Testimony of Mark Greenwood
Before the U.S. House of Representatives Energy and Commerce Subcommittee on Environment and the Economy

Hearing on
"Chemicals in Commerce Act Discussion Draft"

April 29, 2014

Summary

The Subcommittee's Discussion Draft of the Chemicals in Commerce Act ("CICA Discussion Draft") would make important substantive changes to the Toxic Substances Control Act ("TSCA") that would substantially enhance the ability of the U.S. Environmental Protection Agency ("EPA") to improve how chemicals are managed in this country.

The CICA Discussion Draft makes important changes to TSCA's Section 6 authority to regulate existing chemicals in the following areas:

- Removing the "least burdensome requirements" provision in Section 6, which was the source of court-imposed burdens on EPA that frustrated effective implementation of the statute.
- Creating a prioritization step in the existing chemical program that will allow EPA to establish and sustain a coherent agenda.
- Clarifying the substantive standard and factors to be considered in the risk evaluation and risk management stages of the regulatory process.

The CICA Discussion Draft makes important changes to TSCA's Section 4 authority to require testing of existing chemicals in the following areas:

- Integrating the Section 4 information collection authority into the risk management provisions of Section 5, for new chemicals, and Section 6, for existing chemicals.
- Providing EPA with authority to collect testing information by order, without the necessity of rulemaking.

In regard to protection of Confidential Business Information ("CBI") under Section 14, the CICA Discussion Draft incorporates a compromise that has been developed between industry and public interest groups that will substantially resolve policy and procedural disputes that have continued for over twenty years regarding how CBI information should be handled under TSCA.

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Chairman Shimkus, Ranking Member Tonko and members of the Subcommittee, I thank you for the invitation to testify today on the Subcommittee's Discussion Draft of the Chemicals in Commerce Act ("CICA Discussion Draft"), a bill that would make substantial reforms to the Toxic Substances Control Act ("TSCA") and thereby enhance the ability of the U.S. Environmental Protection Agency ("EPA") to improve how chemicals are managed in this country.

My name is Mark Greenwood. I am an attorney currently practicing environmental law through my firm Greenwood Environmental Counsel. I have worked on implementation of TSCA for over twenty-five years, both in government service at EPA and in private practice. From 1988 to 1990, I was EPA's Associate General Counsel for Pesticides and Toxic Substance, and from 1990 to 1994 I served as Director of the Office of Pollution Prevention and Toxics ("OPPT"), the office in EPA with the primary responsibility for the implementation of TSCA. In private practice I have advised a wide range of clients, including chemical producers, downstream companies, non-profit institutions and investors on TSCA-related matters.

My testimony today will offer an historical perspective on some of the major components of the TSCA chemical management program and the significance of the CICA Discussion Draft in

setting a new direction for that program. In some of the commentary on the previous CICA Discussion Draft that the Subcommittee issued in February, there have been suggestions that the bill your Subcommittee is developing represents no significant change from the status quo, or may even be worse than existing law. While it is understood that strong words are spoken in the context of political debate, I have found it puzzling and surprising to hear these kinds of opinions expressed. The CICA Discuss Draft that is before the Subcommittee today would achieve important substantive changes to TSCA and would substantially improve EPA's ability to protect human health and the environment. The remainder of my testimony will highlight some of the most important changes of this nature.

Section 6: The Approach to Existing Chemicals

As originally enacted in 1976, TSCA gave EPA broad authority under Section 6 of the statute to regulate existing chemicals as necessary to protect adequately against unreasonable risk of injury to health or the environment. In accomplishing this goal, EPA was expected to use the "least burdensome requirements." Other than a specific program for polychlorinated biphenyls, TSCA established no agenda of chemicals, or a process for setting such an agenda, under Section 6. At the time, TSCA was hailed as an innovative, flexible new tool for EPA, which would allow the Agency to address public risks of high concern that fell outside the jurisdiction of the other major environmental statutes.

