



NATURAL RESOURCES DEFENSE COUNCIL

February 11, 2014

Honorable Lamar Smith, Chairman
Committee on Science, Space, and Technology
2321 Rayburn House Office Building
Washington, DC 20515

Honorable Eddie Bernice Johnson, Ranking Member
Committee on Science, Space, and Technology
2321 Rayburn House Office Building
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Honorable David Schweikert, Chairman
Subcommittee on Environment
Committee on Science, Space, and Technology
2318 Rayburn House Office Building
Washington, DC 20515

Honorable Suzanne Bonamici, Ranking Member
Subcommittee on Environment
Committee on Science, Space, and Technology
2318 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Smith, Ranking Member Johnson, Chairman Schweikert and Ranking Member Bonamici,

On behalf of the Natural Resources Defense Council, I am writing to provide information that I hope will inform the Environment Subcommittee members' consideration of topics for your February 11th hearing on the discussion draft of a bill entitled the "Secret Science Reform Act of 2014."

The discussion draft of the bill is deeply troubling and should be rejected by subcommittee members. The draft legislation would effectively amend numerous environmental statutes, and it marks a radical departure from longstanding practices. Its end result would be to make it much more difficult to protect the public by forcing EPA to ignore key scientific studies, including those submitted by industry.

The bill proceeds from a faulty premise from which it then undermines EPA's ability to carry out its most basic responsibilities. The notion of "secret science" is a canard and ignores longstanding practices, recognized in law, that protect patient information, intellectual property and industrial secrets. This letter inventories some of the key ways such information is used, and needs to be used by EPA. The Subcommittee has done nothing to demonstrate how the public has suffered as a result before seeking to overthrow law and practice. But it easy to show how the public would suffer if the bill's proscriptions and restrictions were put into effect.

This letter will elaborate on these points:

- The whole notion of "secret science," based on studies of fine soot pollution conducted almost two decades ago, is unfounded.
- The bill would make it impossible for EPA to use many kinds of studies that it necessarily relies on to protect the public because those studies use data that has long been understood to be legitimately confidential.
- The bill would make it impossible for EPA to use many kinds of economic models it routinely relies on because those models are proprietary.
- The bill advantages industry by exempting from its coverage EPA activities where industry is the primary party likely to submit confidential information, such as permitting.

Nonetheless, the bill would make it harder for EPA to consider confidential information from industry in many instances, limiting the agency's ability both to protect the public and to reduce the costs of regulation.

Covered Actions

The draft bill defines a "covered action" to mean "a risk, exposure, or hazard assessment, criteria document, standard, limitation, regulation, regulatory impact analysis, or guidance." This definition creates a fundamental double standard biased in favor of corporations and against public health and safety. The draft legislation (1) restricts the information EPA can use to take a series of actions to protect public health and the environment, while it (2) simultaneously leaves untouched a host of actions that industry needs and desires—notwithstanding that these industry-

avored actions often rely on industry-supplied scientific and technical information that industry may shield from the public.

Consider just a few examples of EPA actions that industry wants or needs EPA to take, and that do *not* fall under the definition of “covered action.” For these actions, EPA can continue to rely on so-called “secret science” supplied by industry that remains shielded:

- Industry permit approvals, revisions and renewals under the Clean Air Act, Clean Water Act and RCRA;
- Industry pesticide registrations, exemptions, and tolerances under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA);
- Applicability determinations under EPA statutes and adjudications under the Administrative Procedure Act that determine whether regulations do or do not apply;
- Requests under some EPA regulations for industry exemptions that may be granted without need for proposed or final regulations by the agency;
- Certifications and compliance reports for vehicles, engines and equipment for various Clean Air Act motor vehicle regulations.

The draft legislation exempts all of these industry-desired or needed agency actions from the bill’s strictures as well as from the bill’s purported concern for transparency.

