Responses to Questions for the Record

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COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON ENVIRONMENT AND THE ECONOMY

On

Regulation of New Chemicals, Protection of Confidential Business Information, and Innovation

Friday, August 16, 2013

The Honorable John Shimkus

1. You make a number of recommendations about changes to the TSCA program.

a. How many of them does EPA already have the authority to do?
b. How many of those remaining from your list could be done administratively versus via statute?

In my testimony, I noted that EPA faces significant challenges with respect to ensuring the safety of new chemicals. Specifically, the federal Toxic Substances Control Act (TSCA) typically gives EPA just 90 days to review pre-manufacturing notices (PMNs),[1] an ambitious schedule for determining whether chemicals may present an unreasonable risk to health.[2] TSCA does not require companies to include toxicity data in PMNs, which means that most are devoid of such information.[3] TSCA places EPA in a "Catch-22" situation where the agency cannot request additional data unless it has tangible evidence that a chemical may pose an unreasonable risk to health, but many times needs that very data to make that determination. According to the U.S. General Accounting Office (GAO), PMNs often lack robust information about how chemicals will actually be used once they go to market.[4] In other words, companies may decide after filing a PMN to produce the chemical in greater volumes or use it in ways that are different than what was described in the PMN.[5] This means that EPA's PMN review may not appreciate actual risks posed by a chemical once on the market.[6]

EPA could theoretically address many of these shortcomings administratively (e.g., rulemakings), but could not strengthen the law's weak "unreasonable risk" standard without the help of Congress.[7] Yet any effort by EPA to make better use of its TSCA authority has faced

staunch opposition from chemical companies, as well as lengthy delays at the U.S. Office of Management and Budget (OMB). For example, EPA used its existing authority to propose a list of high-concern chemicals the agency believes present or may present an unreasonable risk of injury to health or the environment.[8] However, EPA's list continues to languish at OMB where it has been since May 2010.[9]

During her tenure as EPA Administrator, Lisa Jackson directed the agency to make every possible effort to utilize its limited authority under TSCA to reform the way chemicals are reviewed and managed.[10] However, in testimony before the Senate Committee on Environment and Public Works, she noted that legal and procedural hurdles have largely prevented EPA from making progress on this endeavor.[11] For example, Administrator Jackson highlighted the fact that TSCA does not require companies to conduct testing on new chemicals before they enter the market; meaning companies do not have to give EPA all of the information it needs to review a chemical for safety.[12]

Other EPA officials have echoed this sentiment, suggesting that TSCA's limitations have generated significant delays in obtaining data on new chemicals. According to Wade Najjum, EPA inspector general:

> The Agency should have the necessary tools to quickly and efficiently require testing, or obtain other information from manufacturers that is relevant to determining the safety of chemicals, without delays and obstacles currently in place, or excessive claims of confidential business information . . . . TSCA [also] lacks the broad information-gathering and enforcement provisions equivalent to other major environmental statutes. For example, TSCA lacks the administrative authority to seek injunctive relief, issue administrative orders, collect samples, and quarantine and release chemical stocks, among other key authorities. For these reasons and others, there is a compelling case that TSCA must be updated and strengthened.[13]

My testimony also identifies a number of ways to strike a better balance between fostering innovation and protecting public health in the context of protections for confidential business information. In recent years EPA has taken several steps to increase transparency, including reviewing information marked as confidential in health and safety study submissions and declassifying such information when in fact it belonged in the public sphere all along.[14] EPA also has made efforts to encourage voluntary declassification by companies and has published guidance on when confidentiality claims are inappropriate in health and safety studies.[15] More administrative actions to increase transparency should include:

- Giving the public tools to keep better track of the number of claims made for confidential business information, particularly claims made to keep the identities of chemicals secret;
- Requiring justification and substantiation of these claims;
- Requiring re-substantiation of the claims after a period of time; and
- Establishing a presumption that protections for confidential business information will sunset after a period of time unless companies show that protection is still warranted.

However, once again, EPA's efforts to make more of its existing authority under TSCA have been met with vigorous opposition from the chemical industry. Consider a statement made in 2012 by Lawrence Sloan, president of the Society of Chemical Manufacturers and Affiliates, who said that EPA efforts to revise protections for confidential business information could have "significant implications" and "should not be taken lightly."[16]

Congressional action would be required to achieve other necessary improvements to the confidential business information section under TSCA, including:

- Giving EPA authority to impose stronger penalties against companies that make unjustified and overbroad claims of confidential business information;
- Allowing EPA to assess fees for each confidentiality claim made by companies to defray the costs of assessing and auditing whether the information indeed constitutes confidential business information; and
- Making it easier for EPA to share confidential business information with third parties to protect public health and the environment, particularly state and local authorities, first responders, and medical professionals.

2. You state that in contrast to an EPA employee, "a company faces little risk if it abuses confidential business information provisions under TSCA."

a. Does this mean you would support penalties for anyone who abuses CBI, including Third Parties that publish CBI claimed materials?

TSCA already has penalty provisions in place for EPA employees who improperly disclose information designated as confidential.[17] EWG is unaware of any instances where EPA has improperly disclosed such information, suggesting that the criminal penalties for the disclosing party are deterring agency officials from revealing sensitive business information obtained under TSCA to third parties, including state and local regulators, first responders, and medical providers. EWG's view on penalties for third-party disclosure depends on how and whether TSCA's confidential business information provisions are reformed. For example, would penalties be waived if the third party disclosed the information to protect public health? Would penalties be waived if the third party showed that the information had been obtained through reverse engineering or had been publicly disclosed pursuant to other regulatory frameworks at the state level or abroad? Without question, TSCA's provisions protecting confidential business information favor the chemical industry over the public's interest in disclosure. For example, EPA's Office of Inspector General reviewed protections for confidential business information in 2010 and found EPA's procedures for handling confidential business information requests are predisposed to protect industry information rather than to provide public access to health and safety studies.[18] This balance must be recalibrated to increase protections for public health and the environment.

3. Your testimony, by noting TSCA gives EPA just 90 days to review a Pre-manufacture Notice (PMN) for a substance before it goes on the market, implied this leads to poor decision making by EPA. It's my understanding that the regulatory procedures that accompany this provision require EPA to merely *take* action within 90 days, but those actions include options such as requesting an extension or even rejecting the PMN. As a result, the time it takes for final EPA approval can often be much longer than 90 days – and, in fact, may even be years (during which period of time the product cannot be placed on the market). What is your understanding of, or experience with, the PMN review period, especially for substances that fall into EPA categories of concern?

Although EPA can extend its review of a chemical, TSCA requires EPA to show good cause to do so, and such decisions are subject to judicial review.[19]

4. Your statement made several assertions about the lack of testing chemicals under TSCA's new chemicals program, including that:

a. EPA faces a Catch-22 when it comes to new chemicals. The agency cannot request additional data unless it has safety concerns and it cannot adequately address safety concerns without relevant testing data.
b. EPA, with no test data to evaluate the safety of a new chemical, must use computer models, incomplete chemical comparisons and other analyses to predict how it may affect human health and the environment.
c. EPA models and estimates are based on data about previously studied chemicals, not necessarily how a new chemical will be behave.

Based on this testimony:

i. Do you acknowledge that EPA can and does indirectly require companies to test new chemicals under its PMN program?

The lack of test data submitted with PMNs is well documented.[20] Further, EPA rarely requests additional data.[21] In 2010, EPA's Office of the Inspector General estimated that 50 percent of PMN submissions have no test data; 85 percent contain no toxicity data.[22] At the same time, EPA cannot readily require that chemical companies develop test data to include in their PMNs. When EPA lacks information to evaluate a new chemical, it may restrict the use of that substance pending the development of additional information only when it substance "may present an unreasonable risk of injury to health or the environment,"[23] or when the substance is "anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure."[24] As explained above, EPA often needs the information it is seeking to determine whether a chemical may present such a risk. As for the exposure prong, EPA may lack complete information about what a chemical's actual use will be once on the market because chemical companies are not bound to follow the production and use descriptions included in their PMNs.

ii. Do you dispute that EPA's evergreen guidance/Q & As/website on its new chemicals program, for example, make clear that EPA can decide not to approve a PMN without more data/information or to approve a PMN but regulate it more stringently on the basis of default assumptions in the absence of data? See: http://www.epa.gov/oppt/newchems/pubs/qanda-newchems.pdf and http://www.epa.gov/opptintr/newchems/pubs/possible.htm.