A. Addressing the "Least Burdensome Requirement" Provision

At an early point in the history of the TSCA program, EPA decided that it would use the new authority of Section 6 to control exposure to asbestos, a substance that demonstrated clear

adverse health effects and was pervasively used. The EPA rulemaking on asbestos was a complicated and controversial proceeding that took over ten years to complete. On July 12, 1989, EPA issued its final rule on asbestos, which called for a complete ban and phase-out of the chemical. The rule drew legal challenges from multiple parties in the U.S. Court of Appeals for the Fifth Circuit. The court issued its decision on the various challenges to the rule on October 18, 1991 in *Corrosion-Proof Fittings, et al. v. Environmental Protection Agency, 947 F.2d 1201 (5th Cir. 1991).* The decision represented a major loss for the Agency, as the court vacated the primary sections of the rule.

In the history of EPA programs, it is difficult to identify a comparable situation where one court decision on one Agency action has had a more profound and lasting impact on the entire course of a program's future. Since 1991, Section 6 has not been used to take any major regulatory action on an existing chemical in the United States. Instead, EPA has used other TSCA authorities, most notably Significant New Use Rules issued under Section 5 of the statute, as the principal tool for imposing risk management actions on existing chemicals.

Since 1991 there has been substantial public discussion about the court's opinion in the *Corrosion-Proof Fittings* case, in part as a guide to how the TSCA statute might be changed. The clearest point of consensus about the opinion is that the court's expansive interpretation of EPA's burden to identify the "least burdensome requirements" imposed a crippling analytical obstacle that would involve potentially unending assessment of regulatory alternatives. This was certainly EPA's conclusion at the time of the court's decision and that view continues to the current day. Accordingly, one of the most important changes to TSCA made by the CICA

Discussion Draft is its removal of the reference to "least burdensome requirements" from Section 6. By that simple act, enactment of this bill will remove the shadow of the *Corrosion-Proof Fittings* decision from the EPA chemicals program.

Some commenters on the February version of the CICA Discussion Draft have also expressed concern that the retention of an "unreasonable risk" standard in Section 6 would stifle EPA's ability to take effective action to protect the public, in part because an unreasonable risk standard permits consideration of cost-benefit analysis. The historical record does not support such a broad conclusion. In the case of the EPA asbestos rule of 1989, EPA conducted a cost-benefit of the rule under the then-existing Presidential Executive Order on Regulatory Review. Despite the fact that the calculated costs of the ban for certain uses were substantial, the rule proceeded through Administration review at the time and was issued. As noted above, the unreasonable risk standard was not the central rationale for the court's decision to remand the rule.

A more recent example also underscores the point that important regulatory actions to protect public health can be issued under an "unreasonable risk" standard. On March 19, 2014, EPA proposed for comment a major set of upgrades to its Agricultural Worker Protection Standard for workers exposed to pesticides.[1] These standards are being proposed in accord with EPA's broad mandate under the Federal Insecticide, Fungicide, and Rodenticide Act to "prevent unreasonable adverse effects on the environment", which according to EPA's proposed rule includes protections for "agricultural workers and pesticide handlers; vulnerable groups, such as minority and low-income populations, child farmworkers and farmworker families; and the general public." It is notable that the cost-benefit analysis prepared on this rule, in accord with the

[1] 79 Fed. Reg. 15444 (March 19, 2014)

Obama Administration's Executive Order on Regulatory Review, showed quantified costs exceeding quantified benefits, but the Administration determined that the rule offered important qualitative benefits that supported the action.

B. Creating a Prioritization Framework

Section 6(a) of CICA establishes a framework for EPA to set priorities for risk evaluation, an essential step if EPA is to establish a meaningful agenda given the large number of distinct chemicals that are in commerce. This is a critical component of the bill because it addresses a politically important defect in the original statute – the ability to do anything, but the mandate to do nothing on existing chemicals.

