



# IGNORANCE IS BLISS? BALANCING THE PUBLIC'S RIGHT TO KNOW AND INDUSTRY'S CLAIM TO CONFIDENTIAL BUSINESS INFORMATION IN TSCA REFORM

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## I. INTRODUCTION

“We can no longer operate under the assumption that what we do not know about a chemical substance cannot hurt us.”<sup>2</sup> These words were spoken by Senator James B. Pearson (R-KS) during a March 26, 1976 debate concerning enactment of a bill that became the Toxic Substances Control Act of 1976, 15 U.S.C. §§ 2601–2602 (TSCA or the “Act”); however, they remain true today.<sup>3</sup> While consumer awareness is rising, many are still

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<sup>2</sup> ENV'T AND NATURAL RES. POLICY DIV., 94TH CONG., LEGISLATIVE HISTORY OF THE TOXIC SUBSTANCES CONTROL ACT 215 (Comm. Print 1976).

<sup>3</sup> *Id.* TSCA gives the United States Environmental Protection Agency (EPA or the “Agency”) “authority to require reporting, record-keeping and testing requirements, and restrictions relating to chemical substances and/or mixtures.” *Summary of the Toxic Substances Control Act, 15 U.S.C. §2601 et seq. (1976)*, EPA, <http://www2.epa.gov/laws-regulations/summary-toxic-substances-control-act> (last visited Feb. 20, 2014). Some chemicals that TSCA regulates include polychlorinated biphenyls (PCBs), asbestos, radon, and lead-based paint. *Id.* Other chemical substances and mixtures are specifically excluded from TSCA and are regulated by other statutes, such as food, drugs, cosmetics, and pesticides. *Id.*; see, e.g., Federal Food, Drug, and Cosmetic Act

astounded to learn about the overwhelming number of potentially dangerous, toxic, and carcinogenic chemicals that we are exposed to everyday.

Although a wide range of stakeholders—from the American Chemistry Council (ACC) to the Environmental Defense Fund—agrees that TSCA should be reformed, achieving reform has presented a real challenge.<sup>4</sup> While the ACC has said it is committed to working on a bipartisan bill, it has expressed concern that stiffer regulations would be burdensome to companies and would stifle economic growth and job creation.<sup>5</sup> Based on such concerns, chemical industries have ramped up lobbying and spending efforts to block change.<sup>6</sup>

Calls for reform are primarily driven by the concern that TSCA's prohibition on the disclosure of confidential business information (CBI) submitted by industry has interfered with the public's right to know about chemical and physical agents used in consumer products.<sup>7</sup> Under TSCA, information collected by

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(FFDCA), 21 U.S.C. §§ 301–399f (2002) (regulates food, drugs, and cosmetics); Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136–136y (1996) (regulates pesticides).

<sup>4</sup>See Panel Discussion, *TSCA Reform: The Standard of Safety*, 41 ENVTL. L. REP. NEWS & ANALYSIS 11081, 11081 (2011). The ACC is a trade association that represents companies engaged in the business of chemistry. *About ACC*, AM. CHEM. COUNCIL, <http://www.americanchemistry.com/About> (last visited Mar. 20, 2014)). The Environmental Defense Fund is a nonprofit organization dedicated to “preserv[ing] the natural systems on which all life depends.” *Our Mission and History*, ENVTL. DEF. FUND, <http://www.edf.org/about/our-mission-and-history> (last visited Mar. 20, 2014).

<sup>5</sup>See Lynne Peeples, *Chemical Industry Uses Wallet To Block Tighter Regulations, Environmental Advocates Say*, HUFF POST GREEN (Oct. 25, 2012, 7:51 PM), [http://www.huffingtonpost.com/2012/10/25/chemical-industry-campaign-contributions-environmental-regulations\\_n\\_2017412.html?utm\\_hp\\_ref=mostpopular](http://www.huffingtonpost.com/2012/10/25/chemical-industry-campaign-contributions-environmental-regulations_n_2017412.html?utm_hp_ref=mostpopular).

<sup>6</sup>*Id.* According to a report by a nonprofit, nonpartisan citizen's lobbying organization, chemical interests gave over \$23 million to Super Political Action Committees (Super PACs) in the 2012 elections. *Id.* For example, President Barack Obama received \$217,283, and Republican presidential candidate Mitt Romney received \$704,337. *Id.*

<sup>7</sup>Daniel E. Uyesato, *Key Issues in Reform of the Toxic Substances Control Act of 1976*, 41 NO. 4 ABA Trends 12, 12 (2010), available at <http://www.hunton.com/files/Publication/a79a720d-e76a-4859-bc17->

the United States Environmental Protection Agency (EPA or “the Agency”) is generally made available to the public, with one big exception: TSCA allows those required to submit information to EPA to claim much of the information as CBI.<sup>8</sup>

In reforming TSCA, legislators must strive to achieve a proper balance between the industry’s need to protect CBI and the public’s right to know about chemical and physical agents used in consumer products. If these concerns are successfully balanced, TSCA reform can benefit both industry and the public by providing reliable standards based on sound science and by providing the public with assurances of chemical safety. This Note will examine the treatment of CBI under TSCA historically and will offer suggestions for TSCA reform in light of other statutes and regulatory programs. Part II will give an overview of TSCA and discuss the history and purpose of TSCA, the jurisdictional scope of TSCA, and the treatment of CBI under TSCA. Part III will discuss recent TSCA reform efforts and explore the competing perspectives on TSCA reform. Finally, Part IV will argue that TSCA reform legislation should include data exclusivity and data compensation provisions analogous to those governing fertilizer and drug registrations.<sup>9</sup>

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<sup>8</sup> *TSCA Reform: The Standard of Safety*, *supra* note 4, at 11082 (statement by Wendy Cleland-Hamnett); *see also* Panel Discussion, *TSCA Reform: Information Confidentiality, Availability, and Sharing*, 42 ENVTL. L. REP. NEWS & ANALYSIS 10405, 10407 (2012) (Scott M. Sherlock stating that non-CBI TSCA data is made available to and used by other EPA offices, other federal agencies, states, tribes, local governmental chemical risk managers, foreign governments, international agencies, nongovernmental organizations (NGOs), commercial entities, and the general public).

<sup>9</sup> This approach has been suggested by at least one other commentator. *See* Uyesato, *supra* note 7, at 13. This Note will build on this suggestion by examining how such provisions could be structured and the benefits of such an approach.

## II. TSCA OVERVIEW

### A. HISTORY AND PURPOSE

The 1969 National Environmental Policy Act established the President's Council on Environmental Quality (CEQ) as an agency within the Executive Office of the President.<sup>10</sup> Soon after its establishment, the CEQ began a study that examined metals' and synthetic organic chemicals' potential for endangering the environment and human health.<sup>11</sup> The study culminated in the CEQ's 1971 report entitled "Toxic Substances" ("the 1971 CEQ Report"<sup>12</sup>), which found that existing chemical regulations were inadequate and became the impetus for the original TSCA legislation.<sup>13</sup> The CEQ recommended enactment of legislation regulating toxic substances based on its view that: (1) "[t]oxic substances are entering the environment"; (2) "[t]hese substances can have severe effects"; (3) "[e]xisting legal authorities are inadequate"; and (4) "[n]ew legal authority is required."<sup>14</sup> Based on this report, a draft bill was sent to Congress on February 11, 1971, by EPA Administrator William Ruckelshaus.<sup>15</sup> Early versions of TSCA died in the Senate-House Conference Committee.<sup>16</sup> However, in 1976, while Congress was

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<sup>10</sup> EPA, CHEMISTRY ASSISTANCE MANUAL FOR PREMANUFACTURE NOTIFICATION SUBMITTERS, APPENDIX: THE TOXIC SUBSTANCE CONTROL ACT: HISTORY AND IMPLEMENTATION 105 (1997), available at <http://www.epa.gov/oppt/newchemicals/pubs/chem-pmn/appendix.pdf> [hereinafter EPA CHEMISTRY ASSISTANCE MANUAL].

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

<sup>12</sup> U.S. CEQ, Toxic Substances (Apr. 1971), reprinted in LEGISLATIVE HISTORY, *supra* note 2, at 758 [hereinafter 1971 U.S. CEQ REPORT].

<sup>13</sup> David Markell, *An Overview of TSCA, Its History and Key Underlying Assumptions, and Its Place in Environmental Regulation*, 32 WASH. U. J.L. & POL'Y 333, 338 (2010); Lynn L. Bergeson, Lisa M. Campbell & Lisa Rothenberg, *TSCA and the Future of Chemical Regulation*, 15 EPA ADMIN. L. REP. 1, 3 (2000).

<sup>14</sup> See 1971 U.S. CEQ REPORT, *supra* note 12, at 759–60.

<sup>15</sup> EPA CHEMISTRY ASSISTANCE MANUAL, *supra* note 10, at 106.

