a joint testing effort were undertaken, EPA would consider accepting the results of the study in lieu of the ninety day inhalation toxicity test provided for in the Swan consent order.<sup>81</sup>

EPA’s suggestion of a joint study will no doubt have some appeal to manufacturers, users, and processors of nanomaterials given the substantial cost involved in individually conducting a ninety day inhalation toxicity test.<sup>82</sup> However, significant strategic and legal (antitrust) considerations arise.

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<sup>75</sup> 15 U.S.C. § 2619(c)(2).

<sup>76</sup> EPA, Consent Order and Determinations Supporting Consent Order, (redacted version) *available at* <http://www.nanolawreport.com/EPA%20Premanufacture%20Notice%20Number%20P-08-0177.pdf>, at Section II(d)(1).

<sup>77</sup> Consent Order, Preamble, at Section VI.

<sup>78</sup> *Id.*

<sup>79</sup> *Id.*

<sup>80</sup> The United Kingdom’s Natural Environment Research Council (NERC), together with its Engineering & Physical Sciences Research Council, U.K.’s Department for Environment, Food & Rural Affairs and its Environment Agency, in cooperation with the United States Environmental Protection Agency and the National Science Foundation, are in the process of finalizing a major joint research effort to “develop and validate predictive tools and similar conceptual models that predict exposure, bioavailability and effects of manufactured nanomaterials in the environment.” The intent of this effort is to form a “consortia” of U.K. and U.S. investigators using combined but independent national funding from each country. <http://www.nerc.ac.uk/research/programmes/nanoscience/events/jointresearch.asp> (last visited Dec., 2008).

<sup>81</sup> Consent Order, Preamble, at Section VI.

<sup>82</sup> The EPA test protocol is quite detailed in how the study must be conducted and written up after it is completed, setting out a very costly regime. A good example is how the mice that are used to conduct the study must be cared for: “*Animal Husbandry* - Animals should be individually identified, preferably with subcutaneous transponders, to facilitate observations and avoid confusion. The temperature of the experimental animal maintenance room should be 22±3°C. The relative humidity should ideally be maintained in the range of 30 to 70%, though this may not be possible when using water as a vehicle. Before and after exposures, animals may be caged in groups by sex and concentration, but the number of animals per cage should not interfere with clear observation of each animal and should minimize losses due to cannibalism and fighting. When animals are to be exposed nose-only, it may be necessary for them to be acclimated to the restraining tubes. While animals are being exposed whole-body to an aerosol, they should

#### 4. Strategic Considerations

Leaving aside for the moment the possible antitrust implications for a joint scientific study of MWCNTs by competitors in the market place, the practical and strategic considerations of such a study bear serious consideration. The risk-benefit analysis of a company deciding whether to participate in such a joint study would include several factors. First, what benefit would be gained by a joint study? Obviously, a joint study where each participant contributes financing equally or under some equitable formula would be much less expensive than going it alone. Additionally, the study would probably be prestigious and widely accepted, but this can cut both ways if the results of the study are troublesome and a “sponsor” desires to dispute their validity. If a joint study is completed that is financially supported and/or participated in by several industry members either alone or with national and international health/regulatory organizations, the entire nanotechnology industry may be “stuck” with the results of the study, like it or not. Certainly, as a practical matter, sponsors of the study will be locked into its results. Might it, therefore, be advisable not to participate in any joint study and thereby hopefully reserve one’s ability to either accept or dispute the results of the study, depending on its design, methodology and conclusions. A rather large body of science on the health effects of nanomaterials, including but not limited to MWCNT’s, supported by numerous studies is sure to develop in rather short order. It is quite possible that, as is usually the case, different studies will reach totally or partially different results that can be used to help understand the “state of the art” as to scientific knowledge on the pertinent issues. Why go into battle with only one arrow in your quiver when a whole sheath will be available?

Another important consideration is selection of the scientists who will conduct the research and determine the important questions of how the study will be designed, conducted and reported. If Swan or other companies attempting to comply with one or more of the four SNURs either joins or adopts other studies that are already in progress, it might be rather difficult to change (or add) scientists or methodology. A company could, therefore, wind up in the unfortunate situation of funding a study that is not in its best interest.

Additionally, if government entities such as EPA or comparable organizations or agencies of foreign countries have decisive input into the study, their biases and regulatory objectives will most likely influence the design and conduct of the study as well as how it is reported.<sup>83</sup> A similar concern could arise if the scientists selected to conduct the study have already formed opinions as to the health effects of MWCNTs or similar substances and have an ax to grind. The scientists should be selected with great care for their competency, experience, and lack of bias, just as an “impartial” jury in a lawsuit is selected. At the minimum, the published work and speeches of each scientist should be carefully reviewed before they are retained to work on the project. For example, industry sponsors would no doubt be well advised to steer clear of scientists who have demonstrated particularly strong feelings against incorporating developing science into consumer products such as is the case with anti-genetic engineering zealots.