As noted earlier in my testimony, the original TSCA was viewed as the cutting edge of environmental law because it provided EPA with wide discretion to set its own agenda on what existing chemical warranted attention. This freedom to act ultimately became a profound liability for the EPA TSCA program for several reasons. First, the TSCA program could never cite "statutory mandates" to support its resource requests for the existing chemical program. As a result, the TSCA existing chemical program has been relatively small compared to other EPA programs. Second, since the agenda of the TSCA program was not grounded in specific statutory provisions, the program has sometimes been subject to shifting priorities as new teams of political leadership have entered or departed the Agency. Historical examples of efforts to use TSCA in creative ways that were not ultimately successful have included EPA consideration of Section 6 to address issues as diverse as the effect of chlorofluorocarbons on stratospheric ozone, the disposal of used oil, replacement of leaking underground storage tanks and a prohibition on

lead fishing sinkers. Third, the TSCA program has often had great difficulty expediting review of its regulatory actions in Agency and Administration review processes because its actions were almost always "discretionary."

It is certainly not necessary for Congress to set forth by statute how EPA will set priorities for the existing chemical program. In theory, under CICA as under the original TSCA, EPA would have the ability to set such priorities. There are times, however, when the function of legislation for regulatory agencies is not the creation of new legal authorities, but rather providing guidance on the direction that a program should take. For the TSCA program, history teaches us that providing such guidance on the process and criteria that should be used to set priorities would be extremely valuable. The universe of chemicals in commerce is large and the task of regulating chemicals that may already be widely used is inherently complicated. Providing EPA with direction on what chemicals warrant priority consideration provides legitimacy to the Agency's agenda and facilitates sustained implementation of that agenda. Section 6(a) is one of CICA's most important provisions.

C. Clarifying the Standard for Risk Evaluation and Risk Management

When controversial issues arise in legislation, there is natural tendency to resolve disputes through the adoption of ambiguous language that allows all sides to claim that their viewpoint was adopted. This is a particular risk in a complex statute like TSCA, in which there are many specific terms of art that have been subject to EPA interpretations and clarifications over several decades. Ambiguity, however, is the enemy of effective implementation of statutes like TSCA.

To the extent possible, it is important for Congress to be as clear as possible in its statutory directions to EPA under CICA.

Nowhere is this need for clarity more important than in defining the substantive standard for decisionmaking under Section 6. In previous hearings, this Subcommittee has heard EPA Assistant Administrator Jim Jones emphasize the importance of having Committee Members, and related stakeholder groups, achieve a clear understanding of the principles and factors that are to guide EPA's decisions under Section 6. Previous drafts of CICA, as well as the Senate version of TSCA reform in S.1009, have been somewhat ambiguous about what factors will guide EPA's initial "safety determination" (now referred to as the "risk evaluation" in the latest CICA Discussion Draft) and what factors will guide any risk management actions that EPA believes are warranted based on the risk evaluation.

The CICA Discussion Draft before us today has wisely made a particular effort to resolve those ambiguities. First, it articulates two standards for the two distinct decisions. As a first step, EPA must decide whether a high-priority substance presents or will present a "significant risk of harm" to human health or the environment under its intended conditions of use. If a significant risk is present, then EPA must proceed to write a rule under Section 6(c) applying "requirements or restrictions that the Administrator determines are necessary to protect adequately against an unreasonable risk of harm to human health or the environment from the chemical substance under its intended conditions of use."

To eliminate any potential uncertainty that these two standards are intended to be different, this section of the bill specifically identifies different factors to be considered at the two stages in the process. For the "significant risk" decision in the risk evaluation, Section 6(b)(3)(A) identifies exclusively health and environmental factors (including the likely impact on potentially exposed subpopulations) that must be considered, and then further clarifies in Section 6(b)(3)(B) that economic cost and benefit factors shall not be a part of the "significant risk" decision. In turn, when setting forth the basis for a decision in a Section 6(c) rule under the "unreasonable risk" standard, Section 6(c)(4) identifies a set of factors to guide EPA's decision, such as cost-effectiveness, reasonable transition periods and the profile of alternatives, that are clearly distinct from the factors to be considered at the risk evaluation stage of the process.

Taken as a whole, these changes greatly contribute to the clarity of Congressional intent on one of the most strategically important aspects of CICA. If this degree of clarity can be maintained as this bill proceeds forward in the process, Congress will have substantially reduced the likelihood that a new TSCA program will become mired in an unproductive revisiting of the legislative debate that preceded enactment of CICA.

Section 4: An Opportunity for More Strategic and Timely Information Collection

Over its history, the TSCA program has had a mixed record in using its testing authority under Section 4 to generate data about chemicals of potential concern. A brief examination of that history offers insights into the value of certain CICA provisions.