<sup>16</sup> *Id.* at 107.

still considering the bill, Kepone (an insecticide for home use) caused workers in a Kepone factory in Hopewell, Virginia, to suffer severe neurological disorders.<sup>17</sup> Spurred by the national media coverage regarding the Kepone-exposure and growing fears about the risks that toxic substances posed to human health and the environment, the Senate-House Conference Committee reached an agreement on the provisions of TSCA by fall of 1976, and TSCA was enacted shortly thereafter.<sup>18</sup> According to the Senate Report, the purpose of TSCA was to “prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use, or disposal of chemical substances.”<sup>19</sup>

In the end, TSCA was the result of six years of negotiating and compromising among the House and Senate, the CEQ, EPA, the chemical industry, the Commerce Department, and other

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<sup>17</sup> *Id.*; Arthur M. Holst et al., *Kepone (Chlordecone)*, ENCYCLOPEDIA VIRGINIA (Aug. 31, 2012), [http://www.encyclopediavirginia.org/Kepone#start\\_entry](http://www.encyclopediavirginia.org/Kepone#start_entry). Kepone is a synthetic chlorinated insecticide, which was introduced in 1958 to combat leaf-eating insects, ants, roaches, and fly larvae. *Id.* From 1966 to 1975, Allied Chemical produced Kepone at a plant in Hopewell, Virginia, where waste was dumped directly into the James River. *Id.* After an employee was determined to have high levels of Kepone in his blood, the plant was shut down. *Id.* Kepone was found in the James River, its sediment, and all over Hopewell. *Id.* Studies demonstrated that Kepone had negative effects on neurological systems, reproductive systems, the liver, skin, and vision. *Id.*

<sup>18</sup> See EPA CHEMISTRY ASSISTANCE MANUAL, *supra* note 10, at 107; Markell, *supra* note 13, at 336. For example, during a March 26, 1976 Senate debate, Senator John V. Tunney (D-CA), a leading participant in TSCA enactment, stated:

[T]he National Cancer Institute has estimated that 60 to 90 percent of the cancers occurring in this country are a result of environmental contaminants. Many doctors and scientists now believe that cancer, which has been projected to kill as many Americans in 1975 as all the battle deaths in Vietnam, Korea, and the Second World War combined, appears particularly susceptible to a preventive approach through control of toxic substances.

*Id.* at 341 (citing LEGISLATIVE HISTORY, *supra* note 2).

<sup>19</sup> Markell, *supra* note 13, at 338 (quoting S. REP. NO. 94-698, at 1 (1976), reprinted in 1976 U.S.C.C.A.N. 4491, 4491).

interested parties.<sup>20</sup> TSCA has not been amended since it was enacted in 1976.<sup>21</sup>

## B. JURISDICTIONAL SCOPE

TSCA regulates all organic and inorganic chemical substances and mixtures, both synthetic and naturally occurring, except for food, food additives, drugs, cosmetics, nuclear materials, tobacco, and pesticides.<sup>22</sup> TSCA manages both “existing chemicals” (i.e. those chemicals already in commerce at the time of the creation of the original TSCA Inventory in the late 1970s) and “new chemicals” (i.e. substances not yet in commerce that entities want to

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<sup>20</sup> EPA CHEMISTRY ASSISTANCE MANUAL, *supra* note 10, at 105.

<sup>21</sup> *TSCA Reform: The Standard of Safety*, *supra* note 4, at 11081 (Statement by Linda Breggin).

<sup>22</sup> EPA CHEMISTRY ASSISTANCE MANUAL, *supra* note 10, at 107. TSCA specifically defines the term “chemical substance” to mean:

any organic or inorganic substance of a particular molecular identity, including—

- (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature and
- (ii) any element or uncombined radical.

15 U.S.C. § 2602(2)(A). TSCA specifically excludes from the definition of “chemical substance”:

- (i) any mixture,
- (ii) any pesticide . . . when manufactured, processed, or distributed in commerce for use as a pesticide,
- (iii) tobacco or any tobacco product,
- (iv) any source material, special nuclear material, or byproduct material . . .
- (v) [pistols, revolvers, firearms, shells, cartridges] and
- (vi) any food, food additive, drug, cosmetic, or device . . . when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

15 U.S.C. § 2602(B).

introduce).<sup>23</sup> More than 24,000 new chemicals have been added to the TSCA inventory of chemicals since the TSCA's implementation in 1976, which brings the total number of chemicals now in the inventory to about 84,000.<sup>24</sup>

TSCA requires EPA to prevent chemicals from presenting "unreasonable" risks to health and the environment; in determining whether risks of a substance are "unreasonable," EPA must weigh the benefits and the risks of the substance.<sup>25</sup> EPA's charge to protect human health and the environment is further tempered by Congress's direction that EPA not "unduly impede technological innovation" in implementing TSCA.<sup>26</sup>

In enacting TSCA, Congress aimed to increase the availability of information about chemicals and their potential risks.<sup>27</sup> In order to assess the risk of harm to human health and the environment, Section 4(a) of TSCA compels EPA to require chemical manufacturers and processors to test chemical substances or mixtures in two situations.<sup>28</sup> First, EPA must require such testing if it finds that a chemical may present an unreasonable risk of injury, there is insufficient data to determine the risk, and testing is necessary to develop such data.<sup>29</sup> Second, EPA must require testing if it finds that a

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<sup>23</sup> TSCA Reform: Information Confidentiality, Availability, and Sharing, *supra* note 8, at 10406 (2012) (Statement by Scott M. Sherlock); *see also* TSCA § 8(b), 15 U.S.C. § 2607(b)(1).

<sup>24</sup> TSCA Reform: Information Confidentiality, Availability, and Sharing, *supra* note 8, at 10406 (2012) (Statement by Scott M. Sherlock).

<sup>25</sup> EPA CHEMISTRY ASSISTANCE MANUAL, *supra* note 10, at 108.

<sup>26</sup> *Id.*

<sup>27</sup> Markell, *supra* note 13, at 353 (citing 15 U.S.C. § 2601(b)(1)).

<sup>28</sup> TSCA § 4(a), 15 U.S.C. § 2603(a).

<sup>29</sup> TSCA § 4(a)(1)(A), 15 U.S.C. § 2603(a)(1)(A). Specifically, Section 4 of TSCA provides, in relevant part, that EPA must require such testing of a chemical substance or mixture if it finds:

- (i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,

chemical substance will be produced in substantial quantities, there may be significant environmental or human exposure to such substance, there is insufficient data to determine risk, and testing is necessary to develop such data.<sup>30</sup> If EPA makes either of these determinations, EPA must require testing on the substance or mixture to determine whether the “manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture, or that any combination of such activities, does or does not present an unreasonable risk of injury to health or the environment.”<sup>31</sup> EPA may enter into an Enforceable Consent Agreement to compel a party to conduct the necessary testing.<sup>32</sup>

In 2009 testimony to Congress, the Government Accountability Office (GAO) concluded that the TSCA regime

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- (ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and
  - (iii) testing of such substance or mixture with respect to such effects is necessary to develop such data.

*Id.*

<sup>30</sup> TSCA § 4(a)(1)(B), 15 U.S.C. § 2603(a)(1)(B). Specifically, Section 4 of TSCA provides, in relevant part, that EPA must require such testing if it finds:

- (i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture,
- (ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and
- (iii) testing of such substance or mixture with respect to such effects is necessary to develop such data.

*Id.*

<sup>31</sup> TSCA § 4(a), 15 U.S.C. § 2603(a).

<sup>32</sup> Markell, *supra* note 13, at 354.

was flawed because it “places the burden on EPA to demonstrate a need for data on a chemical’s toxicity rather than on a company to demonstrate that a chemical is safe.”<sup>33</sup> Furthermore, the GAO reported that—because of the time and resources involved—EPA has required testing on only about 200 chemicals and has performed “internal reviews” on only about two percent of the chemicals that were in the 1979 TSCA inventory.<sup>34</sup>

### C. TREATMENT OF CBI UNDER TSCA

Section 14 of TSCA sets forth the scope of protections for CBI submitted pursuant to the Act.<sup>35</sup> With certain exceptions, Section 14 prohibits the disclosure of information exempt from disclosure under Subsection (b)(4) of the Freedom of Information Act (FOIA).<sup>36</sup> Subsection (b)(4) of FOIA

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<sup>33</sup> *Id.* at 355 (quoting U.S. Gov’t Accountability Office, GAO-09-428T, Chemical Regulation: Options for Enhancing the Effectiveness of the Toxic Substances Control Act 5 (2009)).

<sup>34</sup> *Id.* For a full discussion of the implementation of TSCA, see generally Markell, *supra* note 13; see also Jessica N. Schifano et al., *The Importance of Implementation in Rethinking Chemicals Management Policies: The Toxic Substances Control Act*, 41 ENVTL. L. REP. NEWS & ANALYSIS 10527 (2011).

<sup>35</sup> TSCA § 14, 15 U.S.C. § 2613.