EPA reviews PMNs for evidence that a chemical may present an unreasonable risk to health. Although EPA can make such a finding, its efforts to do so often are hindered by a lack of meaningful data to evaluate the chemical and its potential uses. As stated in EPA's Draft "Questions and Answers Document for the New Chemicals Program," there is no requirement that PMNs contain a "minimum data set" to establish a floor amount of information about a chemical.[25] Further, companies only have to include the data they have in their possession or control.[26]

iii. Please explain the intersection of your statement with the provisions of TSCA Section 5(e), authority, which allows EPA to impose testing requirements on new chemicals after they are first, introduced into commerce?

Section 5(e)(1)(A) of TSCA states that EPA may restrict or regulate a new chemical lacking data only when the substance "may present an unreasonable risk of injury to health or the environment"[27] or when the substance is "anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure."[28] Both of these thresholds are difficult to meet based on the limited amount of information typically included in PMNs.

EPA has had a hard time taking proactive steps to protect public health and the environment when there are data gaps with respect to a chemical's toxicity.[29] Congress must amend TSCA to make it easier for EPA to demand that companies conduct and disclose more testing before allowing a chemical on the market. GAO has concluded:

> Although EPA has reviewed new chemicals in a timely manner, its process does not ensure that their potential risks are fully assessed before they enter commerce, EPA usually has few if any test data, and it predicts chemicals' potential effects with mixed results. In addition, the data that EPA uses to assess exposure may change substantially after manufacture begins.[30]

5. Please explain why and how you differ with your perspectives of former EPA officials, who have noted the scientifically robust nature of predictive analyses – such as SAR, read-across, PBT profilers – for determining whether a new chemical may present an unreasonable risk?

The lack of toxicity data, coupled with the amount of information designated as confidential, makes it difficult for EWG and others outside of the agency to fully assess how well EPA identifies and responds to the risks posed by new chemicals during the PMN review process. The

staggering number of data gaps for most chemicals makes it virtually impossible to evaluate the robustness of EPA's predictive modeling tools. According to the Organisation for Economic Co-operation and Development (OECD), which reviewed EPA's predictive modeling capacity in 1994, the models have "good predictive capabilities for ecotoxicity, but [ ] limited predictive capabilities for general systemic health effects."[31] More recently, GAO found that EPA modeling can be "problematic because the models are not always accurate in predicting chemical properties," particularly when little information is available about chemicals with similar molecular structures.[32]

To demonstrate the limitations of EPA's new chemical review program, consider the case of Firemaster 550. In 2003, EPA approved the substance as a suitable replacement for the fire retardant Penta PBDE.[33] EPA concluded that Firemaster 550 was "not persistent, bioaccumulative or toxic to aquatic organisms."[34] Yet subsequent problems have come to light about the widespread use of Firemaster 550. Component chemicals have been found in the tissues of marine mammals, suggesting bioaccumulation.[35] Furthermore, EPA's review failed to predict worrisome signs of toxicity to human health — including obesity, early puberty, insulin resistance, and disrupted thyroid hormone signaling, as reported in a recent academic study.[36]

Four former EPA officials note that EPA's predictive modeling tools have played a significant role in EPA's new chemical review. However, these officials go on to urge further refinement of these tools:

> Progress can be made in the future to improve SAR methods using newer insights about toxicology mechanisms and new high throughput technologies for biological assays, as well as providing EPA with additional authority to obtain information when required.[37]

The stakes are high for public health and the environment with respect to new chemicals. That is why Congress must give EPA more authority to compel the development of toxicity data.

6. Your testimony claims that when health and safety data are restricted from disclosure the public pays. However, section 14 specifically provides that EPA "shall disclose [CBI] if the Administrator determines it necessary to protect health or the environment against an unreasonable risk of injury to health or the environment"?

a. Do you dispute that such a provision exists in TSCA section 14(a)(3)?

No. However, showing that an action is necessary to protect against an unreasonable risk of injury to health and the environment is difficult in practice, meaning that it will be used only in the most limited of circumstances.

b. Do you dispute that data from health and safety studies are not protected from release under TSCA section 14(b)?

No. I do not dispute that information from health and safety study submissions are made available to the public. However, this information is virtually useless because the identity of the chemicals in these studies often is kept secret.[38] In 2009, EWG analysis showed that the identity of approximately 17,000, or 20 percent, of the more than 84,000 chemicals on EPA's inventory were designated confidential.[39] As a result, the public cannot take the necessary steps to manage the risks associated with each chemical.

7. Your testimony asserts that 95% of all pre-manufacture notices (PMNs) for new chemicals contain information manufacturers have designated as confidential.

a. Since EPA is the regulator, has the CBI and can review it, and the PMN substances are not in commerce, what is the relevance of this statistic to your testimony?

EPA's new chemicals program staff have access to confidential information. But secrecy claims can limit the access of other scientists within EPA, as well as independent scientists and consumer advocates to information about high-concern chemicals. Consider again the case of Firemaster 550. Dr. Linda Birnbaum, EPA's top expert on fire retardants when Firemaster 550 was reviewed, and now director of the National Institute of Environmental Health Sciences at the National Institutes of Health, expressed concerns that Firemaster 550's ingredients could present health risks similar to those associated with Penta BDE, a flame retardant that was phased out due to toxicity concerns. Firemaster 550's chemical contents were designated confidential under TSCA's provisions for protecting confidential business information. As a result, that information was not readily available for review, apparently even among key EPA officials. According to Dr. Birnbaum, the chemical contents of Firemaster 550 were kept secret from her, even though she was EPA's leading scientist on flame-retardants.[40] Had Dr. Birnbaum and other EPA scientists known the identity of the chemicals in Firemaster 550, the product would likely have faced greater scrutiny from scientists within the agency.

b. Doesn't EPA have the authority not to approve the PMN if the agency is concerned about the potential health or environmental effects of a PMN confidential substance?

Yes, EPA has the authority to limit the use of new chemicals based on information in the PMN regardless of whether it is designated as confidential. However, this does not change the fact that EPA must clear a high threshold to do so, once again based on TSCA's standard that EPA find that a chemical may present an unreasonable risk to health.

c. Can't the agency also approve the PMN but issue a significant new use rule (SNUR) on the chemical if it wants to review the substance again before it is used in any other new application?

Yes, EPA has the authority to issue a SNUR to reevaluate chemicals subsequent to reviewing their PMNs. However, SNURs must be done through lengthy rulemakings, which are costly and take a long time to complete. As a result, practice has shown that EPA uses them infrequently to review chemical substances again. Therefore, EPA's SNUR authority should not be wholly relied on as a cure for the flaws I have identified with respect to the new chemical review program under TSCA.

8. Your testimony applauds EPA for its recent efforts to audit and declassify claims of confidential chemical identity in approximately 900 health and safety studies. As I understand it, EPA's CBI Declassification Challenge to industry actually determined that 11,553 (almost 75%) of 15,752 cases believed to contain CBI, after review, were shown to not contain any CBI at all.

a. Do you dispute that 11,553 of 15,752 cases were found not to contain any CBI?

In 2010, EPA announced a new policy of reviewing health and safety study submissions to declassify information improperly marked as confidential therein.[41] As of Mar. 31, 2013, EPA has reviewed more than 16,200 cases under this policy, looking for health and safety study submissions containing information improperly flagged as confidential and declassifying that information accordingly.[42] Of the 16,2000 cases, 12,043 fell outside of the EPA's parameters of being a health and safety study submission that contains confidential information.[43] Of the 4,258 cases where EPA found information marked as confidential in a health and safety study submission, 909 of them were determined to not to be entitled to confidential treatment.[44] In other words, more than 20 percent of the cases EPA reviewed containing confidential information in a health and safety study submission should have been made public.[45]

b. Does this statistic alter your perception about alleged industry abuses of CBI? If not, why not?

No. This does not allay EWG's views with respect to companies abusing TSCA's protections for confidential business information. Through this initiative, EPA was forced to spend its limited resources and staff time reviewing overbroad and baseless claims made by industry, which kept information out of the public's eye that could be used to identify potential risks associated with chemicals. If anything, EPA's the review underscores the need for upfront substantiation of claims made to keep information confidential and requirements for chemical companies re-substantiate claims after a period of time. Quite often, companies have the ability to reverse engineer their competitors' products, unveiling the names of previously secret chemicals. This creates a situation where it is only the public that is barred access to this information, as well as state and local regulators, medical professionals, academic researchers, and public interest groups.