While TSCA was enacted in 1976, EPA did not start issuing Section 4 rules to any significant degree until the mid-1980's. What some would see as a delay in the testing program reflected a combination of EPA-centered decisions. For example, EPA had to focus on other aspects of the TSCA program, including establishment of the TSCA Inventory and the new chemical program, as well as the initiation of a substantial regulatory program to address PCBs. In addition, EPA made a decision to create a series of Section 8 rules that would collect information about what was already known about chemicals of interest before issuing Section 4 testing rules.

Once EPA began to issue Section 4 testing rules in the 1980's, those rules came under legal attack by the chemical industry. Most of this litigation challenged the scope of EPA's authority under Section 4, and the Agency was inclined to await the outcomes of those cases before initiating a significant number of new rules. The court decisions issued in response to these challenges generally affirmed EPA's interpretations of its authority, but in some areas EPA was compelled to clarify further what information would be necessary to support a Section 4 testing rule.[2] Completion of these policy clarifications occurred in 1993.[3]

In the 1990's EPA began a series of testing initiatives using Section 4 in combination with other mechanisms for collecting data. EPA developed a Master Testing List ("MTL") that attempted to assemble an agenda for Section 4 testing that would identify the testing needs of the TSCA program as well as the testing needs of other EPA programs and other government entities. The list included "chemical categories of concern" that had been identified through the TSCA new

[2] Leading cases on these issues included *Shell Chemical vs. EPA*, 826 F.2d 295 (5th Cir. 1987), *CMA vs. EPA*, 859 F.2d 977 (D.C. Cir. 1988), and *CMA vs. EPA*, 899 F.2d 344 (D.C. Cir. 1990).

[3] 58 Fed.Reg. 28736 (May 14, 1993).

chemical program, as well as chemicals that were being released in high volumes according to EPA's annual Toxic Release Inventory.[4] In addition, the MTL identified a set of chemical testing needs that had been expressed by other EPA programs, such as air toxics, indoor air contaminants and hazardous waste constituents. The MTL further identified testing needs for other agencies, including the Occupational Safety and Health Administration, the Consumer Product Safety Commission, the Agency for Toxic Substances and Disease Registry, and the Organization for Economic Cooperation and Development ("OECD"). The MTL included hundreds of chemicals and far exceeded EPA's capacity for issuing Section 4 test rules, but it set the stage for a series of testing initiatives that followed on a variety of fronts.

One of the more important developments in the 1990's was the advent of voluntary testing initiatives in which EPA collaborated with stakeholders and other governmental organizations, such as the OECD. The most notable of these efforts was the High Production Volume ("HPV") Challenge Program under which companies committed to provide screening level toxicity information, based on the OECD Screening Information Data Set, on chemicals produced or imported in the United States in quantities of one million pounds or more.[5] According to EPA, the HPV program received commitments for development and disclosure of information on over 2,200 chemicals, leading to the submission of thousands of studies.[6] Another important voluntary data development initiative that occurred during this period was the Voluntary Children's Chemical Evaluation Program (VCCEP), which focused on assembling valuable

[4] At that time, the Toxic Release Inventory was managed by the same EPA office that administered TSCA.

[5] The HPV Challenge program was initiated by EPA, Environmental Defense, the American Chemistry Council, and the American Petroleum Institute in 1998.

[6] http://www.epa.gov/chemrtk/pubs/general/basicinfo.htm

toxicity information concerning a set of chemicals to which children had a high likelihood of exposure.[7]

In response to concerns about the possibility that certain chemicals might cause adverse effect to humans and wildlife through the mechanism of endocrine disruption, the Congress enacted legislation in 1996 creating a mandate for testing that has become known as the Endocrine Disruptor Screening Program (EDSP). While this program focused initially on pesticides, EPA expanded the program to include other industrial and commercial chemicals, and the staff of the TSCA testing program was responsible for that aspect of the EDSP. Under the program, EPA was authorized to issue testing orders to companies to produce tests regarding the potential for certain chemicals to affect the endocrine system. EPA began issuing such orders in 2009. While these orders are being issued pursuant to the 1996 statute, rather than Section 4 of TSCA, the EDSP provides another example of how information is being collected on chemicals under the jurisdiction of TSCA.