<sup>36</sup> *Id.* Specifically, Section 14(a) of TSCA prohibits disclosure of information exempt from disclosure under Subsection (b)(4) of FOIA:

except that such information—

(1) shall be disclosed to any officer or employee of the United States—

(A) in connection with the official duties of such officer or employee under any law for the protection of health or the environment, or

(B) for specific law enforcement purposes;

(2) shall be disclosed to contractors with the United States and employees of such contractors if in the opinion of the Administrator such disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States entered into on or after October 11, 1976, for the performance of work in connection with this chapter and under such conditions as the Administrator may specify;

specifically exempts from disclosure “matters that are . . . trade secrets and commercial or financial information obtained from a person and privileged or confidential.”<sup>37</sup> Such matters are generally referred to as CBI. Courts generally consider information to be CBI when “its release will harm the competitive position of the submitter or will impair the government’s ability to obtain similar information in the future.”<sup>38</sup> However, Section 14 of TSCA excludes from CBI protection certain data from health and safety studies.<sup>39</sup>

From TSCA’s inception, EPA has been forced to adopt cumbersome security procedures to protect CBI.<sup>40</sup> Soon after TSCA’s enactment, the Polaroid Corporation, who wanted guarantees of confidentiality before submitting information to EPA, sued EPA.<sup>41</sup> In response to the suit, EPA agreed to implement a secure CBI document protection system similar to the military’s classified document safeguards.<sup>42</sup> The CBI document protection system included a security manual, locked rooms, controlled access, and passwords, which sharply curtailed access by both EPA employees and contractors.<sup>43</sup>

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(3) shall be disclosed if the Administrator determines it necessary to protect health or the environment against an unreasonable risk of injury to health or the environment; or

(4) may be disclosed when relevant in any proceeding under this chapter, except that disclosure in such a proceeding shall be made in such manner as to preserve confidentiality to the extent practicable without impairing the proceeding.

*Id.*

<sup>37</sup> 5 U.S.C. § 552(b)(4).

<sup>38</sup> Elizabeth C. Brown et al., *A Practitioner’s Guide to the Toxic Substances Control Act*, in ELIZABETH C. BROWN ET. AL., THE ENVIRONMENTAL LAW REPORTER: TSCA DESKBOOK 80 (1999) (citing *Anderson v. U.S. Dep’t of Health & Human Servs.*, 907 F.2d 936 (10th Cir. 1990)).

<sup>39</sup> TSCA § 14(b), 15 U.S.C. § 2613(b).

<sup>40</sup> Schifano et al., *supra* note 34, at 10537.

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

<sup>42</sup> *Id.*

<sup>43</sup> *Id.*

EPA has struggled to protect legitimate claims of CBI while advancing the goals of TSCA, and CBI claims have remained a substantial barrier to effective TSCA implementation.<sup>44</sup> The Congressional Research Service has noted that “EPA protects from disclosure the identities of as many as 90% of . . . new chemicals due to formal assertions by manufacturers that the information is confidential business information.”<sup>45</sup>

### III. TSCA REFORM

#### A. PROPONENTS OF REFORM

Recent studies and media reports have fueled the resurfacing of consumer fears about the risks that toxic substances pose to human health and to the environment. For example, a recent report released by the Center for Health, Environment and Justice reveals that children’s vinyl back-to-school supplies contain high levels of toxic chemicals such as phthalates, which disrupt hormones and have been linked to birth defects, infertility, early puberty, asthma, ADHD, obesity, diabetes, and cancer.<sup>46</sup> These supplies included popular name brands—such as Disney Princess, Spiderman, and Dora the Explorer—lunchboxes, backpacks, three-ring binders, rainboots, and raincoats.<sup>47</sup> None of these products had labels warning that they contained toxic chemicals.<sup>48</sup>

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<sup>44</sup> *Id.* at 10531–33. For a full discussion of the development of EPA’s treatment of CBI claims, see generally Schifano et al., *supra* note 34.

<sup>45</sup> Markell, *supra* note 13, at 372 (quoting EPA, REDUCING RISK: CRS REPORT FOR CONGRESS: THE TOXIC SUBSTANCES CONTROL ACT (TSCA): IMPLEMENTATION AND NEW CHALLENGES 9 n.25 (Updated July 18, 2008)).

<sup>46</sup> MICHAEL SCHAEDE, CENTER FOR HEALTH, ENVIRONMENT & JUSTICE, HIDDEN HAZARDS: TOXIC CHEMICALS INSIDE CHILDREN’S VINYL BACK-TO-SCHOOL SUPPLIES 3 (2012), available at <http://chej.org/wp-content/uploads/HiddenHazardsReportFINAL.pdf>. The investigation revealed that eighty percent of popular school supplies contained elevated levels of phthalates, which have been banned in children’s toys but not school supplies. *Id.* at 3, 3 n.1. Low levels of heavy metals were also detected in forty percent of the school supplies tested. *Id.* at 4.

<sup>47</sup> *Id.* at 3–6.

<sup>48</sup> *Id.* at 4.

A study by the Environmental Working Group on newborn infants found more than 200 synthetic industrial chemicals in the infants' blood, including dioxins, furans, flame retardants, active ingredients in stain removers and carpet protectors, lead, polychlorinated biphenyls (PCBs), and pesticides banned more than thirty years ago.<sup>49</sup>

Another recent study by scientists from the Center for Disease Control and Prevention (CDC) found measurable levels of many phthalate metabolites in the general U.S. population, which indicates that phthalate exposure is widespread.<sup>50</sup> Furthermore, adult women had higher levels than men of phthalate metabolites for phthalates that are used in soaps, body washes, shampoos, cosmetics, and similar personal care products.<sup>51</sup>

Finally, a recent report by the Interagency Breast Cancer and Environmental Research Coordinating Committee (IBCERCC) explained that the number of women diagnosed with breast cancer continues to rise despite decades of research, which highlights the need to intensify the study of chemical factors in order to identify and mitigate the environmental causes of breast cancer.<sup>52</sup>

Reports such as these are leading many to question government regulation of toxic chemicals in consumer products and the efficacy of TSCA.<sup>53</sup> For example, the IBCERCC

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<sup>49</sup> Kenneth A. Cook, President of the Env'tl. Working Grp., Testimony before the Subcomm. on Superfund, Toxics and Env'tl. Health, U.S. Senate Comm. on Env't Pub. Works, on Current Sci. on Pub. Exposure to Toxic Chemicals (Feb. 4, 2010), *available at* [http://epw.senate.gov/public/index.cfm?FuseAction=Files.View&FileStore\\_id=31bcb6cf-26ff-4415-b04d-87988118af33](http://epw.senate.gov/public/index.cfm?FuseAction=Files.View&FileStore_id=31bcb6cf-26ff-4415-b04d-87988118af33).

<sup>50</sup> *Factsheet: Phthalates*, CDC 2 (2009), [http://www.cdc.gov/biomonitoring/Phthalates\\_FactSheet.html](http://www.cdc.gov/biomonitoring/Phthalates_FactSheet.html).

<sup>51</sup> *Id.*

<sup>52</sup> IBCERCC, BREAST CANCER AND THE ENVIRONMENT: PRIORITIZING PREVENTION 1-1-1-2 (2013), *available at* [http://www.niehs.nih.gov/about/assets/docs/ibcercc\\_full.pdf](http://www.niehs.nih.gov/about/assets/docs/ibcercc_full.pdf) [hereinafter IBCERCC Report].

<sup>53</sup> *See, e.g.*, Sarah Evans, *Reform Laws to Keep Harmful Chemicals from Children*, CTPOST (Oct. 12, 2012, 2:48 PM), <http://www.ctpost.com/opinion/article/Reform-laws-to-keep-harmful-chemicals-from-3943348.php>. Indeed, consumer concerns have even led stores

specifically called for improving TSCA in their recent report.<sup>54</sup> Even the inspector general of EPA has stated that “EPA does not have integrated procedures and measures in place to ensure that new chemicals entering commerce do not pose an unreasonable risk to human health and the environment.”<sup>55</sup> Indeed, the American public, regardless of party affiliation, has overwhelmingly expressed support for TSCA reform.<sup>56</sup>

Reform proponents have argued that TSCA must be reformed in order to protect the public’s right to know about chemical agents used in consumer products, to enhance EPA’s ability to identify and manage chemical risks, to provide consistency in regulation, and to increase consumer faith in the safety of American products.

Proponents of reform argue that weaknesses in TSCA have eroded public confidence in the federal government’s regulation of chemicals.<sup>57</sup> Reforms that increase the amount of

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such as Target and Walmart to begin eliminating certain products from these stores. John Repogle, *We Need Regulation to Remove Chemicals from the Supply Chain*, THE GUARDIAN (Dec. 20, 2013, 4:49 PM), <http://www.theguardian.com/sustainable-business/regulation-remove-toxic-chemicals-supply-chain-household>.

<sup>54</sup> IBCERCC Report, *supra* note 52, at 6-46 (“Improving the TSCA is a priority for collecting the data needed to generate and test hypotheses regarding the effects of a wider range of chemicals on breast cancer risk and, ultimately, for preventing environmentally caused disease.”) (internal citations omitted).

<sup>55</sup> David Martin, *Lax Regulations on Toxics Put Kids at Risk, Experts Testify*, CNN (March 17, 2010, 5:04 PM), <http://thechart.blogs.cnn.com/2010/03/17/lax-regulations-on-toxics-put-kids-at-risk-experts-testify/?iref=allsearch/>.