I also should note the exponential use of TSCA's protections for confidential business information. When the first TSCA inventory was compiled early in the 1980s, approximately 5 percent of the chemical identities included in the inventory were claimed confidential.[46] However, as time has progressed, this number has skyrocketed to include nearly two-thirds of the 20,403 new chemicals added to the list in the past 33 years.[47] The public only has access to the generic names for these chemicals substances.[48]

The Honorable Henry A. Waxman

1. Does the Environmental Working Group still support placing the burden on manufacturers to demonstrate that their products do not pose risks to consumers, workers, hotspot communities, and vulnerable populations?

Yes. EWG believes that manufacturers should have the burden of ensuring the safety of their chemicals *prior* to being placed on the market. Not only does this make sense in terms of protecting public health and the environment, but also in terms of achieving greater efficiency. After all, manufacturers often are in the best position to identify and assess the hazards posed by the chemical substances they produce, as well as the eventual chemical uses. Current law places the burden of assessing chemical hazards on EPA, but the agency is constrained by incomplete data and the fact it cannot readily demand that companies develop safety data. As a result, many chemicals end up on the market that have not been adequately reviewed for safety, thus causing consumers, workers, hot spot communities and other vulnerable populations to bear the burden and risks these chemicals pose to health and the environment.[49] Any meaningful reform of TSCA must create a framework that fundamentally shifts the burden to chemical companies to assess the safety of chemicals.

In addition, companies should have to provide EPA information to show that a chemical can be used with reasonable certainty of no harm. In 1996, Congress passed the Food Quality Protection Act (FQPA) to increase oversight of pesticides to ensure they are safe for people, particularly when pesticide residues are detected on food. One of the hallmarks of the FQPA is its strong safety standard, which requires a finding that a pesticide can be used with "reasonable certainty of no harm," which is far more health protective than TSCA's "unreasonable risk" standard. A reformed TSCA should adopt the safety standard that appears in FQPA. Doing so will go a long way toward ensuring that the chemicals used in consumer products are at least as safe as pesticides. This is particularly critical given the fact that the public is exposed to far more chemicals regulated under TSCA than pesticides.

2. Does the Environmental Working Group still support reducing overclaiming of confidentiality and promoting transparency?

Yes, absolutely. Although EWG recognizes the importance of preserving incentives that spur innovation, particularly in the area of green chemistry, current law allows chemical companies to make overly broad and unsubstantiated claims to protect basic information about the chemicals they produce. This is a great disservice to the public. Further, EPA has limited resources to audit confidentiality claims made by companies and the public is left with few means to evaluate whether they are being given all of the information they need to avoid potentially harmful exposures. The identities of approximately 20 percent of the 84,000 chemicals on EPA's inventory list are treated as confidential,[50] and will likely remain that way without a presumption that confidential claims sunset after a period of time. It is not sufficient that a limited number of officials at EPA have access to such information. In addition, state and local regulators, medical personnel, and first responders must have access to such information, as well. EWG applauds EPA's recent efforts to declassify CBI in health and safety studies, but this is not enough either.

It is abundantly clear that current law must be reformed to strike a better balance between encouraging innovation and protecting public health rather than inviting chemical companies to largely err on the side of secrecy.

3. Should those important principles be included in any effort to reform TSCA?

Yes. Comprehensive reform must include measures that reign in the number of overbroad and unsubstantiated claims made by companies in the name of protecting confidential business information. One of the primary purposes of TSCA is to ensure that adequate data is developed with respect to chemicals.[51] The law's framework for treatment of confidential business information greatly undermines that purpose. Specifically, it does not require companies to pay fees for the number of claims made or substantiation of those claims. It also does not establish a sunset for claims after a certain number of years absent re-substantiation. As long as companies readily withhold important information about chemicals – save for allowing just a tiny handful of EPA employees access to such information – then the more likely it is that chemical risks may fly under the radar until it is too late. This is unacceptable.

4. **What other reforms are essential to include in TSCA reform if the statute is to be made effective and protective for everyone, including vulnerable populations?**

Comprehensive reform must address a number of critical flaws found in current law. First, EPA must be given authority to review all chemicals in production and use, including those grandfathered in when TSCA was enacted in 1976. Second, the current safety standard, which requires EPA to show that a chemical presents an unreasonable risk, places too heavy of a burden on regulators to act dutifully to protect vulnerable populations from potentially harmful chemical exposures. A reformed TSCA should have a health based safety standard like "reasonable certainty of no harm," which has been the law for pesticides since 1996. Third, manufacturers should be required to submit minimum amounts of toxicity data to ensure that EPA has at least a baseline level of knowledge to assess a chemical's risks. Fourth, EPA should be given greater authority to demand additional testing from companies to fill in any gaps. Fifth, hard deadlines are needed prevent unnecessary delays in the review process. Sixth, more emphasis should be placed on protecting vulnerable populations, for example, allowing EPA to exercise greater caution when chemicals are detected in the cord blood of newborn babies. Seventh, courts need to be directed to give more deference to EPA when it determines that a chemical presents an actionable risk to public health and the environment. Eighth, EPA must have authority to readily ban chemicals such as asbestos that are clearly known are harmful to human health. Finally, we need a law that preserves a complementary relationship between EPA and state and local authorities in an effort to ensure that chemicals are in fact safe.

5. Are those reforms included in the bill recently introduced in the Senate to reform TSCA?

No. The Chemical Safety Improvement Act, S. 1009, is critically flawed, lacking many of the key reforms needed to fix our broken federal toxics law. Although the bill would achieve some improvements, it retains some of the worst features of current law while blocking state and local

efforts to complement EPA's efforts to ensure that chemicals are safe. As a result, the bill in some ways would create a framework that is worse than the one we have under TSCA. For example, the bill perpetuates a weak safety standard and heightened standard of judicial review while blocking many new and existing state laws designed to protect the public from harmful chemical exposures. This cannot be the reform we have been waiting for.

6. Does the Environmental Working Group have concerns about that bill?

There are a host of reasons why EWG believes the Chemical Safety Improvement Act, S. 1009, is an unacceptable vehicle for reforming federal toxics law. EWG's concerns are shared by dozens of other public health and environmental groups, as well as legal experts. In June 2013, EWG sent to Sens. Barbara Boxer and David Vitter several letters signed by these parties that identify some of the most fundamental problems with the bill. Please find copies of these letters in Exhibit A. I have also attached a detailed memorandum (Exhibit B) outlining EWG's concerns with the bill, including its weak safety standard, failure to protect vulnerable populations, its state preemption provisions and its limit on private tort actions.

The TSCA reform principles espoused by the American Chemistry Council (ACC) and EPA suggest the two may have concerns about the Chemical Safety Improvement Act, as well.[52] For example, both the ACC and EPA underscore the need to ensure that EPA has sufficient resources to effectively implement and utilize its authority to regulate chemical safety. The Chemical Safety Improvement Act does not mention fees or cost-sharing — critical components of making sure EPA can accomplish its tasks under federal toxics law. The EPA's principles also state that "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." However, the Chemical Safety Improvement Act does not require companies to submit a minimum data set placing the burden on EPA to get necessary data from manufacturers. Even the ACC says that companies throughout the chain should be responsible for providing necessary information.

7. At the July 11, 2013 hearing, industry witnesses testified that current disclosures, including structurally descriptive, generic chemical names are sufficient for consumer. Do you agree with that statement?

No. EWG does not agree with that statement. Unnecessary secrecy claims do not serve the public's interest because it shields the ability of public advocates, local and state officials, and scientists from examining the harmful effects of chemicals on the TSCA inventory. To underscore this point, please consider again the example of Firemaster 550. The components of this flame retardant mixture were originally marked as proprietary, therefore the public and independent researchers did not know their identity. However, had this information been known there would have been a clear cause for concern. It was later discovered that one of the chemicals used in Firemaster 550 is bis(2-ethylhexyl) tetrabromophthalate (TBPH). This compound is a brominated version of the known reproductive toxicant bis(2-ethylhexyl)phthalate (DEHP). The other components of Firemaster 550 have little safety information but recent studies have raised

concern that they may disrupt hormone signaling. These discoveries have all been made after Firemaster 550 went to market allowing time for significant human exposure.