A review of more recent Section 4 activity by EPA indicates that EPA has been less active in requiring testing. As an example, one of the commitments EPA made in the context of the HPV Challenge Program was to use its Section 4 testing authority to pursue screening level testing for chemicals that met the volume threshold for the program but had not been the subject of a voluntary industry commitment to provide the testing. These so-called "unsponsored HPV Chemicals" were divided into four groups and were to be the subject of four separate Section 4 test rules. EPA issued a rule on the first of these groups in 2006 (71 Fed.Reg. 13708). In 2011, EPA issued final rules for the second group (76 Fed.Reg. 1067) and the third group (76 Fed.Reg.

[7] http://www.epa.gov/oppt/vccep/index.html

65385). A proposed rule to address the fourth group was proposed for comment on October 21, 2011, but a final rule on this group of chemicals has not been issued by EPA.[8]

EPA's experience in using its TSCA Section 4 testing authority offers important lessons about what conditions can make that program most successful. Fortunately, the Subcommittee's CICA Discussion Draft addresses those conditions. First, it has proven very difficult for EPA to move forward on testing proposals that are not directly related to TSCA-based risk management actions. The MTL that EPA developed in the 1990's included a long list of chemicals that were of interest to other EPA programs and to other federal agencies. Yet EPA only completed three significant rules that were responsive to these needs – a rule on hazardous waste constituents (40 CFR §799.5055), a rule on drinking water constituents (40 CFR §799.5075), and a rule on chemicals of interest to the Occupational Safety and Health Administration (40 CFR §799.5115).

In contrast, EPA has been much more successful obtaining needed testing in the context of the new chemical program, where it has mandated data development through the issuance of Section 5(e) Orders. In those circumstances, the data of interest is directly related to a risk management decision that EPA will make under TSCA. Both the Agency and PMN submitter understand the relevance and importance of the data for the chemical under review. In this context, EPA has been able to obtain the information it needs on a reasonable schedule that it specifies.

In the CICA Discussion Draft, the information collection authority under Section 4 has been closely linked to both the Section 5 new chemical program and the Section 6 existing chemical program. While EPA would retain a general authority to require testing to assist other programs

[8] Press reports have indicated that EPA set this rule aside due to other priority matters under TSCA.

and agencies under Section 4, the clear signal in the bill is that the primary role of EPA's information collection authorities is to make sure that TSCA decisions related to new and existing chemicals are well-informed. This is an important direction to EPA that will ground the testing program in the central risk management functions of the law, reducing the possibility that EPA testing resources will be diverted into special projects that do not advance the core mission of the TSCA program.

The other lesson learned for the TSCA program, particularly based on recent experience with Section 4, is that rulemaking is a slow-moving tool. The long timelines that have developed in federal rulemaking are not attributable to any one cause, nor are they unique to the TSCA program or to EPA. Nonetheless, it is quite clear that rulemaking takes much longer to complete today than it did when TSCA was enacted in 1976. As a result, one of the most important new elements of TSCA that would result from enactment of the CICA Discussion Draft is Section 4(a)(2)(C), which authorizes EPA to require the generation of data through the issuance of an order. This authority, which would bypass the ponderous nature of the rulemaking process, would allow EPA to obtain information in a more expeditious manner.

It should be noted that this new order authority will not always provide the best approach for collecting new testing data. In cases where it is unclear what specific parties make up the universe of manufacturers or processors that should be providing the data, issuance of a rule will still be warranted. The new order authority for existing chemicals, however, will undoubtedly be of great value to EPA. The Agency's experience with other order authorities to mandate the generation of data, such as Section 3(c)(2)(B) of the Federal Insecticide Fungicide and

Rodenticide Act for pesticides and Section 5(e) of TSCA for new chemicals certainly suggest that a similar authority for existing chemicals would be one of the most important changes to the TSCA program in its history.