<sup>56</sup> See Uyesato, *supra* note 7, at 12. The Lake Research Partners for Safer Chemicals Healthy Families, an opinion research firm and coalition of over 100 activist groups advocating greater chemicals regulation, conducted a poll in August 2009. *Id.* This nationwide phone survey of 1000 registered voters found widespread bipartisan support for TSCA reform. *Id.* When given a brief description of TSCA reform, seventy-one percent of those surveyed supported reform, and fifty-three percent expressed strong support. *Id.* Although Democrats expressed the greatest support for TSCA reform (eighty-one percent), Independents (sixty-three percent) and Republicans (sixty-six percent) also expressed strong support for TSCA reform. *Id.*

<sup>57</sup> Charles Franklin & Allison Reynolds, *TSCA Reform and Preemption: A Walk on the Third Rail*, 27 NAT. RESOURCES & ENV’T 14, 14 (2012).

information available to the public could help boost consumer confidence, assist consumers in making informed choices, and increase the safety of available chemicals. For example, the IBCERCC has argued that policies that ensure the public's right to know "can shape the public's ability to make choices that reduce exposures and to request that companies provide safer products."<sup>58</sup> Furthermore, EPA and NGOs assert that better access to CBI will help markets shift to safer chemicals.<sup>59</sup>

Proponents of reform also argue that weaknesses in TSCA have impeded EPA's ability to identify and regulate chemical risks to human health and the environment.<sup>60</sup> TSCA's current structure imposes significant hurdles on EPA's ability to request information that would allow EPA to determine whether chemicals present a risk to human health or the environment.<sup>61</sup> More specifically, before EPA can even begin its rulemaking process, EPA has the burden to show that a chemical may present an unreasonable risk.<sup>62</sup> Moreover, because of current restrictions on CBI, it is difficult for EPA to share information with those who are managing chemical risks in state governments or other countries.<sup>63</sup>

The IBCERCC has expressed the concern that TSCA's current CBI protections impede research on chemical safety and prevent chemical hazards from being identified.<sup>64</sup> The IBCERCC believes that requiring companies to report chemical source, use, discharge information, and manufacturing volume could help researchers more fully understand the relationship between chemical exposures and breast cancer.<sup>65</sup> Overall, it appears that the current CBI process presents unnecessarily burdensome

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<sup>58</sup> IBCERCC Report, *supra* note 52, at 8-25.

<sup>59</sup> Uyesato, *supra* note 7, at 13.

<sup>60</sup> Franklin & Reynolds, *supra* note 57, at 16.

<sup>61</sup> *TSCA Reform: The Standard of Safety*, *supra* note 4, at 11083 (statement by Wendy Cleland-Hamnett).

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

<sup>63</sup> *Id.*

<sup>64</sup> IBCERCC Report, *supra* note 52, at 8-25.

<sup>65</sup> *Id.* at 8-26.

barriers to identifying potential risks to health and the environment.

Proponents also argue that reform of TSCA is necessary in order to ensure consistency in regulation. A patchwork of ballot initiatives, laws, and regulations has been promulgated at the state and local level in order to fill perceived gaps in the federal system.<sup>66</sup> State and local level actions are not always supported by scientific rationales, and stakeholders from industry, the NGO community, and academia have questioned whether these actions have actually improved public health or have just increased the public's fears.<sup>67</sup> This state-by-state "balkanization" of chemical laws and policies makes it harder and harder for U.S. companies to compete locally, nationally, and internationally.<sup>68</sup> Therefore, advocates for TSCA reform also argue that a stronger federal chemical control framework is needed to help U.S. companies compete, to increase consumer faith in the safety of U.S. products, and to protect manufacturers and retailers from extreme and sometimes scientifically unsubstantiated chemical and product scare tactics.<sup>69</sup>

## B. INDUSTRY'S PERSPECTIVE

Several industry groups have expressed support for TSCA reform. Industry leaders have stated that it is critical that the Senate work towards a bipartisan solution in order to help rebuild the economy and preempt states from creating a patchwork of regulations. For example, the ACC has expressed its commitment to working with the Senate Committee on Environment & Public Works to pursue TSCA reform.<sup>70</sup> The

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<sup>66</sup> Franklin & Reynolds, *supra* note 57, at 16–17. In 2012, a search of the U.S. State-Level Chemicals Policy Database revealed more than 1,100 laws or policies in place or under consideration at the state level. *Id.* at 17 (providing the Lowell Center for Sustainable Production's "US State-Level Chemicals Policy Database" as the source of the search).

<sup>67</sup> *Id.*

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

<sup>69</sup> *Id.*

<sup>70</sup> Press Release, Am. Chem. Council, ACC Committed to Working on Bipartisan TSCA Reform (July 25, 2012), *available at*

ACC has encouraged Democratic Senators to work with Republican proposals that will attract bipartisan support in order to “create a world-class regulatory system that provides for the safe use of chemicals, protects American jobs and maintains U.S. global leadership in innovation.”<sup>71</sup> Similarly, the Adhesive and Sealant Council (ASC) called for the U.S. Senate to find a bipartisan solution to reform TSCA.<sup>72</sup> The ASC stated that it was critical for all concerned parties to find common ground “in a timely manner in order to preempt efforts by states and local municipalities to introduce their own chemical regulatory efforts.”<sup>73</sup> Mark Collatz, ASC’s Director of Government Relations, has stated that “[g]iving everyone added confidence in the federal chemical management system is just another step forward in rebuilding the American economy.”<sup>74</sup>

However, the ACC and the ASC have both expressed concern with the TSCA reform efforts, such as the Safe Chemicals Act of 2010.<sup>75</sup> Specifically, the ACC has stated that it believes the Safe Chemicals Act is “fundamentally flawed” because, among other things, it would “undermine long-standing protections of trade secrets, seriously hampering innovations in new products and

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<http://www.americanchemistry.com/Media/PressReleasesTranscripts/ACC-news-releases/ACC-Commits-to-Working-on-Bipartisan-TSCA-Reform.html>.

<sup>71</sup>*Id.*

<sup>72</sup> Press Release, Adhesive and Sealant Council, ASC Urges Bipartisan TSCA Reform Legislation (Feb. 2, 2012), *available at* [http://www.ascouncil.org/docs/default-document-library/pr\\_collinscoonsvisit\\_2\\_2\\_2012.pdf?sfvrsn=0](http://www.ascouncil.org/docs/default-document-library/pr_collinscoonsvisit_2_2_2012.pdf?sfvrsn=0).

<sup>73</sup>*Id.* Mark Collatz, ASC’s Director of Government Relations, explained that “[w]ithout bipartisan action by Congress, we are likely to end up with a patchwork of requirements for managing chemicals that ultimately will inflict harm on U.S. manufacturing and result in the job losses.” Press Release, Adhesive and Sealant Council, ASC Pushes for Bipartisan TSCA Reform in New Congress (Jan. 16, 2013), *available at* <http://www.ascouncil.org/industry-intelligence/industry-intelligence-detail-view/asc-pushes-for-bipartisan-tsca-reform-in-new-congress>.

<sup>74</sup> Press Release, ASC, *supra* note 72.

<sup>75</sup>*See* Safe Chemicals Act of 2010, S. 3209, 111th Cong. (April 15, 2010), *available at* <http://www.gpo.gov/fdsys/pkg/BILLS-111s3209is/pdf/BILLS-111s3209is.pdf>.

technologies.”<sup>76</sup> The ASC has also expressed concern, stating both that the Safe Chemicals Act failed to address important issues involving chemical assessments and that it represented a step backward from the existing TSCA framework.<sup>77</sup> The ASC has also emphasized the need to protect intellectual property because “American manufacturers are continually seeking to develop new products through expensive research development efforts, which could be stifled unless confidential business information remains protected.”<sup>78</sup>

As seen from the above examples, industry will fiercely contest the release of CBI to the public. Chemical manufacturers fear that with the knowledge of the chemical identity, a competitor could use reverse engineering to obtain their formula and other key manufacturing information.<sup>79</sup> Furthermore, companies fear that public disclosure of testing and other data would result in the loss of trade secret protection for such data and the loss of proprietary rights.<sup>80</sup> Loss of protection would disincentivize companies from investing resources in developing new chemicals.<sup>81</sup>

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<sup>76</sup> Press Release, ACC, *supra* note 70. The ACC has also stated that it believes the bill is flawed because it would “establish an unworkable safety standard,” “require an enormous amount of additional government resources to implement,” and “dramatically increase the time it would take for the Environmental Protection Agency (EPA) to review new chemicals . . .” *Id.*

<sup>77</sup> Miles Moore, *ASC Calls for TSCA Reform*, RUBBERNEWS (Jan. 18, 2013), <http://www.rubbernews.com/article/20130118/NEWS/130119954/asc-calls-for-tasca-reform>. The ASC also noted that the Safe Chemicals Act did not contain a preemption provision forbidding states and municipalities from making their own chemical regulations. *Id.*

<sup>78</sup> Press Release, ASC, *supra* note 72.

<sup>79</sup> Uyesato, *supra* note 7, at 13.