8. Do these redacted notices provide enough information for consumers to make informed choices and avoid these chemicals if they so desire?

No. These redacted notices merely put consumers on notice that there are unknown chemicals in use or production that may cause serious health consequences (e.g., severely dysfunctional pathological changes), denying them the ability to avoid exposure by masking information that would allow identification of the referenced chemicals. Allowing redaction of notices in this way unnecessarily puts the public at great risk.

9. **Like many in the public interest community, the Environmental Working Group has sought up-front substantiation of confidentiality claims. In your view, should substantiation like this be sufficient? [Exhibit]**

No. There is no factual basis provided in the exhibit to support such a conclusory statement that disclosing the chemical's identity would harm efforts to commercialize the chemical. If this is all a company has to provide to designate information in health and safety studies as confidential then the public may be put at great risk. For example, the limited toxicity testing described in the exhibit reports that "severely dysfunctional pathological changes" of male and female reproductive organs were observed in addition to adverse hematological effects. This indicates that it is important for the identity of the chemical to be revealed to the public. We believe that secrecy claims must be substantiated upfront with an actual basis. EPA also should require secrecy claims to be re-evaluated periodically, to ensure the fewest restrictions to chemical information while protecting the ability to innovate.

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[1] 15 U.S.C. § 2604; 40 C.F.R. §§ 720.40, 720.75.

[2] See Richard A. Dennison, Ten Essential Elements in TSCA Reform, 39 Envtl. L. Reporter 10020, 10024 (2009), http://www.edf.org/sites/default/files/9279_Denison_10_Elements_TSCA_Reform_0.pdf ("[M]ajor constraints" associated with EPA's ability to review PMNs include the fact that "TSCA grants EPA typically one bite at the apple—a one-time, 90-day review opportunity.").

[3] Oversight Hearing on the Federal Toxic Substances Control Act: Hearing Before the Sen. Comm. on Envt. & Public Works, 111th Cong. 5 (2009) (statement of John Stephenson, Dir. Natural Res. & Envt., GAO), http://www.gao.gov/assets/130/123792.pdf.

[4] Id.

[5] Id.

[6] Id.

[7] See, e.g., John S. Applegate, Worst Things First: Risk, Information, and Regulatory Structure in Toxic Substances Control, 9 Yale J. on Reg. 277, 285 (1992) ("Adoption of the unreasonable risk standard, in sum, has resulted in extraordinary demands for information concerning the regulation of toxic substances.").

[8] Semiannual Regulatory Flexibility and Semiannual Regulatory Agenda, 75 Fed. Reg. 21,872, 21,873 (Apr. 26, 2010) (shifting focus to address high-concern chemicals).

[9] U.S. Office of Info. & Regulatory Affairs, TSCA Chemicals of Concern List Under Section 5(b)(4) of the Toxic Substances Control Act (2070-AJ70), http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201010&RIN=2070-AJ70# (last visited Aug. 14, 2013).

[10] Press Release, EPA, EPA Administrator Jackson Unveils New Administration Framework for Chemical Management Reform in the United States (Sept. 29, 2009), http://yosemite.epa.gov/opa/admpress.nsf/d985312f6895893b852574ac005f1e40/d07993fdcf801c2285257640005d27a6!OpenDocument.
[11] Oversight Hearing on the Federal Toxic Substances Control Act: Hearing Before the Sen. Comm. on Envt. & Public Works, 111th Cong. (2009) (statement of Lisa P. Jackson, Administrator, EPA), http://www.epw.senate.gov/public/index.cfm?FuseAction=Files.View&FileStore_id=07100a89-d2f0-4298-80af-db5597364928.
[12] Id.
[13] EPA Office of Inspector Gen., EPA Needs a Coordinated Plan to Oversee Its Toxic Substances Control Act Responsibilities 20 (2010) [hereinafter EPA OIG, EPA Needs A Coordinated Plan], http://www.epa.gov/oig/reports/2010/20100217-10-P-0066.pdf.
[14] EPA, Increasing Transparency in TSCA, http://www.epa.gov/oppt/existingchemicals/pubs/transparency.html (last visited Aug. 14, 2013).
[15] Id.
[16] Joe Kamalick, US Chem Leader Warns Against Government Disclosure of Technology, ICIS, Mar. 6, 2012, http://www.icis.com/Articles/2012/03/06/9538825/us-chem-leader-warns-against-government-disclosure-of-technology.html.
[17] 15 U.S.C. § 2613(d).
[18] EPA OIG, EPA Needs A Coordinated Plan, supra note 13, at 26.
[19] 15 U.S.C. § 2604(c).
[20] See EPA OIG, EPA Needs A Coordinated Plan, supra note 13, at 4.
[21] Id.
[22] EPA OIG, EPA Needs A Coordinated Plan, supra note 13, at 6.
[23] 15 U.S.C. § 2604(e)(1)(A)(ii)(I).
[24] Id. § 2604(e)(1)(A)(ii)(II).
[25] EPA Office of Pollution Prevention & Toxics, Draft Questions and Answers Document for the New Chemicals Program, http://www.epa.gov/oppt/newchems/pubs/qanda-newchems.pdf (last visited Aug. 14, 2013).
[26] Id.
[27] 15 U.S.C. § 2604(e)(1)(A)(ii)(I).
[28] Id. § 2604(e)(1)(A)(ii)(II).
[29] Dennison, supra note 2, at 10020 ("In the absence of clear evidence of harm, companies have largely been free to produce and use such chemicals as they've seen fit. This policy contrasts sharply with the 'presumed guilty until proven innocent' approach adopted for pharmaceuticals and pesticides.").
[30] GAO, Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective (1994), http://archive.gao.gov/t2pbat2/152799.pdf.
[31] EPA OIG, EPA Needs A Coordinated Plan, supra note 13, at 6.
[32] GAO, Chemical Regulation: Actions Are Needed to Improve the Effectiveness of EPA's Chemical Review Program (2006), http://www.gao.gov/assets/120/114641.pdf.
[33] Heather B. Patisaul et al., Accumulation and Endocrine Disrupting Effects of the Flame Retardant Mixture Firemaster 550 in Rats: An Exploratory Assessment, 27 J. Biochem. Molecular Toxicology 124, 124-36 (2013).
[34] Press Release, EPA, Brominated Flame Retardants To Be Voluntarily Phased Out (Oct. 3, 2003), available at http://yosemite.epa.gov/opa/admpress.nsf/0/26f9f23c42cd007d85256dd4005525d2?OpenDocument.
[35] James C. W. Lan et al., Temporal Trends of Hexabromocyclododecanes (HBCDs) and Polybrominated Diphenyl Ethers (PBDEs) and Detection of Two Novel Flame Retardants in Marine Mammals from Hong Kong, South China, 43 Envtl. Sci. & Tech. 6944, 6944-49 (2009), http://pubs.acs.org/doi/abs/10.1021/es901408t.
[36] Patisaul, supra note 33.
[37] James V. Aidala Jr., et al., Practical Advice for TSCA Reform: An Insider Perspective (2010), http://www.epw.senate.gov/public/index.cfm?FuseAction=Files.View&FileStore_id=86806f67-e47e-4cf3-9612-550104e7685a.
[38] See EWG, Off The Books: Industry's Secret Chemical (2009) [hereinafter EWG, Off The Books], http://www.ewg.org/sites/default/files/report/secret-chemicals.pdf.

[39] Id. at 2.
[40] Linda Birnbaum, Statement at American Public Health Association Conference Panel Discussion Titled "PBDE Flame Retardants: Case Study in Public Health Protection" (Nov. 9, 2004).
[41] Claims of Confidentiality of Certain Chemical Identities Submitted Under Section 8(e) of the Toxic Substances Control Act, 75 Fed. Reg. 3,462 (Jan. 21, 2010).
[42] EPA, Declassifying Confidentiality Claims to Increase Access to Chemical Information, http://www.epa.gov/oppt/existingchemicals/pubs/transparency-charts.html (last visited Aug. 14, 2013).
[43] Id.
[44] Id.
[45] Id.
[46] EWG, Off The Books, supra note 38.
[47] Id. at 2.
[48] Id. at 6.
[49] EWG, Body Burden: The Pollution in Newborns (2005), http://www.ewg.org/reports/bodyburden2/execsumm.php.
[50] Id. at 2; see also EPA, TSCA Chemical Substance Inventory, http://www.epa.gov/oppt/existingchemicals/pubs/tscainventory/ (last visited Aug. 14, 2013).
[51] 15 U.S.C. § 2601(b)(1).
[52] Am. Chem. Council, 10 Principles for Modernizing TSCA, http://www.americanchemistry.com/Policy/Chemical-Safety/TSCA/10-Principles-for-Modernizing-TSCA.pdf (last visited Aug. 15, 2013); EPA, Essential Principles for Reform of Chemical Management Legislation, http://www.epa.gov/opptintr/existingchemicals/pubs/principles.html (last visited Aug. 15, 2013).