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be housed individually to prevent ingestion of test article due to grooming of cage mates. Conventional laboratory diets may be used, except during exposure, accompanied with an unlimited supply of municipal drinking water. Lighting should be artificial, the sequence being 12 hours light / 12 hours dark.” OECD 413 Guideline, Section 8, available at <http://www.oecd.org/dataoecd/37/24/40277898.doc>.

<sup>83</sup> One can only imagine what it would be like for a single company or even a group of potential nanotechnology users to join the “consortia” study being proposed by the UK’s Natural Environment Research Council in cooperation with the U.S. Environmental Protection Agency and National Science Foundation. See note 81, *supra*. Effective control over this study will surely rest with the sponsoring UK and US agencies and organizations.

## 5. Antitrust Considerations

The antitrust laws govern the conduct of business in the United States. They are designed to protect competition and are found at both the federal and state level. These laws generally frown upon and hold suspect most types of agreements between competitors, including joint research and development agreements. This is true because it is believed that competition promotes better products at lower prices. The Antitrust Division of the Department of Justice<sup>84</sup> has strongly asserted this position.<sup>85</sup> Thus, competition to develop a better (safer) product is just as important as price competition.

### A. Enforcement of the Antitrust Laws

There are three main ways in which the federal<sup>86</sup> antitrust laws are enforced: (i) criminal and civil enforcement actions brought by the Antitrust Division, (ii) civil enforcement actions brought by the Federal Trade Commission (FTC), and (iii) lawsuits brought by private parties asserting damage claims.

#### i. Criminal and Civil Actions by the Department of Justice

The criminal provisions of the federal antitrust laws are enforced by the Antitrust Division. Both the corporation and individual committing the antitrust violation may be penalized. Officers and directors may be personally indicted, tried, and convicted. If an antitrust issue was taken with a joint research project, the challenge would probably come under Section 1 of the Sherman Act which prohibits contacts, combinations and conspiracies which unreasonably restrain trade.<sup>87</sup> Violation of the Sherman Act is a felony punishable by a fine of up to \$100 million for corporations, and a fine of up to \$1 million and/or ten years imprisonment for individuals.<sup>88</sup>

It is doubtful that these criminal provisions would be applied against a joint research venture unless it was coupled with other illegal conduct such as price fixing or market division.

The civil provisions of the antitrust laws enforced by DOJ deal mainly with mergers and acquisitions, which DOJ may seek to prevent by seeking injunctive relief. In this regard see the section below entitled "The National Cooperative Research and Production Act".

#### ii. Civil Enforcement Actions Brought by the FTC<sup>89</sup>

The FTC is an independent agency that reports to Congress. The Commission protects consumers against unfair, deceptive or fraudulent practices through its Bureau of Consumer Protection. The Bureau enforces a variety of consumer protection laws enacted by Congress, as well as trade regulation rules issued by the Commission. Its actions include individual company

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<sup>84</sup> The Antitrust Division of the United States Department of Justice is charged with enforcing the U.S. antitrust laws. <http://www.usdoj.gov/atr/overview.html> (last visited July, 2009).

<sup>85</sup> U.S. Department of Justice, "Antitrust Enforcement and the Consumer," (2007) [http://www.usdoj.gov/atr/public/div\\_stats/211491.htm](http://www.usdoj.gov/atr/public/div_stats/211491.htm).

<sup>86</sup> Most states have antitrust laws that are based upon and comparable to the federal antitrust laws. However, the various states may have added language or entire provisions to their antitrust statutes. Thus, the antitrust statutes of a particular state must be reviewed when determining the applicable law of that state.

<sup>87</sup> 15 U.S.C. § 1.

<sup>88</sup> *Id.*

<sup>89</sup> The discussion in this section is taken from a publication disseminated on line by the FTC entitled, "A Guide To The Federal Trade Commission," available at <http://www.ftc.gov/bcp/edu/pubs/consumer/general/gen03.shtm> (last visited Aug., 2009).

and industry-wide investigations, administrative and federal court litigation, rulemaking proceedings, and consumer and business education.

The Bureau of Competition is the FTC's antitrust arm through which it seeks to prevent anticompetitive mergers and other anticompetitive business practices in the marketplace. If the FTC believes that a person or company has violated the law or that a proposed merger may violate the law, the agency may attempt to obtain voluntary compliance by entering into a consent order with the company.

If a consent agreement cannot be reached, the FTC may issue an administrative complaint or seek injunctive relief in the federal courts. The FTC's administrative complaints initiate a formal proceeding that is much like a federal court trial but before an administrative law judge. If a law violation is found, a cease and desist order may be issued.