<sup>80</sup> *Id.*

<sup>81</sup> *Id.*

### C. THE ESSENTIAL PRINCIPLES FOR REFORM OF CHEMICALS MANAGEMENT LEGISLATION (THE “ESSENTIAL PRINCIPLES”)

EPA has stated that it believes it is important to reform TSCA in order to “increase confidence that chemicals used in commerce, which are vital to our Nation’s economy, are safe and do not endanger the public health and welfare of consumers, workers, and especially sensitive sub-populations such as children, or the environment.”<sup>82</sup> On September 29, 2009, EPA issued the Essential Principles to help inform TSCA reform efforts in Congress.<sup>83</sup> Of these six principles, two are relevant to the treatment of confidential business information. First, Principle No. 2 states that:

**Manufacturers Should Provide EPA with the Necessary Information to Conclude That New and Existing Chemicals are Safe and Do Not Endanger Public Health or the Environment.**

Manufacturers should be required to provide sufficient hazard, exposure, and use data for a chemical to support a determination by the Agency that the chemical meets the safety standard. Exposure and hazard assessments from manufacturers should be required to include a thorough review of the chemical’s risks to sensitive subpopulations

Where manufacturers do not submit sufficient information, EPA should have the necessary authority and tools, such as data call in, to quickly

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<sup>82</sup>*Essential Principles for Reform of Chemicals Management Legislation*, EPA, <http://www.epa.gov/oppt/existingchemicals/pubs/principles.html> (last visited Mar. 20, 2014).

<sup>83</sup> News Release, EPA, EPA Administrator Jackson Unveils New Administration Framework for Chemical Management Reform in the United States (Sept. 29, 2009), available at <http://yosemite.epa.gov/opa/admpress.nsf/0/Do7993FDCF801C2285257640005D27A6>.

and efficiently require testing or obtain other information from manufacturers that is relevant to determining the safety of chemicals. EPA should also be provided the necessary authority to efficiently follow up on chemicals which have been previously assessed (e.g., requiring additional data or testing, or taking action to reduce risk) if there is a change which may affect safety, such as increased production volume, new uses or new information on potential hazards or exposures. EPA's authority to require submission of use and exposure information should extend to *downstream processors and users of chemicals*.<sup>84</sup>

In other words, while current TSCA regulations place the burden on EPA to demonstrate a need for data,<sup>85</sup> Principle No. 2 seeks to shift the burden to manufacturers to provide information that demonstrates a chemical is safe.<sup>86</sup> Additionally, EPA seeks to expand its authority to require submission of use and exposure information to "downstream processors and users of chemicals."<sup>87</sup>

Principle No. 5 directly addresses the treatment of confidential business information, and it provides that:

**Green Chemistry Should Be Encouraged and Provisions Assuring Transparency and Public Access to Information Should Be Strengthened.**

The design of safer and more sustainable chemicals, processes, and products should be encouraged and supported through research,

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<sup>84</sup> *Essential Principles for Reform of Chemicals Management Legislation*, *supra* note 82 (emphasis added).

<sup>85</sup> Markell, *supra* note 13, at 355; *TSCA Reform: The Standard of Safety*, *supra* note 4, at 11083 (statement by Wendy Cleland-Hamnett).

<sup>86</sup> See *Essential Principles for Reform of Chemicals Management Legislation*, *supra* note 82.

<sup>87</sup> *Id.*

education, recognition, and other means. The goal of these efforts should be to increase the design, manufacture, and use of lower risk, more energy efficient and sustainable chemical products and processes.

TSCA reform should include stricter requirements for a manufacturer's claim of Confidential Business Information (CBI). Manufacturers should be required to substantiate their claims of confidentiality. Data relevant to health and safety should not be claimed or otherwise treated as CBI. EPA should be able to negotiate with other governments (local, state, and foreign) on appropriate sharing of CBI with the necessary protections, when necessary to protect public health and safety.<sup>88</sup>

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<sup>88</sup> *Id.* The other principles are:

**Principle No. 1: Chemicals Should be Reviewed Against Safety Standards that are Based on Sound Science and Reflect Risk-based Criteria Protective of Human Health and the Environment.**

....

**Principle No. 3: Risk Management Decisions Should Take into Account Sensitive Subpopulations, Cost, Availability of Substitutes and Other Relevant Considerations.**

....

**Principle No. 4: Manufacturers and EPA Should Assess and Act on Priority Chemicals, Both Existing and New, in a Timely Manner.**

....

**Principle No. 6: EPA Should Be Given a Sustained Source of Funding for Implementation.**

Implementation of the law should be adequately and consistently funded, in order to meet the goal of assuring the safety of chemicals, and to maintain public confidence that EPA is meeting that goal. To that end, manufacturers of chemicals should support the costs of Agency implementation, including the review of information provided by manufacturers.

Principle No. 5 addresses two potentially—but not necessarily—conflicting goals: promoting innovation and limiting CBI claims. Successful TSCA reform efforts must work to meet both of these goals.

#### D. CONGRESSIONAL AND EPA REFORM EFFORTS

In 2009, the GAO added EPA’s assessment and control of toxic chemicals to its list of “high-risk” areas.<sup>89</sup> The House Energy and Commerce Committee’s Subcommittee on Commerce, Trade and Consumer Protection, the House subcommittee with TSCA oversight, and the Senate Environment and Public Works Committee also examined EPA’s regulation of toxic chemicals and held hearings in 2009.<sup>90</sup>

On September 29, 2009, then acting EPA Administrator Lisa Jackson announced the Obama Administration’s support for TSCA reform and introduced the Essential Principles.<sup>91</sup> In 2010, EPA asked companies to voluntarily declassify documents they claimed as CBI if the claims were “inconsistent with the law or no longer necessary” in order to increase transparency.<sup>92</sup> Furthermore, EPA issued a new policy in which it stated that it will deny—with limited exceptions—confidentiality claims for the identity of chemicals in health and safety studies and data

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<sup>89</sup> U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-09-271, HIGH RISK SERIES: AN UPDATE 2 (2009), available at <http://www.gao.gov/new.items/d09271.pdf>. Areas are identified as high risk either due to their “greater vulnerabilities to fraud, waste, abuse, and mismanagement” or due to their need for “broad-based transformation to address major economy, efficiency, or effectiveness challenges.” *Id.*

<sup>90</sup> Uyesato, *supra* note 7, at 12.

<sup>91</sup> News Release, EPA, *supra* note 83.

<sup>92</sup> TSCA CBI Declassification Challenge, EPA, <http://www.epa.gov/oppt/existingchemicals/pubs/declassification-cbi.html> (last visited Mar. 20, 2014). As an incentive, EPA has stated that companies who fail to review and declassify documents will be subject to review and administrative actions consistent with TSCA by EPA. *Id.* Nearly 1000 documents formerly claimed as CBI have been made public since EPA issued the challenge. *Id.*

from health and safety studies.<sup>93</sup> In addition, EPA commenced a review of the more than 16,000 chemical identities currently claimed as CBI.<sup>94</sup>

In 2010, several bills were introduced including the Safe Chemicals Act of 2010 in the U.S. Senate<sup>95</sup> and the Toxic Chemicals Safety Act in the U.S. House of Representatives.<sup>96</sup> In 2010, EPA also took steps to limit CBI claims under Section 8(e) of TSCA, with or without congressional TSCA reform.<sup>97</sup>

On April 14, 2011, Senator Frank Lautenberg (D-NJ) introduced the Safe Chemicals Act of 2011.<sup>98</sup> The Safe Chemicals Act of 2011 closely tracked the Safe Chemicals Act of 2010, but went further by adding plans for risk prioritization.<sup>99</sup> The Safe Chemicals Act would have dramatically increased

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<sup>93</sup> Claims of Confidentiality of Certain Chemical Identities Contained in Health and Safety Studies and Data from Health and Safety Studies Submitted Under the Toxic Substances Control Act, 75 Fed. Reg. 29754 (May 27, 2010), available at <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2010-0446-0001>.

<sup>94</sup> Confidential Business Information, EPA, <http://www.epa.gov/opptintr/tsca8e/pubs/confidentialbusinessinformation.html> (last visited Mar. 2, 2014).

<sup>95</sup> Safe Chemicals Act, *supra* note 75. Senator Frank Lautenberg (D-NJ) introduced the Safe Chemicals Act of 2010. *Id.*

<sup>96</sup> Toxic Chemicals Safety Act, H.R. 5820, 111th Cong. (July 22, 2010), available at <http://www.gpo.gov/fdsys/pkg/BILLS-111hr5820ih/pdf/BILLS-111hr5820ih.pdf>. The Toxic Chemicals Safety Act was introduced on July 22, 2010 by Representatives Bobby Rush (D-IL), Kathy Castor (D-FL), Diana DeGette (D-CO), John Sarbanes (D-MD), Janice Schakowsky (D-IL), and Henry Waxman (D-CA). *Id.* This Act died at the end of the 2010 congressional session. *Id.*

<sup>97</sup> Increasing Transparency in TSCA, EPA, <http://www.epa.gov/oppt/existingchemicals/pubs/transparency.html> (last visited Mar. 20, 2014). EPA challenged industry to voluntarily declassify unwarranted CBI claims and issued new guidance outlining EPA's plans to deny confidentiality claims for chemical identity in health and safety studies under TSCA. *Id.*

<sup>98</sup> Safe Chemicals Act of 2011, S. 847, 112th Cong. (2011), available at <http://www.gpo.gov/fdsys/pkg/BILLS-112s847is/pdf/BILLS-112s847is.pdf>.