EXHIBITS

EXHIBIT A: **Sign-On Letters Expressing Concerns with Chemical Safety Improvement Act**

EXHIBIT B: **EWG Memorandum on Differences Between Chemical Safety Improvement Act and Safe Chemicals Act**

June 12, 2013

Senator Barbara Boxer
Chairman
Environment & Public Works Committee
410 Dirksen Senate Office Building
Washington, D.C. 20510

Senator David Vitter
Ranking Member
Environment & Public Works Committee
456 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Chairman Boxer and Ranking Member Vitter:

We the 24 undersigned environmental and occupational health, environmental justice, and public interest organizations have worked for decades to reform the Toxic Substance Control Act and protect the public from the hazards of chemical exposure.

We respect and appreciate the current effort to identify areas of bipartisan compromise and consensus on chemical safety legislation. However, we believe that the resulting Chemical Safety Improvement Act, S. 1009, has serious limitations and would fall far short of our shared goal of safeguarding human health from the risks posed by exposure to toxic chemicals**.** As a result, we will oppose this bill as it is currently written unless it is amended to address our key concerns.

The proposed CSIA would fail to provide a policy framework essential to securing much-needed health protections that have been lacking for nearly 40 years under current law. The compromise measure, if passed in its current form, could undermine a number of state protections, including California's Proposition 65 law, without ensuring any real improvement in federal toxic substances controls. CSIA could have a crippling effect on every state's freedom to regulate toxic chemicals and protect its own residents. Many of our organizations have fought for and helped enact state laws restricting the use of hazardous chemicals in consumer products. Most other major federal environmental laws allow states to take more aggressive action to protect citizens from environmental threats. CSIA, in contrast, may actually preempt state laws requiring warning labels on toxic products. Furthermore, the bill may also prevent private citizens from taking action in state or federal court for harm and injury caused by chemical exposure.

We are also troubled by the fact that CSIA would not explicitly protect pregnant women and children. It would not require EPA to consider the cumulative burden of chemical pollution for residents of highly polluted communities and for workers, which is essential for Americans living and working in or near contaminated industrial and military sites; including many in Louisiana, New Jersey, Indiana, Alaska, and California.

In addition, the CSIA would not require that chemicals be shown to be safe before manufacturing begins. EPA would still face the daunting challenge of rapidly assessing thousands of industry submissions on new chemicals, the majority of them containing absolutely no health and safety data. Moreover, the agency would be required to justify any requests for safety testing and would be allowed to grant chemical companies permission to begin production before it completes its safety determination. This practice of "conditional registration" has been widespread in EPA's

pesticides program, which has allowed thousands of pesticides to sidestep important aspects of the traditional approval process.

The proposed bill would do no better at setting up a system to protect the public from the hazards of the 84,000 chemicals already on the market. Overall, it would set a high bar for EPA to enact any restrictions on chemicals, and the burden would remain on the agency to prove that chemicals are harmful, rather than requiring manufacturers to prove they are safe.

CSIA would retain TSCA's current weak safety standard instead of the more protective standard previously proposed by Sen. Lautenberg in his Safe Chemicals Act. Furthermore, it-would set no clear timelines to ensure that EPA assesses hazardous chemicals in a timely manner, and it would not establish a quick timeframe for action on chemicals known to be hazardous to human health, including persistent, bioaccumulative toxins.

Finally, the bill would offer too many secrecy protections for chemical companies and may limit the ability of doctors, nurses, first responders and public health departments to obtain vital information about a particular substance to identify and treat people who have been injured by these so-called "secret chemicals."

For these and other reasons the Chemical Safety Improvement Act is not acceptable in its current form. We look forward to working with you to pass legislation that makes public health a priority.

Sincerely,

Pamela K. Miller
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Alaska Community Action on Toxics

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June 12, 2013

The Honorable Barbara Boxer
Chairman
Committee on Environment & Public Works
410 Dirksen Senate Office Building
Washington, DC 20510

The Honorable David Vitter
Ranking Member
Committee on Environment & Public Works
456 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Boxer and Ranking Member Vitter:

The undersigned are thirty-four law professors, legal scholars, and public interest lawyers from across the country who have years of collective experience in the fields of administrative, public health, and environmental law, with a particular focus on state and federal toxics policy. We write to express serious reservations with the "Chemical Safety Improvement Act," which was introduced by Sen. David Vitter and the late Sen. Frank Lautenberg on May 22, 2013. Supporters have heralded the bill as a "historic step" toward reforming our broken framework for regulating chemicals on the market. However, for reasons explained herein, we cannot support the bill as written, which must be strengthened to fix current law and ensure that chemicals are safe for people, particularly vulnerable populations such as children.

In our expert opinion, the bill:

• Essentially preserves the same inadequate safety standard used in current law, which has been read by at least one court to require the U.S. Environmental Protection Agency (EPA) to engage in an onerous balancing of costs and benefits to justify restrictions on toxic chemicals;

• Retains the same obstructive standard of judicial review that appears in current law, which requires judges to demand substantial evidence from EPA to justify any safety determination or restriction of a chemical that poses risks to public health and the environment;

• Contains sweeping preemption language that would prevent states from enforcing existing, and adopting new, laws designed to supplement federal law in protecting people and the environment from exposures to harmful substances; and

• Takes the extraordinary step of making any safety determination by EPA dispositive on the question of whether a chemical is safe in federal and state courts. This would effectively bar judges and juries from taking into account other relevant evidence regarding the safety of a chemical, particularly new evidence developed after the determination is made.

Here are our four major concerns presented in detail:

Safety Standard. The bill defines "safety standard" as one that "ensures that no *unreasonable risk* of harm to human health or the environment will result from exposure to a chemical substance." Chemical Safety Improvement Act, S. 1009, 113th Cong. § 3(16) (emphasis added). This definition fundamentally reproduces the same safety standard found in current law.

*See*Toxic Substances Control Act § 6(a), 15 U.S.C. § 2605(a). Unlike strictly health-based standards (*e.g.*, "reasonable certainty of no harm"), laws that use "unreasonable risk" language have been interpreted to require EPA to complete a complex balancing of costs and benefits before the agency can impose a restriction on a chemical to address safety concerns. *E.g.*, John S. Applegate, *Synthesizing TSCA and REACH: Practical Principles for Chemical Regulation Reform*, 35 Ecology L.Q. 721 (2008); *see also* Noah M. Sachs, *Jumping the Pond: Transnational Law and the Future of Chemical Regulation*, 62 Vand. L. Rev. 1817 (2009). Therefore, even without language in the safety standard directing EPA to restrict a chemical using the "least burdensome requirements," Toxic Substances Control Act § 6(a), 15 U.S.C. § 2605(a), by retaining the "unreasonable risk" language, the Chemical Safety Improvement Act might be read to place a heavy burden on EPA to impose even modest restrictions on a chemical. As a result, we believe that the same outcome in *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991) (striking down EPA asbestos ban and phaseout rule) could be possible under the safety standard proposed in this bill, particularly with the heightened judicial review discussed in the next paragraph.