Section 14: A "Treaty" on Confidential Business Information

One of the strengths of the CICA Discussion Draft is the new framework it sets forth under Section 14 for the protection of Confidential Business Information ("CBI"). The elements of this provision have not been as controversial as other elements of CICA or of S.1009. That fact is the strength of these changes to Section 14.

EPA's approach to CBI protection under TSCA was first developed in the context of the top priority matters that the Agency had to address immediately after the enactment of the statute in 1976. Specifically, EPA needed to establish the TSCA Inventory of existing chemical and provide for review of new chemicals that were being brought to market. To conduct an effective review of a new chemical, EPA necessarily needed access to data about the specifics of the chemical, its production process, the company's intended markets and its planned production volume, information that would routinely be maintained as trade secrets to protect innovation and business strategy. As a result, the TSCA program put in place a set of policies and procedures for the handling of CBI information that were, and remain today, the most rigorous approach to this issue found in any part of EPA. Those procedures required that each CBI document would be catalogued and tracked, staff handling CBI data had to receive training on required procedures and pass a proficiency test, CBI documents were to be kept in locked safes

when not in use, and office areas where CBI data was under review were kept under lock and key so unauthorized personnel could not enter the area.

The prevailing view of CBI data among TSCA staff during this period was that the data warranted absolute protection because such an approach facilitated industry's willingness to provide such data expeditiously and thus allow EPA to do its job – conduct a full review of the data and make a judgment about the safety of a new chemical for introduction into commerce. At that time EPA did not view its role as promoting public access to information collected under TSCA, particularly in regard to information that had been claimed as CBI.

This perspective began to change in the late 1980's. In response to the Bhopal, India chemical accident of 1984 and a 1985 chemical release at a facility in Institute, West Virginia, Congress enacted the Emergency Planning and Community Right to Know Act of 1986 ("EPCRA"). A central feature of that statute was the establishment of the Toxic Release Inventory Program ("TRI"), the first program in EPA history where the primary purpose of the Agency's information collection effort was to disseminate the information for public use. This TRI program was further expanded by the Pollution Prevention Act ("PPA"), which passed in 1990.

In assigning responsibility for the administration of EPCRA, EPA decided to assign the TRI to the Office of Toxic Substances (the predecessor of OPPT), to align that program with the expertise of the office and the data that had been collected and assessed under TSCA.[9] This new alignment created a rather unique juxtaposition of program cultures - a traditional TSCA

[9] The emergency response and planning functions of EPCRA were assigned to the Office of Solid Waste and Emergency Response to align this work with EPA's responsibilities under the Superfund program.

program that did see the data it collected as a resource for public use and a new TRI program that viewed public use of information as the central purpose of all of its activities. The office was further challenged when the Agency assigned the broader functions and staff of the PPA to the TSCA office. When I became the Director of this office in 1990, the need to align these differing perspectives became one of our first priorities.

Two other events were influential on EPA strategy at this time. The Agency had commissioned a contractor study that reviewed the types of data that were being routinely claimed as CBI in the new chemical program.[10] While the study found that the vast majority of data claimed as CBI fell into categories that were legitimate trade secrets, there were many examples of frivolous claims by new chemical submitters that were not justified (e.g., CBI claims for newspaper articles and corporate annual reports.) The second major event, discussed above, was the 1991 court remand of the Section 6 rule on asbestos, which forced EPA to reconsider its entire strategy for addressing existing chemicals under TSCA.

What emerged from OPPT's discussions of how best to integrate these new responsibilities and program limitations was the adoption of a set of four principles to guide the office's work, a new name for the office (i.e., it became OPPT), and a reorganization to facilitate the new direction of the office. Of particular importance to the issue of CBI protection, one of the core principles adopted by OPPT became known as the "Going Public" effort, a commitment to providing public access to health and safety information. In the reorganization, OPPT created an Information Access Branch of staff to facilitate the dissemination of toxics information collected under TSCA, EPCRA and the PPA. OPPT also committed staff resources to the review and

[10] Hampshire Associates, "Influence of CBI Requirement on TSCA Implementation," (March 1992)

challenge of unjustified CBI claims related to health and safety studies, in light of the high value of public access to such studies and the explicit recognition in Section 14 that such studies could not be the subject of CBI claims.