Final decisions issued by the Commission may be appealed to the U.S. Court of Appeals and, ultimately, to the U.S. Supreme Court. If the Commission's position is upheld, the FTC, in certain circumstances, may then seek consumer redress in court. If the offending company ever violates the order, the Commission also may seek civil penalties or an injunction.

In some circumstances, the FTC can go directly to court to obtain an injunction, civil penalties or consumer redress. For example, in the merger enforcement arena, the FTC may seek a preliminary injunction to block a proposed merger pending a full examination of the proposed transaction in an administrative proceeding. The FTC also seeks federal court injunctions in consumer protection matters typically in cases of ongoing consumer fraud.

The Commission also can issue Trade Regulation Rules. If the FTC staff finds evidence of unfair or deceptive practices in an entire industry, it can recommend that the Commission begin a rulemaking proceeding. An FTC rule may be challenged in any of the U.S. Courts of Appeal. When issued, these rules have the force of law.

### ***iii. Private Civil Actions***

Private parties who are injured by antitrust violations may bring suit against the wrongdoers to recover for injuries to their business or property. In this regard Section 4 of the Clayton Act provides:

[A]ny person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws may sue therefore . . . and shall recover threefold the damages by him sustained, and the cost of suit, including a reasonable attorney's fee.<sup>90</sup>

An antitrust offender maybe sued in civil court by persons or corporations suffering injury as a result of the illegal conduct. The antitrust laws permit a successful plaintiff to recover treble damages, costs and attorneys fees. Recoverable costs may include fees for expensive expert witnesses which alone can run into the hundreds-of-thousands-of-dollars range. Antitrust suits are complex and usually drag on for years. Thus, having to pay both sides' legal fees and litigation costs could involve millions of dollars. This is in addition to paying treble damages.

### ***B. The National Cooperative Research and Production Act***

The National Cooperative Research and Production Act ("NCRPA")<sup>91</sup> deals with the application of the U.S. antitrust laws to joint research and development ("R&D") activities, joint production activities and, after recent amendment, with conduct by a qualifying standards development

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<sup>90</sup> 15 U.S.C. § 15.

<sup>91</sup> 15 U.S.C. §§ 4301-06.

organization (“SDO”) while engaged in a standards development activity.<sup>92</sup> The purpose of NCPRA is to “promote innovation, facilitate trade, and strengthen the competitiveness of the United States in world markets by clarifying the applicability of the rule of reason standard and establishing a procedure under which businesses may notify the Department of Justice and Federal Trade Commission of their cooperative ventures and thereby qualify for a single-damages limitation on civil antitrust liability.”<sup>93</sup>

A joint venture is defined rather broadly under NCRPA to include each or any combination of activities engaged in by two or more persons for any of the following purposes: theoretical analysis, experimentation, or systematic study of phenomena or observable facts; development or testing of basic engineering techniques; extension of investigative findings or theory of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, prototypes, equipment, materials, and processes; collection, exchange, and analysis of research or production information.<sup>94</sup> One or more of these activities appears to encompass the joint study suggested by EPA. Thus, without more, the suggested joint research would appear to be risky under the antitrust laws. The NCRPA may provide some protection, however.

The NCRPA establishes a voluntary procedure where the Attorney General and the FTC may be notified of a joint R&D or production venture. Once notice is properly filed by the participants in the joint venture, the statute limits the monetary relief that may be obtained in private civil suits against the participants in the venture to actual rather than treble damages, if the challenged conduct is covered by the statute and within the scope of the notification.

Additionally, NCRPA requires U.S. courts to judge the competitive effects of a challenged joint R&D or production venture under the “rule of reason,” where the offending conduct is judged on the basis of its reasonableness within properly defined relevant markets, taking into account all relevant factors affecting competition, including, but not limited to, effects on competition.<sup>95</sup> This is an important provision since it prevents application of the “*per se*”<sup>96</sup> rule under which the conduct is conclusively presumed to be “unreasonable” and thus, illegal. When a *per se* offense is charged, all the Government or private plaintiff need establish to make out a Section 1 violation is that the defendant has, in fact, engaged in the proscribed practice; illegality follows as a matter of law, no matter how slight the anticompetitive effect, how small the market share of the defendants, or how proper their motives. Avoidance of the onerous *per se* doctrine is quite advantageous.

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<sup>92</sup> As amended by the Standards Development Organization Advancement Act of 2004, Pub. L. No. 108-237, 118 Stat. 661 (2004).

<sup>93</sup> Pub. L. 103-42, June 10, 1993.

<sup>94</sup> 15 U.S.C. § 4301.

<sup>95</sup> 15 U.S.C. § 4302.