Judicial Review. Courts typically use a reasoned decisionmaking standard to review agency actions, meaning they will not strike down a regulation unless an agency has acted in an arbitrary or capricious manner. *E.g.*, *Allied Local & Regional Reg'l Mfrs. Caucus v. EPA*, 215 F.3d 61, 77 (D.C. Cir. 2000) (EPA consideration of factors listed in statute "adequate to constitute reasoned decisionmaking"); *see also* Administrative Procedure Act, 5 U.S.C. § 706. In contrast, the Chemical Safety Improvement Act, like the Toxic Substances Control Act, would require courts to apply a heightened standard of judicial review when evaluating rules made pursuant to the bill. Specifically, courts would have to set aside rules requiring the development of more test data, safety determinations, and restrictions on chemicals unlikely to meet the safety standard if, in their opinion, EPA has not supported them with "substantial evidence." Chemical Safety Improvement Act, S. 1009, 113th Cong. § 16(2). In practice, this standard can be read to "impose[ ] a considerable burden" on EPA to develop a record that can withstand a hard look from courts, particularly when all of the other procedural hurdles in the bill are factored in. *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1214 (5th Cir. 1991), quoting *Mobile Oil Co. v. Fed. Power Comm'n*, 483 F.2d 1238, 1258 (D.C. Cir. 1973).

Preemption. The Chemical Safety Improvement Act would appear to largely preempt state regulations designed to protect public health and the environment from exposure to harmful chemicals. It would preempt existing and future state regulations that: require the development of test data or information on chemicals for which companies have to submit similar information to EPA; restrict the manufacture, processing, distribution, or use of a chemical after EPA has issued a safety determination for that chemical; or require notification for the use of a chemical substance if EPA has determined that it is a significant new use that must be reported to the agency. Chemical Safety Improvement Act, S. 1009, 113th Cong. § 15(a). The bill also would prohibit states from creating new restrictions on the manufacture, processing, distribution, or use of a chemical that EPA has classified as high- or low-priority. *Id.* § 15(b). This preemption provision is sweeping in nature and raises serious questions as to whether states could even enact or continue to enforce laws that simply require companies to disclose information about chemicals to consumers or require that products carry warning labels. Numerous states have passed laws in recent years in the absence of federal regulatory action to protect the public from

toxic chemicals. *E.g.*, Safer Chemicals Healthy Families, *Healthy States: Protecting Families from Toxic Chemicals While Congress Lags Behind* (2010), http://www.saferstates.com/attachments/HealthyStates.pdf. If this bill were to become law, it would perpetuate many of the Toxic Substances Control Act's shortcomings while preventing states from protecting public health and the environment in the absence of a robust federal law — or in the case of a strong federal regulatory framework, from complementing EPA's efforts to achieve this important goal.

Private Remedies. The bill takes the extraordinary step of making a safety determination by EPA admissible in any federal or state court and dispositive as to whether a chemical substance is safe. Chemical Safety Improvement Act, S. 1009, 113th Cong. § 15(e). As a result, the bill's section on private remedies could significantly encroach on the right of judges and juries to evaluate and weigh relevant evidence regarding the potential injuries caused by toxic chemicals. In turn, this could have the effect of granting chemical companies immunity from legal actions by private parties once EPA has issued a positive safety standard determination, even when subsequent evidence calls into question the agency's reasoning.

In view of these issues, and others identified by public health and environmental groups, we believe the Chemical Safety Improvement Act preserves some of the most problematic features of the Toxic Substances Control Act, while making it harder for state and private actors to ensure the safety of chemicals in the absence of a strong federal backstop for regulating these substances. As a result, the bill, as currently drafted, takes a step backward in the protection of public health. We respectfully ask that the bill be made stronger to achieve meaningful reform of current toxics law and are available to provide substantive recommendations as needed.

Sincerely,

Note: Institutions listed for identification purposes only. The signators do not purport to represent the views of their institutions.

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June 12, 2013

Senator Barbara Boxer
112 Hart Senate Office Building
Washington, D.C. 20510

Dear Senator Boxer:

As organizations that have fought for decades to protect Californians from the dangers of toxic chemicals, we are writing to express our serious concerns about the Chemical Safety Improvement Act (CSIA) introduced by Senators David Vitter and the late Frank Lautenberg.

While the Toxic Substances Control Act (TSCA) is highly flawed and in desperate need of an overhaul, it is critical that any reform measure provide meaningful protection for our children, communities, workers and other vulnerable populations by fixing TCSA's problems without creating new loopholes and bureaucratic dead-ends. That is the spirit of the toxic chemicals policy reform movement that has gained such dramatic momentum in recent years among consumers, parents, state policy makers and environmentally minded companies. We are extremely disappointed that the Chemical Safety Improvement Act fails to provide the policy framework needed to secure the needed protections and could, if enacted, stymie progress and undermine the long-term push for reform.

Some of our concerns with the bill include a weak safety standard, which on its face allows for "reasonable" injuries to public health from toxic chemicals. The bill contains no clear deadlines for EPA action on or assessment of chemicals, few safeguards for vulnerable populations such as children and pregnant women, and no minimum testing requirements for old or new chemicals. We are also troubled that CSIA does not seem to provide fast action on and special protections from persistent, bioaccumulative and toxic chemicals and does not protect workers or communities disproportionately affected by chemical exposures.

Furthermore, the broad language on state-level preemption could tie California's hands and prevent the state from continuing to be a leader on toxic chemical issues. While the Clean Air Act, the Clean Water Act, TSCA and many other federal environmental laws allow states to take more aggressive action to protect their residents from potential environmental threats, any such action would be severely limited under the Chemical Safety Improvement Act. For these and other reasons, the Chemical Safety Improvement Act is not acceptable in its current form.

We urge you to do all you can to strengthen this draft bill as your committee examines the issue of TSCA reform. We realize that a spirit of compromise is always essential in developing major federal legislation. In the end, however, we must have legislation that explicitly emphasizes the imperative to protect the next generation and beyond from the daily onslaught of chemicals that are polluting our bodies and the planet.

We are deeply grateful for your ongoing commitment to protecting all Americans from dangerous chemicals in their food, air, drinking water, consumer products and workplaces. Your bold leadership on this issue is needed now more than ever.

Sincerely,

Janette Robinson Flint
Executive Director
Black Women for Wellness

Annie Sartor
Policy and Campaigns Coordinator
Breast Cancer Action

Jeanne Rizzo, RN
President
Breast Cancer Fund

Jane Williams
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Judi Shills
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Teens Turning Green

Jora Trang
Interim Executive Director and Managing Attorney
Worksafe

cc: The Honorable Dianne Feinstein
The Honorable Henry Waxman, Rank Member House Energy & Commerce Committee

MEMORANDUM

Date: June 11, 2013

Re: Key Differences Between Chemical Safety Improvement Act and Safe Chemicals Act

The Chemical Safety Improvement Act takes a dramatically different approach to reforming the federal Toxic Substances Control Act compared to the Safe Chemicals Act, as amended in 2012. This memorandum overviews some of the key differences between the Chemical Safety Improvement Act and the Safe Chemicals Act. Some of those differences include a weaker safety standard, heightened judicial review, lack of minimum data requirements, broad preemption language, lack of fee and cost-sharing provisions, and glaring lack of attention to vulnerable populations and biomonitoring data, among other things. The following comparison is limited by the fact that the Chemical Safety Improvement Act and the Safe Chemicals Act bear very little resemblance to each other. In particular, many of the critical reform provisions that appear in the Safe Chemicals Act, not to mention its predecessor, the Kid-Safe Chemicals Act, are completely missing from the Chemical Safety Improvement Act.

1. **Complete new framework for regulating chemicals compared to Safe Chemicals Act. [Sections 1-2]**

Unlike the Safe Chemicals Act, the Chemical Safety Improvement Act places far less emphasis on whether individual chemicals are safe and focuses very little on the need to protect vulnerable populations.

Title. The name of the bill, the "Chemical Safety Improvement Act," Section 1(a) (p. 1, line 6) [Short Title], emphasizes the issue of chemical safety generally without saying much about the importance of ensuring that individual chemicals are in fact safe. This is a departure from the Safe Chemicals Act, and certainly the Kid-Safe Chemicals Act introduced before that.

Findings. In contrast to the Safe Chemicals Act, the Chemical Safety Improvement Act's findings, policy, and intent section, Section 2 (p. 2), makes no reference to vulnerable populations; the extent to which chemicals burden our bodies as evidenced by biomonitoring studies; increased incidences of diseases and disorders linked to chemical exposures; or the fact that for years the public has been exposed to chemicals that have not been adequately reviewed and may harm human health and the environment. The Chemical Safety Improvement Act's findings suggest that "unmanaged risks," instead of individual chemicals themselves, "may pose a danger to human health and the environment." Section 2(b) (p. 3, line 7-9) [Findings]. The rest of the bill's findings focus on restoring public confidence in federal regulation of chemicals; the importance of chemicals to the economy; and the need for uniform regulation of such substances, among other things.