Beginning in 1992, OPPT also engaged stakeholder groups to obtain public comments on a broader set of policy changes and activities to enhance the "Going Public" effort. In 1993, OPPT issued a document responding to the comments that had been received and set forth a set of actions that it intended to initiate on these matters.[11] The list of actions in this document included measures that have remained part of the debate on CBI protection to the current day, including upfront substantiation of CBI claims, periodic re-substantiation of CBI claims, certification of CBI claims by executive-level corporate officers, and strategies to provide states with access to CBI information where they have CBI protection programs comparable to EPA's protections.

While we did not appreciate it at the time, these initiatives marked the beginning of a long period of public debate, characterized by substantial discord, about the appropriate level of CBI protection to be afforded to chemical information under TSCA. What we have seen over the last twenty years on these issues can best be characterized as a guerilla war fought among industry, EPA and the NGO community. The intensity of the debate has varied over the last two decades depending on the relative attention that EPA has given to the issues, but the perception that CBI protection is a systemic problem with the TSCA statute has remained a constant element of the push for statutory reform.

[11] U.S. EPA, "Proposed Actions to Reform TSCA Confidential Business Information," (May 20, 1993).

The substantive debate on this topic has tended to be very polarized, and thus less productive. As an example, when OPPT first proposed these reforms in 1992, one of the primary critiques of the Agency from the chemical industry was that TSCA was not a "right to know" statute, despite the clear language in Section 14 that health and safety studies were not subject to CBI protection. On the other side of the debate, some NGO representatives (including law professors) have argued that trade secret protections are no longer needed because modern patent law can provide all the protection that industry needs. Such an argument, however, is not grounded in the reality of global commerce and the fact that U.S. patent law principles are not accepted as enforceable international norms. To maintain the ability to innovate in the modern world, trade secret protection is likely to be more important today than it was 20 years ago.

As stakeholder groups have been working on statutory reforms of TSCA over the last several years, a quiet but extremely useful dialogue has occurred. Mainly in the context of the Senate bill, representatives of industry and NGO groups engaged in a series of discussions aimed at bridging areas of disagreement about TSCA CBI protection. What has resulted from these discussions is a significant rewrite of Section 14, which first appeared in S. 1009 and has been substantially accepted in the latest CICA Discussion Draft, articulating the principles of an historic compromise on these issues.

The compromise would include the following elements:

- Section 14 lists the categories of information that will generally be protected as CBI and the categories of information that will generally not be protected as CBI.

- In presenting a claim for confidentiality, the information submitter must provide upfront substantiation of a claim for confidentiality regarding the identity of the chemical substance that is the subject of the submission.
- EPA may provide states access to TSCA CBI for purposes of development, administration or enforcement of a law, where the state has procedures in place that are as stringent as those used by EPA.
- EPA may provide CBI information about a chemical to specified medical professionals to aid diagnosis or treatment of individuals who have likely been exposed to the chemical, with differing procedural obligations for these professionals in emergency and non-emergency circumstances.
- The section specifies procedural rules for the duration of confidentiality claims and how those claims may be re-asserted by the information submitter.
- When EPA denies a CBI claim, the statute specifies when EPA may release the information to the public or specific parties, in recognition of the information submitter's right to bring a timely legal challenge to the Agency's decision.

These changes represent a reasonable accommodation of the interests that need to be balanced, providing EPA with much clearer direction on how it should handle disputes that might arise on access to TSCA data. While no statutory provisions can eliminate all issues that might arise in a complex area like this one, enactment of the CICA Discussion Draft's revised Section 14 would substantially resolve a set of issues that have plagued the TSCA program for decades. In historical terms, the CICA Discussion Draft incorporates what might be referred to as the "TSCA CBI Treaty of 2014" that would resolve a 20 year guerilla war of unproductive public

discourse on how sensitive business information should be handled under the statute. Enactment of this provision can only be a success story.

Conclusion

Chairman Shimkus, Ranking Member Tonko and Members of the Subcommittee, I thank you again for the opportunity to testify before you today. I applaud you efforts to work together on these revisions to TSCA that offer the opportunity for substantial improvement in EPA's chemical management program.