<sup>99</sup> Brandon H. Barnes et al., *Pesticides, Chemical Regulation, and Right-to-Know*, 2011 ABA ENV'T ENERGY, & RESOURCES L.: YEAR IN REV. 114, 114 (2012).

EPA's oversight, limited CBI claims, and imposed high data generating and reporting requirements on the industry.<sup>100</sup> The bill languished in the Senate Subcommittee on Superfund, Toxics and Environmental Health after deadlocked stakeholder meetings in late 2011.<sup>101</sup>

In 2011, EPA continued to attempt to limit CBI claims under Section 8(e) of TSCA.<sup>102</sup> In February of 2011, EPA "notified five companies that the identities of 14 chemicals associated with a number of health and safety studies submitted under [8(e)] . . . [were] not eligible for confidential treatment."<sup>103</sup> These studies were declassified pursuant to EPA's "effort to increase the public's access to chemical information previously classified as CBI by companies."<sup>104</sup>

In August 2011, EPA issued the final TSCA Chemical Data Reporting Rule ("CDR Rule") to bolster reporting requirements.<sup>105</sup> The CDR Rule aims to limit CBI claims and increase public access to chemical information, and it indicates that the EPA will be focusing on limiting CBI claims in the

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<sup>100</sup> *Id.*

<sup>101</sup> *Id.*

<sup>102</sup> *Id.* at 115 (citing Press Release, EPA, EPA Removes Confidentiality Claims on Studies of Chemicals Submitted under TSCA/Action Part of Ongoing Commitment to Transparency (Feb. 10, 2011), available at <http://yosemite.epa.gov/opa/admpress.nsf/docf6618525a9efb85257359003fb69d/fb73e2f72dc2fc98852578330053cf62!OpenDocument>).

<sup>103</sup> Barnes et al., *supra* note 99, at 115. (quoting Press Release, EPA, *supra* note 102).

<sup>104</sup> Barnes et al., *supra* note 99, at 115. (quoting *TSCA Submissions with Newly Declassified Claims for Confidential Business Information (CBI)*, EPA, [http://www.epa.gov/oppt/existingchemicals/pubs/declassified/declassified\\_claims.html](http://www.epa.gov/oppt/existingchemicals/pubs/declassified/declassified_claims.html) (last visited Mar. 20, 2014)).

<sup>105</sup> Barnes et al., *supra* note 99, at 115 (quoting Press Release, EPA, *supra* note 102).

future.<sup>106</sup> Under the CDR Rule, companies are required to provide new and updated exposure information.<sup>107</sup>

EPA has continued to review CBI claims,<sup>108</sup> and, on February 22, 2013, EPA made publicly available almost 300 health and safety submissions in which the chemical identity had formerly been confidential.<sup>109</sup> By January of 2014, EPA had completed reviews of over 16,200 cases that could include CBI claims for the chemical identity.<sup>110</sup> At that time, only 7,246 TSCA cases still needed to be reviewed.<sup>111</sup>

On April 10, 2013, Senator Lautenberg reintroduced his comprehensive chemical safety bill as the Safe Chemicals Act of 2013.<sup>112</sup> Obtaining little support for the Safe Chemicals Act of 2013,<sup>113</sup> Senator Lautenberg responded by introducing the

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<sup>106</sup> Barnes et al., *supra* note 99, at 115 (“EPA’s efforts suggest that future TSCA reform, at least from an agency perspective, will focus on limiting CBI while increasing data reporting and collection requirements.”)

<sup>107</sup> *Id.* (“In some instances, the CDR Rule modifies reporting triggers, specifies the data to be reported, and amends CBI reporting procedures.”) (citing *TSCA Inventory Update Reporting Modifications, Chemical Data Reporting*, 76 Fed. Reg. 50, 816 (Aug. 16, 2011) (codified at 40 C.F.R. Parts 704, 710, 711)).

<sup>108</sup> *Declassifying Confidentiality Claims to Increase Access to Chemical Information*, EPA, <http://www.epa.gov/oppt/existingchemicals/pubs/transparency-charts.html#progressreview> (last visited Mar. 20, 2014).

<sup>109</sup> *Existing Chemicals: Recent Announcements*, EPA, <http://www.epa.gov/oppt/existingchemicals/recentadditions.html> (last updated Mar. 20, 2014).

<sup>110</sup> *Declassifying Confidentiality Claims to Increase Access to Chemical Information*, *supra* note 108.

<sup>111</sup> *Id.*

<sup>112</sup> Safe Chemicals Act of 2013, S. 696, 113th Cong. (2013), available at <http://www.gpo.gov/fdsys/pkg/BILLS-113s696is/pdf/BILLS-113s696is.pdf>.

<sup>113</sup> Beveridge & Diamond, P.C., *Bipartisan TSCA Modernization Bill, Chemical Safety Improvement Act, Introduced in Senate* (May 24, 2013), <http://www.bdlaw.com/news-1478.html>.

Chemical Safety Improvement Act (CSIA) on May 22, 2013.<sup>114</sup> Under the CSIA, CBI would remain confidential as long as certain requirements are met.<sup>115</sup> While most existing CBI claims would not need to be resubstantiated, new claims would need to be substantiated.<sup>116</sup> Furthermore, manufacturers would be able to protect chemical identities—even if these identities were present in health and safety studies.<sup>117</sup> CSIA would also allow submitters to request the time period for CBI-protection, with certain exceptions.<sup>118</sup>

#### IV. TSCA REFORM SUGGESTIONS

While the aims of protecting public health and the environment and of appeasing industry's concerns are often seen as in conflict, in reality the conflict may not be as large as some perceive. Furthermore, although protecting public health and the environment must remain the primary aim of reform legislation, reform efforts that do not take into account industry concerns will be detrimental to the nation's economy, will fail to garner bipartisan support, and—most significantly—will impede technological progress.<sup>119</sup> Therefore, in order to find a workable

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<sup>114</sup> Chemical Safety Improvement Act, S. 1009, 113th Cong. (2013), available at <http://www.gpo.gov/fdsys/pkg/BILLS-113s1009is/pdf/BILLS-113s1009is.pdf>.

<sup>115</sup> Beveridge & Diamond, P.C., *supra* note 113.

<sup>116</sup> *Id.*

<sup>117</sup> *Id.* However, if a manufacturer wished to protect chemical identities contained in health and safety studies, the manufacturer would be required to provide additional substantiation, structurally-descriptive generic name would be made available to the public, and certain exceptions would apply (e.g. a medical emergency). *Id.*

<sup>118</sup> *Id.* For example, data would not be protected if the submitter withdrew the CBI claim or EPA found the claim to be unsubstantiated. *Id.*

<sup>119</sup> Many examining TSCA reform efforts have stressed the importance of protecting technological innovation. For example, Mark A. Greenwood stated that:

The importance of technological innovation for this country's future cannot be overstated. It is essential to the success of our economy. Of equal importance, technological innovation

solution, reform efforts should be aimed at aligning the twin goals of promoting health and environmental protection with industry's ability to innovate. Indeed, this is not a new concept; aligning health and environmental protection with technological progress is a key principle in the areas of green design, green chemistry, and green energy,<sup>120</sup> and this principle should be at the heart of TSCA reform efforts.

#### A. POTENTIAL NEGATIVE CONSEQUENCES FOR THE U.S. ECONOMY AND CHEMICAL INNOVATION

Legislators must consider the potentially negative impact of new legislation on the U.S. economy and chemical innovation. EPA's Essential Principle No. 2 seeks both to place the burden on industry to evaluate the safety of chemicals and to expand EPA's authority to require submission of use and exposure information to "downstream processors and users of chemicals."<sup>121</sup> Shifting the burden of evaluating the safety of chemicals to industry may have a significant detrimental impact on industry, as was seen with the recently passed Consumer Product Safety Improvement Act (CPSIA). Similar to the approach to current TSCA reform proposals, CPSIA placed the burden on industry to evaluate the safety of their products.<sup>122</sup> Specifically, Section 101 of CPSIA treats any children's product containing more than specified amounts of lead as a banned hazardous substance under the Federal Hazardous Substances

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plays a key role in addressing a broad spectrum of public issues concerned with environmental protection, sustainable energy, national security, public health, food supply, and poverty.

Mark A. Greenwood, *TSCA Reform: Building A Program That Can Work*, 39 ENVTL. L. REP. NEWS & ANALYSIS 10034, 10037 (2009).

<sup>120</sup> See *id.* at 10037.

<sup>121</sup> See *Essential Principles for Reform of Chemicals Management Legislation*, *supra* note 82.

<sup>122</sup> See Consumer Product Safety Improvement Act of 2008 § 101, 15 U.S.C. § 1278a (2008); see also Consumer Product Safety Improvement Act of 2008, H.R. 4040, 110th Cong. § 101 (2008), available at <http://www.gpo.gov/fdsys/pkg/BILLS-110hr4040enr/pdf/BILLS-110hr4040enr.pdf>.