Missing Themes Throughout. Unlike the Safe Chemicals Act, the Chemical Safety Improvement Act makes no explicit reference in the entire bill to the following terms: "**workers**," "**pregnant**," "**children**," "**kids**," "**aggregate**" or "**cumulative**" exposure. The bill makes one reference to "**bioaccumulation**," "**persistence**," and "**biomonitoring**" in the context of listing the kind of information EPA may consider when developing guidelines for test data. Section 4 (p. 43-44, lines 3-9) [Chemical Assessment Framework, Types of Health & Environmental Data]. The only mention of "**vulnerable**" in the bill is where it mentions "vulnerability of exposed subpopulations" in the context of what kind of exposure information EPA has to consider when conducting a chemical safety assessment. Section 6 (p. 63, lines 3-4) [New Chemicals & Significant New Uses, Hazard, Use & Exposure Information]. (More on this point, the language here indicates that EPA is not being directed to take into account vulnerable populations when assessing hazards, at least not explicitly.)

2. **Safety standard substantially less rigorous than one in Safe Chemicals Act [Section 3, 6]**

The Chemical Safety Improvement Act's safety standard is defined as a "standard that ensures that no unreasonable risk of harm to human health or the environment will result from exposure to a chemical." Section 3 (p. 9, lines 1-5). This is not a strictly health-based standard like the one used in the Safe Chemicals Act, which, as a matter of law, does not allow for cost-benefit analysis when developing a regulation. Rather, the unreasonable risk language — which is used in current law — has been read to require a cost-benefit analysis because the language implies there is such thing as reasonable or acceptable risk. See John S. Applegate, The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control, 91 Colum. L. Rev. 261 (1991).

Although the Chemical Safety Improvement Act says that EPA must evaluate whether a chemical meets the safety standard "based solely on considerations of risk to human health and the environment," Section 6 (p. 64-65), this does not change the fact that the safety standard, as defined, still involves some consideration of costs and benefits given the way "unreasonable risk" has been interpreted by the courts and certainly the Office of Management and Budget, which will review any proposed regulatory action by EPA under this bill.

Safe Chemicals Act by Comparison. In contrast, the Safe Chemicals Act would have required EPA to use a far more health-protective standard requiring a showing that there is "reasonable certainty that no harm will result to human health or the environment from aggregate exposure to the chemical substance," SCA Section 7 (p. 100-01), which means that for the safety determination, EPA would not have to consider the benefits of using a particular chemical.

Cumulative and Aggregate Exposures. Finally, note that no reference is made to aggregate or cumulative exposure when applying the safety standard under the Chemical Safety Improvement Act, which are both explicitly mentioned in the Safe Chemicals Act safety standard. Assessing aggregate exposure to chemicals is critical to ensuring public safety and

has been recommended by the National Academy of Sciences. In assessing the safety of a chemical it is necessary to consider exposure from different sources and through different exposure routes. It is also important to consider the cumulative effects from simultaneous exposure to different chemicals that affect the body through the same modes of action (MOA).

3. **Risk management requirements amount to pursuing least burdensome approach like what appears in current law**.
[Section 6]

If EPA determines that a chemical does not meet the safety standard, it must decide which risk-management measures it should take with respect to that chemical. Section 6 (p. 67-72). EPA may pursue a variety of restrictions, including, but not limited to, warnings, use restrictions, production restrictions, phase outs, and bans. Section 6 (p. 67-70). If EPA wants to phase out or ban a chemical, the agency has to conduct and present a careful cost-benefit analysis, including a discussion of technically and economically feasible alternatives, risks posed by each of those alternatives compared to the chemical being considered for regulation, and the economic and social costs and benefits of the proposed restriction compared to potential alternatives, among other things. Section 6 (p. 71-72). Therefore, although the CSIA removes the current law's least-burdensome restriction language, it reads it back into the bill with these requirements to pursue a phase out or ban.

Although the CSIA does not explicitly require the same analysis for other types of restrictions, in practice, it can be expected that EPA will have to perform similar analysis because of the unreasonable risk language in the safety standard. (Once again, this is certainly how the Office of Management and Budget will review any restriction proposed under the CSIA's risk-management provisions.)

In contrast, the Safe Chemicals Act's health-based safety standard does not allow for the same cost-benefit analysis and nothing in the risk-management section of the bill requires EPA to develop a detailed record, studying alternatives, economical and social costs, and the like.

4. **Exemptions allowed without EPA showing 'clear and convincing evidence.'**
[Section 6]

Like the Safe Chemicals Act, the Chemical Safety Improvement Act allows EPA to exempt chemicals from risk management under certain circumstances (e.g., national security interest and avoiding significant economic disruption). However, the Safe Chemicals Act would have required EPA to justify an exemption decision with "clear and convincing evidence," SCA Section 7 (p. 126), whereas the Chemical Safety Improvement Act only says EPA "may exempt the use of a chemical substance from any additional restrictions" if it meets these conditions, with nothing said about EPA's burden of proof to justify the exemption, making

them much more likely. Section 6 (p. 72, lines 4-24) [Safety Assessments & Determinations, Determination Chemical Substance Does Not Meet Safety Standard, Exemptions].

5. **No minimum information set requirements for new chemicals and prioritization**. **[Sections 4, 5]**

The Safe Chemicals Act had a specific section requiring chemical companies to submit minimum information sets necessary for EPA to evaluate new chemicals, new uses of chemicals, and to evaluate for prioritization, among other things. SCA Section 5 (p. 16) [Minimum Information Sets & Testing of Chemical Substances].

In contrast, the Chemical Safety Improvement Act does not require chemical manufacturers to submit to EPA minimum data sets for new chemicals and chemicals being assessed for safety. It only speaks generally about information EPA may need to evaluate chemicals. E.g., Section 4 (p. 29, lines 17-25 & p. 30, lines 1-4) [Chemical Assessment Framework, Development of New Test Data & Information]. Furthermore, the bill gives EPA the option of letting companies market new chemicals before it has enough information to decide if they are safe. Section 5 (p. 53, lines 11-15) [New Chemical and Significant New Uses, Additional Data and Information].

6. **Broad preemption language**.
[Section 15]

The Chemical Safety Improvement Act's section on preemption, Section 15 (p. 114-15), is both explicit and broad in effect and raises serious concerns on its impact of state laws such as California Proposition 65.

The bill states that no state may require additional development of test data or information on a chemical or chemical class for which companies have to submit similar information to EPA (e.g., for EPA chemical assessments). Section 15 (p. 114, lines 10-22) [Preemption]. Under laws such as Proposition 65, regulators have to develop data before listing a chemical or to determine certain safe harbor levels. The Chemical Safety Improvement Act's preemption language raises questions whether states could continue to carry out these steps to develop such data.

The bill goes on to say that no state may create a new, or continue to enforce an existing, restriction on the manufacture, processing, distribution, or use of a chemical after EPA completes a safety determination for that chemical. Section 15 (p. 114, lines 10-25 & 15, lines 1-9) [Preemption]. Further, states are prohibited from creating new restrictions on such chemicals' manufacture, processing, or distribution for chemicals EPA classifies as high- or low-priorities. Section 15 (p. 115, lines 10-24) [Preemption]. At the very least, this language is ambiguous as to whether states could still require companies to disclose to consumers information about chemicals and/or require that products carry warning labels since companies will be likely to argue that "distribution" covers product packaging decisions.

In contrast, the Safer Chemicals Act states that the bill would not affect the ability of individual states to impose additional safety requirements on chemicals, unless complying with state and federal law would be impossible. SCA Section 18 (p. 214).

7. **More protection of confidential business information than in Safer Chemicals Act**. **[Section 14]**

Chemical identity within health and safety data. In a striking departure from current law, the Chemical Safety Improvement Act would allow information elements—such as chemical identity—within health and safety studies and health and safety data submitted to the EPA in notices of substantial risk to be claimed confidential. Section 13 (p. 99-100).

Grandfathering of claims. The Chemical Safety Improvement Act would grandfather confidential business information (CBI) claims made before enactment, preventing EPA from requiring re-substantiation of such claims, Section 13 (p.113, lines 1-11) [Confidential Information, Applicability], unless the claims covered chemical identities or inventory information for chemicals classified by EPA as high-priority. Section 13 (p. 107, 22-25 lines & 108, lines 1-9) [Confidential Information, Redocumentation].