<sup>96</sup> In construing and applying the Sherman Act’s ban against contracts, combinations and conspiracies in restraint of trade, the “rule of reason” is usually applied whereby the trier of fact (court or jury) reviews the particular actions that constitute the alleged restraint of trade to determine whether they are unreasonable. In considering the “reasonableness” of the actions the trier of fact can consider the business justifications for the conduct and its impact on competition. However, the Supreme Court has held that certain agreements or practices are so “plainly anticompetitive,” *National Society of Professional Engineers v. United States*, 435 U.S. 679, 692 (1978); *Continental T.V., Inc. v. GTE Sylvania, Inc.*, 433 U.S. 36, 50 (1977), and so often “lack any redeeming virtue,” *Northern Pac. R. Co. v. United States*, 356 U.S. 1, 5 (1958), that they are conclusively presumed illegal without further examination. Thus, these practices are “*per se*” illegal under the antitrust laws. Price fixing is one of these practices. It has long been settled that an agreement to fix prices is unlawful *per se* and will not be tolerated. It is no excuse that the prices fixed are themselves reasonable. *See, e.g., United States v. Trenton Potteries Co.*, 273 U.S. 392, 397-398 (1927). Joint boycotts are also deemed *per se* illegal.

A prevailing plaintiff may obtain his costs and reasonable attorneys' fees, as is the situation in a normal antitrust law suit.<sup>97</sup> However, under NCRPA a prevailing defendant may also recover her costs and reasonable attorneys' fees if the claim, or the claimant's conduct during the litigation of the claim, was frivolous, unreasonable, without foundation, or in bad faith.<sup>98</sup>

Thus, if a joint research project is undertaken, even if the venture is properly noticed under NCRPA, the joint venturers will still be exposed to actual damages and court costs, including both sides' attorneys' and expert witness fees.<sup>99</sup> The benefits of giving the government notice of the joint project are application of the "rule of reason" when determining the legality of the conduct, limiting damages to those stemming directly from the actual amount of injury instead of treble damages, and the possibility of the defendant recovering his costs and reasonable attorneys' fees. There also may be somewhat of a psychological advantage in noticing the joint venture with the Justice Department and having it not take immediate issue with the proposed venture. However, this by no means will prevent a subsequent suit against the joint venture and its participants by either the government or a private party.

As a practical matter, if after filing proper notice under NCRPA, a company such as Swan joins a joint research venture that is controlled by such government entities as EPA and NIH, antitrust risk should be minimal. However, this risk coupled with the practical considerations discussed above, should be carefully evaluated before engaging in any joint study.

Care would have to be taken not to overstep the bounds of NCRPA if joint research was accomplished under its protection. No agreements on the commercialization of the test results could be undertaken. For example, it has been suggested that long straight nanotube fibers may be more dangerous than short or tangled fibers due to their alleged asbestos-like qualities.<sup>100</sup> An agreement among competitors not to use long straight nanotube fibers in their products might very well run afoul of the antitrust laws. Also, there could be no tangential agreements or understandings among competitors dealing with such market issues as prices, territories, products, etc. Agreements of this nature would not be protected under NCRPA and would run the risk of being deemed *per se* illegal under Section 1 of the Sherman Antitrust Act which prohibits contracts, combinations and conspiracies which unreasonably restrain trade.<sup>101</sup> Free and open competition in the market place for the nanomaterials would have to be maintained between all competitors, including but not limited to, those who funded or participated in the joint study.

## X. Conclusion

EPA's recent consent orders and SNURs covering four nanoscale materials under TSCA clearly show a case-by-case approach to the regulation of nanoscale materials, rather than the implementation of new generalized approach argued for by many environmental, health, and safety advocates. While EPA has taken its job seriously and is requiring (or at least suggesting) that animal inhalation studies be undertaken to get at the science of whether or not these materials

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<sup>97</sup> 15 U.S.C. § 4304.

<sup>98</sup> *Id.*

<sup>99</sup> A substantially prevailing claimant is entitled to recover the cost of suit, including a reasonable attorney's fee. 15 U.S.C. § 4304.

<sup>100</sup> C. Poland, *et al.*, *Carbon Nanotubes Introduced Into The Abdominal Cavity Of Mice Show Asbestos-Like Pathology In A Pilot Study*, 3 *NATURE NANOTECHNOLOGY* 423, (2008); and A. Kane, *et al.*, *The Asbestos Analogy Revisited*, 3 *NATURE NANOTECHNOLOGY* 378-79 (2008). *But see* Monica & Monica, *A Nano-Mesothelioma False Alarm*, 5 *NANOTECHNOLOGY LAW & BUSINESS* 319 (2008).

<sup>101</sup> 15 U.S.C. § 1.

present human health concerns, the tests themselves are limited and are not designed for use with nanoscale materials. Additionally, the tests mandated by EPA will be insufficient to establish either scientific or legal causation. EPA should work with OECD to promulgate nano-specific animal inhalation tests, as well as long-term testing techniques, to accompany any future consent orders or SNURs it may issue.