Act (FHSA).<sup>123</sup> Section 102 of CPSIA requires manufacturers of children’s products to have the products tested by an accredited third party for compliance with CPSIA and to certify that the products comply.<sup>124</sup> While Section 102 requires only manufacturers to have products tested, retailers or resellers of children’s products are also subject to CPSIA’s regulations, and they could face large fines if a product they carry is noncompliant with CPSIA.<sup>125</sup> Thus, retailers—from large retailers to second-hand stores—are responsible for monitoring their inventory and can be held liable under CPSIA for selling products that fail to meet CPSIA’s requirements.<sup>126</sup>

CPSIA’s requirements proved to be a significant burden on industry.<sup>127</sup> Small and medium sized businesses, which often lack the resources of large manufacturers and retailers to conduct product testing, were hit especially hard.<sup>128</sup> Furthermore, CPSIA did not exempt children’s products already on the market, which meant that second hand shops would be required to either test or throw out their entire inventory.<sup>129</sup> These burdensome requirements would likely force small manufacturers and retailers out of business.<sup>130</sup> These potential

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<sup>123</sup> *Id.*

<sup>124</sup> H.R. 4040 § 102.

<sup>125</sup> Brett H. Oberst et al., *Obama and EPA Take on TSCA Reform*, 40 ENVL. L. REP. NEWS & ANALYSIS 10123, 10125 (2010), available at <http://elr.info/news-analysis/40/10123/obama-and-epa-take-tsc-a-reform> (“For example, § 217 of [CPSIA] provides that failure to conform with the product safety standards outlined in [CPSIA] is punishable by a civil fine of up to \$100,000 for each violation.” (citing 15 U.S.C. § 2069(a))).

<sup>126</sup> Oberst et al., *supra* note 125, at 10125.

<sup>127</sup> *Id.*

<sup>128</sup> *Id.* Rather than perform the testing themselves, small and medium sized businesses must use expensive outside labs. *Id.*

<sup>129</sup> See *id.*

<sup>130</sup> *Id.* For example, Marilyn Seitz, owner of Pennyworth Thrift Store in Silver Spring, Maryland, has stated that she will be forced to throw away or give away her entire inventory of children’s items. Kate Bolduan, *New Lead Rules May be Toxic to Thrift Stores*, CNN (Feb. 8, 2009), <http://www.cnn.com/2009/US/02/08/thrift.stores.lead/index.html>. She fears

consequences led small business groups to vehemently protest CPSIA, which forced the Consumer Product Safety Commission to impose a one-year stay of testing and certification requirements on January 30, 2009.<sup>131</sup>

EPA's TSCA reform proposals may have a similarly detrimental impact on the economy, with the most significant effects felt by small businesses. If TSCA reform legislation requires manufacturers to produce data for all 80,000 chemicals in commerce regardless of a chemical's exposure or frequency of use, industry will suffer.<sup>132</sup> Similar to CPSIA, TSCA reform could be especially harmful to small businesses that lack the resources to test every chemical.<sup>133</sup> Furthermore, overly broad TSCA reform may make businesses less willing to invest in developing new chemicals because of the costly testing required.<sup>134</sup> More specifically, based on information from industry experts, the Congressional Budget Office (CBO) estimated that if the Safe Chemicals Act of 2011 had been enacted near the end of 2012, manufacturers and processors of chemicals would "incur costs of \$1 million or more per chemical to demonstrate compliance with safety standards."<sup>135</sup> The CBO also estimated that EPA's workload would have increased by about thirty percent each year, which means that EPA would have required an estimated additional \$30 million annually over the following five years to implement and enforce TSCA.<sup>136</sup>

Public disclosure of testing and other data and the resulting loss of trade secret protection and proprietary rights would

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that the federal government's attempt at protecting children will drive her store and thousands of other thrift stores out of business. *Id.*

<sup>131</sup> See Oberst et al., *supra* note 125, at 10125.

<sup>132</sup> *Id.* at 10126.

<sup>133</sup> *Id.*

<sup>134</sup> *Id.*

<sup>135</sup> CONGRESSIONAL BUDGET OFFICE, COST ESTIMATE S. 847 SAFE CHEMICALS ACT OF 2011, 5 (Oct. 1, 2012), available at <http://www.cbo.gov/sites/default/files/cbofiles/attachments/s847.pdf>.

<sup>136</sup> *Id.* at 3. This estimate is based on historical information about how other large regulatory programs have been implemented by EPA and on other information provided by EPA. *Id.*

disincentivize companies from investing resources in developing new chemicals.<sup>137</sup> Furthermore, if EPA, relying on data provided by the development company, allows an equivalent product to enter the market, development companies would have no incentive to incur the heavy costs necessary to bring new products to market. TSCA reform proposals must address these concerns effectively in order to promote innovation and incentivize companies to invest in developing safer chemicals.

## B. PROPOSED INCLUSION OF DATA EXCLUSIVITY AND DATA COMPENSATION PROVISIONS

In order to effectively promote innovation and incentivize companies to invest in developing safer chemicals, TSCA reform legislation should include data exclusivity and data compensation provisions; reforms could incorporate provisions analogous to those governing fertilizer and drug registrations.

### 1. Data Exclusivity and Data Compensation

In the United States, a data exclusivity regime exists for both medicines and agrochemicals.<sup>138</sup> Under a data exclusivity regime, no other company may seek regulatory approval of an equivalent product based on data submitted by the originator company without the originator's approval for a specified period of time.<sup>139</sup> Furthermore, data exclusivity laws prohibit regulators from using the originator's data to approve a generic product during the exclusivity period—even if the generic product is equivalent to the already approved product.<sup>140</sup>

Data exclusivity rights are extremely attractive to industry because data exclusivity rights are stronger than patent rights.

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<sup>137</sup> See Discussion *infra* Section III, B.

<sup>138</sup> Charles Clift, *Data Protection and Data Exclusivity in Pharmaceuticals and Agrochemicals*, in INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES (Anatole Krattiger et al. eds., 2007), available at <http://www.iphandbook.org/handbook/ch04/p09/>.

<sup>139</sup> See *id.*

<sup>140</sup> *Id.*

For example, data exclusivity can protect a product independent of patent rights; if a product is not patented or has an expired patent, data exclusivity will preclude generic products from entering the market until the period of data exclusivity terminates.<sup>141</sup> Furthermore, whereas a patent is not automatic, data exclusivity is automatic, and an originator does not need to incur fees for application or maintenance of the right.<sup>142</sup> Finally, data exclusivity rights are attractive to industry because data exclusivity rights do not contain exceptions that allow governments to alter the law to national circumstances.<sup>143</sup> Thus, granting data exclusivity rights is a strong incentive for industry to invest in a new product.

In contrast, under data compensation provisions, a company seeking to have a generic product approved must provide compensation to the originator for the use of the originator's data during an exclusivity period.<sup>144</sup> For example, "the United States provisions for agrochemicals allow for a further five years of exclusivity during which the originator data may be relied on to approve a generic product, provided compensation for the use of the data is paid to the originator."<sup>145</sup>

## **2. Pesticides and the Federal Insecticide, Fungicide, and Rodenticide Act**

TSCA reform proposals could include provisions analogous to those in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),<sup>146</sup> which provides for federal control of pesticide distribution, sale, and use. Recognizing that a substantial amount of scientific data is required to support the registration of a pesticide and that this data can be very costly to the data submitter, Congress included provisions in FIFRA that provide

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<sup>141</sup>*Id.* Conversely, data exclusivity rights may delay the entry of generic products, which would keep costs higher for consumers.

<sup>142</sup>*Id.*

<sup>143</sup>*Id.*

<sup>144</sup>*See* Clift, *supra* note 138.

<sup>145</sup>*Id.*

<sup>146</sup> FIFRA, 7 U.S.C. §§ 136–136y (1996).

data submitters rights to the data they submit to EPA.<sup>147</sup> Specifically, data submitted to EPA to support registrations are accorded “exclusive use” and “compensation rights” under Section 3(c)(1)(F) of FIFRA.<sup>148</sup> “Exclusive-use” treatment for data precludes other applicants or registrants from relying on data submitted to EPA in support of previous FIFRA registration.<sup>149</sup> Data submitted to support the initial registration of a product containing a new active ingredient is given exclusive-use treatment for ten years beginning on the date of the original registration.<sup>150</sup> “Compensation rights” for data submitted to EPA to support registration provides even broader protection. Specifically, “[w]hile exclusive-use rights apply to data submitted to EPA in support of the first registration of a pesticide, ‘compensation’ rights extend to all data necessary to support or maintain a registration or that are necessary to support [] an experimental use permit.”<sup>151</sup> FIFRA’s compensation rights provision requires applicants and registrants who seek to rely on data that retain compensation rights to offer the data submitter compensation for the use of the data; otherwise, applicants and reregistrants are prohibited from using the data.<sup>152</sup> After data is submitted to EPA in support of a registration, the data is accorded fifteen years of protection under Section 3(c)(1)(F) of FIFRA.<sup>153</sup>

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<sup>147</sup> EPA, PESTICIDE REGISTRATION MANUAL: CHAPTER 10 - DATA COMPENSATION REQUIREMENTS (2010), available at <http://www.epa.gov/opprdo01/registrationmanual/chapter10.html#FIFRA> (“EPA PESTICIDE REGISTRATION MANUAL”). In fact, according to industry analysis, in 2000 the development of a new crop protection chemical cost over \$180 million and took over nine years from discovery to commercialization. Position Paper, *On the Protection of Safety and Efficacy Data for Existing and New Crop Protection Chemicals*, CROPLIFE INT’L 3 (Jan. 15, 2008), [www.croplife.org/view\\_document.aspx?docId=349](http://www.croplife.org/view_document.aspx?docId=349).