Access hurdles for Medical Personnel. The Chemical Safety Improvement Act also makes it harder than the Safe Chemicals Act for EPA to share the identity of confidential chemicals to medical personnel when that information is needed for treating patients or managing emergency situations. Section 13 (p. 103-106) [Confidential Information, Exceptions to Protection for Disclosure].

The Safe Chemicals Act would require EPA to disclose upon request confidential information to "public health or environmental health professionals or medical personnel" if EPA found disclosure to be in the public interest; found no conflict of interest or competitive interest on the part of the requester; and obtained a confidentiality agreement from the requester. SCA Section 14 (p. 184-85) [Disclosure of Data, Mandatory Exemptions].

The Chemical Safety Improvement Act makes it harder for public health officials to obtain confidential business information about chemicals from EPA. First, the bill refers to "health professional employed by a Federal or State agency or a treating physician or nurse" in a nonemergency situation rather than using broad language such as "public health officials" or "medical personnel" as the terms appear in the corresponding section of the Safe Chemicals Act. Section 13 (p. 104, lines 17-21) [Confidential Information, Exceptions to Protection for Disclosure]. For emergency situations, the Chemical Safety Improvement Act only allows disclosure treating physicians and nurses, with no mention made of healthcare professionals, regardless of whether they are employed by a federal or state agency. Section 13 (p. 105, lines 18-19) [Confidential Information, Exceptions to Protection for Disclosure].

Second, the Chemical Safety Improvement Act requires EPA to follow more detailed procedures before providing to these parties the confidential information. In nonemergency situations, the requester must first submit a "written statement of need" that contains a reasonable basis to suspect that the information is needed to diagnose or treat someone and that knowledge of the chemical identity will assist with such efforts. Section 13 (p. 104, lines 22-24 & p. 105, lines 1-9) [Confidential Information, Exceptions to Protection for Disclosure]. In emergencies, the bill requires this information to be provided as soon as practicable. Section 13 (p. 106, lines 12-15) [Confidential Information, Exceptions to Protection for Disclosure]. The Safe Chemicals Act did not spell out all of these procedures.

8. **Priority review no longer given to some of most troubling chemicals in use**. **[Section 4]**

The Safer Chemicals Act specifically focused on the need to make regulating persistent, bioaccumulative, and toxic (PBT) chemicals a top priority. In contrast, the Chemical Safety Improvement Act only mentions concerns about persistence and bioaccumulation in one place where it says EPA has the option of developing test guidelines for use in safety assessments. Section 4 (p. 44, lines 3-9) [Chemical Assessment Framework, Types of Health & Environmental Data & Information].

This same paragraph contains the only reference in the bill to "biomonitoring," where it says EPA may develop test guidelines on the "presence of the chemical substance or mixture in human blood, fluids, or tissue." Section 4 (p. 43-44, lines 3-9) [Chemical Assessment Framework, Types of Health & Environmental Data].

9. **Judges can still require "substantial evidence" from EPA to support rulemaking**. **[Section 16]**

The Chemical Safety Improvement Act uses the same judicial standard of review that appears in Toxic Substances Control Act, allowing courts to "hold as unlawful and set aside [a] rule if the court finds that the rule is not supported by substantial evidence." Section 16 (p. 122, lines 15-19) [Judicial Review]. As the 5th Circuit noted in Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (1991) (ruling prevented EPA from banning asbestos under TSCA), this standard of review is considered more rigorous and invites considerably more general judicial review than the standard of review used to evaluate rules under other environmental statutes, which only require an agency to show that it acted reasonably. The Safe Chemicals Act would have reformed the Toxic Substances Control Act to replace the substantial evidence standard with a reasonableness standard, SCA Section 19 (p. 214-16).

Further, the Chemical Safety Improvement Act states that safety determinations by the EPA are considered "final agency action," "subject to judicial review." Section 6 (p. 73, lines 3-4) [Safety Assessments & Determinations, Safety Determination, Final Agency Action]. In contrast, the Safe Chemicals Act would have made ineligible for judicial review any safety determination by the EPA, SCA Section 7 (p. 103).

10. **Opportunities for companies to delay review process and absence of clear deadlines**.

Deadlines. Language throughout the Chemical Safety Improvement Act provides no clear deadlines for EPA to complete safety reviews of chemicals, including, but not limited to, EPA's directive to prioritize chemicals and make safety determinations.

The bill directs EPA to "make every effort to complete the prioritization of all active substances **in a timely manner**," Section 4 (p. 18, lines 22-25) [Chemical Assessment Framework, Timely Completion of Prioritization Process] (emphasis added). It also says EPA only has to publish a list of chemicals being considered for prioritization "**from time to time**." Section 4 (p. 19, lines 21-23) [Chemical Assessment Framework, Timely Completion of Prioritization Process] (emphasis added). The bill also gives EPA the opportunity to delay with respect to meeting deadlines for safety assessments and determinations. Section 6 (p. 59, lines 16-24) [Safety Assessments & Determinations] ("deadlines . . . may vary among chemical substances to grant the Administrator **flexibility**; and . . . shall allow for r**easonable extensions** after an adequate public justification") (emphasis added). Moreover, it directs EPA to make safety determinations "**as soon as possible**." Section 6 (p. 64, lines 5-11) [Safety Assessments & Determinations, Safety Determination] (emphasis added). Missing are the hard deadlines that appear in the Safe Chemicals Act. E.g., SCA Section 7 (p. 80-81) (EPA must categorize a first batch of chemicals no later than 180 days after issuing categorization and prioritization regulations).

Additional Opportunities for Delay. The bill gives chemical companies a number of opportunities to delay EPA's review of chemicals, as well. For example, if EPA determines that additional test information is needed to make a safety assessment, the agency is directed to "provide an opportunity for interested persons to submit the additional information," but gives no deadlines for that information to be developed. Section 6 (p. 63, lines 9-13) [Safety Assessments & Determinations, Additional Test Information]. In other words, companies would have the option of taking their time to produce this information if they choose to do so, thus delaying the review process.

11. **Lack of fees and cost-sharing provisions**.

Another significant difference between the Chemical Safety Improvement Act and the Safe Chemicals Act is with respect to giving EPA the ability to require fees from chemical manufacturers to help share the cost of reviewing chemicals for safety and managing associated risks. The Safe Chemicals Act would allow EPA to require by rule "payment of a reasonable fee from any person required to submit data to defray the cost" of administering provisions in the bill. SCA Section 23 (p. 221). In contrast, the Chemical Safety Improvement Act has nothing to say about fees or cost-sharing, making it more difficult for EPA to obtain and develop the test data needed to evaluate the safety of individual chemicals.

12. **Lack of authority to regulate new nanomaterials**.

The Safe Chemicals would give the EPA authority to regulate nanomaterials as separate chemical substances by allowing the agency to consider a variant of a chemical substance as a new chemical substance. SCA Section 4 (p. 9). It also would allow the EPA by order or rule to establish the physical, chemical, or biological characteristics, other than molecular identity, that may significantly affect the risks posed by a chemical substance. SCA Section 4 (p. 13).

In contrast, the Chemical Safety Improvement Act fails to update the definition of "chemical substance" that is contained in current law, which limits the differentiation of chemical substances to particular molecular identities.

13. **No sections on hot spots, green chemistry, or children's health research; little emphasis on information sharing with international partners**.

The Safe Chemicals Act had specific sections addressing "hot spots," or locations with disproportionately higher exposure levels to chemicals, SCA Section 34 (p. 238); creating a children's environmental health research program, SCA Section 29 (p. 224); spurring the development of safer alternatives through green chemistry, SCA Section 31 (p. 234); and encouraging international cooperation to manage and regulate chemical risks, SCA Section 32 (p. 237).

The Chemical Safety Improvement Act has none of these sections. The only discussion of safer alternatives or safe chemistry appears briefly in two places, see Section 2 (p. 4, lines 10-12) [Findings] ("innovation in the development of new chemical substances, especially safer chemical substances, should be encouraged . . . ."); Section 2 (p. 7, lines 1-5) [Intent] ("implement this Act to protect the health of the people . . . in such a manner as not to unduly impede commerce or create unnecessary economic barriers . . . to innovation, including safer chemistry.").