<sup>148</sup> EPA Pesticide Registration Manual, *supra* note 147.

<sup>149</sup> *Id.*

<sup>150</sup> *Id.* This ten-year period of protection also extends to data submitted to support the addition of any new use to that registration during the ten-year. *Id.*

<sup>151</sup> *Id.*

<sup>152</sup> *Id.*

<sup>153</sup> EPA PESTICIDE REGISTRATION MANUAL, *supra* note 147.

### 3. Pharmaceuticals and the Hatch-Waxman Act

Pharmaceutical regulations also contain data exclusivity provisions to protect the interests of originators, which are often referred to as “marketing exclusivity” provisions.<sup>154</sup> Generally, Hatch-Waxman or new drug product exclusivity provides for five-year marketing exclusivity for new chemical entities (NCEs) and three-year marketing exclusivity for non-NCE drugs for which new clinical investigations were submitted.<sup>155</sup> To obtain five-year exclusivity, the approved drug must contain a new active ingredient that is an NCE not previously approved by the FDA.<sup>156</sup> To obtain exclusivity, an originator must submit a new drug application (NDA), and for five years from FDA approval of an originator’s NDA, the FDA cannot accept a second entrant’s application that relies on the data submitted in support of the NDA.<sup>157</sup> The holder of an NDA can file a supplemental NDA (“sNDA”) to market a modified version of its drugs and obtain additional exclusivity protection.<sup>158</sup> For example, the holder of an NAS may wish to make changes, such as:

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<sup>154</sup>According to Pharmaceutical Research and Manufacturers of America (PhRMA), the U.S. pharmaceutical industry’s advocacy group, it costs \$1.3 billion to bring a new drug to market. See Michael Hiltzik, *How Big Pharma Distorts the Costs of Developing New Drugs*, L.A. TIMES (Apr. 3, 2011), <http://articles.latimes.com/2011/apr/03/business/la-fi-hiltzik-20110403>. However, estimates such as this have been criticized as being industry-supported studies done by industry-supported economists that lack of transparency. See Roger Collier, *Drug Development Cost Estimates Hard to Swallow*, 180(3) CAN. MED. ASS’N J. 279, 279–80 (Feb. 3, 2009), available at <http://www.cmaj.ca/content/180/3/279>.

<sup>155</sup>Valerie Junod, *Drug Marketing Exclusivity Under United States and European Union Law*, 59 FOOD & DRUG L.J. 479, 489 (2004); see Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355(b), (j), (l); 35 U.S.C. §§ 156, 271, 282) (Hatch-Waxman Act). For a full discussion of drug marketing exclusivity, see Junod, *supra* note 155.

<sup>156</sup>Junod, *supra* note 155, at 494.

<sup>157</sup>*Id.* at 493.

<sup>158</sup>*Id.* at 496.

[N]ew indications for the same drug (e.g., colon cancer in addition to breast cancer), new dosage forms (e.g., tablet in addition to syrup), new strengths (e.g., 30 mg in addition to 10 mg), new routes of administration (e.g., injectable drug in addition to oral form), new patient population, [or] new conditions of use (e.g., new dosage schedule).<sup>159</sup>

In addition to introducing a “change” to an approved drug product, three other conditions must be met for a company to benefit from three-year exclusivity: it must have “(i) conducted or sponsored (ii) clinical trials (iii) which were essential for the approval of the application or of the supplement.”<sup>160</sup> This three-year exclusivity protects only the new “change” to the drug and not the already-approved aspects of the drug.<sup>161</sup>

#### **4. Suggested TSCA Data Exclusivity and Data Compensation Provisions**

Legislators should consider adopting data exclusivity provisions and data compensation provisions similar to those contained in FIFRA or the Hatch-Waxman Act in TSCA reform legislation.

New legislation could contain provisions analogous to those in FIFRA and provide for exclusive use and compensation rights for data submitted to EPA to support registration actions. Other applicants and registrants would be precluded from relying on data submitted to EPA by previous applicants or registrants to support TSCA registration. Under a data exclusivity provision, data submitted to EPA by applicants or registrants to support TSCA registration could be given exclusive-use treatment, for example, for a ten-year period beginning on the date of the original registration of the chemical. New legislation could also contain a compensation rights provision. Such a provision could require applicants and registrants who seek to rely on data that

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<sup>159</sup> *Id.* at 496–97.

<sup>160</sup> *Id.* at 497.

<sup>161</sup> Junod, *supra* note 155, at 500.

retain compensation rights to offer the data submitter compensation for the use of the data for a fifteen-year period following the date of submission of that data to EPA.

If hypothetical Company A submitted data to support TSCA registration for New Chemical A in 2015, Company A would be given exclusive-use treatment until 2025. Other applicants would not be allowed to rely on the data submitted by Company A. Furthermore, under compensation provisions, if Company B sought to rely on Company A's data, Company B would be required to offer Company A compensation for the use of the data until 2030.

Alternatively, new legislation could contain marketing exclusivity provisions similar to those of the Hatch-Waxman Act. TSCA could provide for five-year marketing exclusivity for "new chemicals" and three-year marketing exclusivity for "existing chemicals" for which new clinical investigations were submitted. Under the five-year marketing exclusivity provision, for five years from EPA's approval of an originator's new chemical application, EPA would be precluded from accepting a second entrant's application that relies on the data submitted in support of the originator's application. TSCA reform could also include provisions under which an originator could file a supplemental application to market a modified version of the chemical and obtain exclusivity protection for an additional three years. The additional three years would protect only the new "addition" to the chemical and not the already-approved aspects of the chemical.

For example, if Company A submitted data in support of New Chemical A in 2015, EPA would be precluded from accepting Company B's application if it relied on data submitted by Company A until 2020. If in 2019, Company A submits a supplemental application to market a modified version of New Chemical A (e.g. liquid form in addition to powder form, use in water bottle manufacture in addition to use in clothing manufacture, etc.), Company A would receive marketing exclusivity until 2022.

Provisions analogous to those found in FIFRA or the Hatch-Waxman Act would help address EPA, industry, and consumer concerns. In line with EPA's Essential Principle Number Two, EPA would be able to require manufacturers to "provide EPA with the necessary information to conclude that new and existing chemicals are safe and do not endanger public health or

the environment.”<sup>162</sup> At the same time, these provisions would also be in line with EPA Essential Principle Number Five, which calls for encouraging green chemistry<sup>163</sup> and would address concerns that TSCA reform would stifle innovation and disincentivize companies from investing in developing new, safer chemicals. Specifically, provisions analogous to those found in FIFRA or the Hatch-Waxman Act would allow companies to share information while retaining proprietary rights.

Furthermore, this approach would be in line with EPA Essential Principle Number Five’s call for assuring transparency and strengthening public access to information.<sup>164</sup> More specifically, provisions analogous to those found in FIFRA or the Hatch-Waxman Act would prevent companies from claiming information as CBI to keep information secret and would allow EPA to share more information with the public. Therefore, in order to pass a bill that would address all interested party concerns, Congress should strongly consider adding data exclusivity and compensation rights provisions.

## V. CONCLUSION

TSCA must be reformed in order to address the risks that toxic substances pose to human health and the environment and restore consumer confidence in U.S. chemicals. However, in order to design a feasible chemical management program, reform efforts must work to protect technological innovation and the economy. The potential impact on manufacturers and businesses cannot be ignored, especially given the weakened economy. Government policymakers must consider—in addition to public health and the environment—how TSCA reform will affect the nation’s economy and the ability of industry to design safer and more sustainable chemicals, processes, and products. Government policymakers must strive to align the twin aims of promoting health and environmental

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<sup>162</sup> See *Essential Principles for Reform of Chemicals Management Legislation*, *supra* note 82.

<sup>163</sup> See *id.*

<sup>164</sup> See *id.*

protection with industry's ability to innovate. In doing so, they should work to achieve a proper balance between industry's need to protect CBI and the public's right to know about chemical and physical agents used in consumer products.

Legislators should consider adopting provisions analogous to those found in FIFRA or the Hatch-Waxman Act in TSCA reform proposals in order to address EPA, industry, and consumer concerns. Such provisions would permit EPA to require manufacturers to provide EPA with the necessary safety information and would incentivize companies to invest in developing new, safer chemicals. Industry would be able to share information with EPA and the public without losing proprietary rights.

Adopting provisions analogous to those found in FIFRA or the Hatch-Waxman Act in TSCA reform proposals would help ensure that a successful balance between industry's need to protect CBI and the public's right to know about chemical and physical agents used in consumer products. By balancing these interests, TSCA reform can benefit both industry and the public by providing reliable standards and providing the public with assurances of chemical safety.