Examples of Health Protections That the Draft Bill Would Obstruct

The following examples are drawn from just some of the statutory responsibilities and authorities that EPA has under current law. The draft bill would limit EPA’s ability to review relevant information that current law allows EPA to consider to protect public health, safety and the environment:

- EPA could not establish a drinking water standard or health advisory for a contaminant under the Safe Drinking Water Act based on information that industry claims was protected confidential business information (CBI).
- EPA could be hindered in responding to emergency situations. For example, initially some of the data on the chemical Freedom Industries spilled last month in West Virginia was not publicly disclosed. It was eventually released in response to a letter from Congressman Waxman to the manufacturer of the chemical, Eastman Chemical. The draft legislation is problematic in the extreme by allowing industry to decide selectively what information EPA can use to issue a health advisory or a risk or hazard assessment, based on industry claiming that information to be CBI.
- EPA could not establish a drinking water standard or health advisory based on epidemiological evidence or clinical studies where the medical records of the patients were confidential under the Health Insurance Portability and Accountability Act (HIPAA) or other patient confidentiality requirements, or where the study would not be “reproducible” because of restrictions on access to confidential patient information. These confidentiality safeguards for patient data are routine in the field of medical research, yet the draft legislation renders important advances and understandings in health and environmental research off-limits to EPA when carrying out the law to protect Americans.

- EPA could not issue a risk/hazard assessment or a cancellation of a pesticide based upon (1) studies containing CBI; (2) epidemiological or clinical studies where the medical records of the patients are confidential under HIPAA or other patient confidentiality requirements; or (3) where the study would not be “reproducible” because of restrictions on access to confidential patient information. For example, studies completed by Columbia University doctors have shown certain pesticides used indoors harm pregnant mothers and their fetuses, causing smaller head circumferences, and interfering with children’s brains’ development as they grow up. These patient records have been aggregated and published in peer-reviewed journal literature, but underlying medical records are required to be kept confidential under HIPAA and agreements with patients.
- EPA could not regulate or issue guidance to prevent lead poisoning of children in housing being renovated, or lead-contaminated water or plumbing, based upon clinical and epidemiological studies, where the medical records of the patients are confidential under HIPAA or other patient confidentiality requirements, or where the study would not be “reproducible” because of restrictions on access to confidential patient information. For example, many of the studies of the adverse impacts of lead follow patients who have been exposed to lead, and those records would be protected from public disclosure.
- EPA could not conduct risk/hazard assessments necessary to inform and govern the cleanup of Superfund sites, to the extent that potentially responsible parties asserted CBI protections over company information potentially implicating their contribution to a site, or CBI relating to specific chemicals. The draft legislation thus would allow any assertion of confidentiality claims by responsible parties engaged in Superfund cleanups to delay or thwart those cleanups in local communities, including the jobs associated with those activities.

In each of these examples, the draft legislation would mark a radical retreat from current law, by preventing EPA from considering key studies in deciding how to protect public health, safety and the environment.

Hazard Assessments and Imminent and Substantial Endangerment

The draft bill would prohibit EPA from taking actions under federal laws like the Resource Conservation and Recovery Act (RCRA) and the Clean Air Act to protect Americans against “imminent and substantial endangerment,” to the extent EPA relies upon any health studies involving confidential patient data or relies upon industry CBI. The latter could include industrial chemical or product formulations, process data, industry testing or research or trade secrets. EPA must conduct hazard and risk assessments to understand the nature of chemical and oil spills, explosions or other hazards endangering the public. Under current law, there are no restrictions on EPA conducting those hazard assessments, protecting the industry CBI *and* safeguarding the public. The draft legislation radically changes that. To the extent that any information covered by the draft bill is relied upon by EPA, the agency could not act against imminent and substantial endangerment of public health nor could EPA even “disseminate” warnings to the public.

“Dissemination,” Censorship and Reckless Retroactivity

The draft bill’s astonishingly broad language prohibits EPA from “disseminating” any “risk, exposure, or hazard assessment, criteria document, standard, limitation, regulation, regulatory impact analysis, or guidance” that relied on scientific and technical information meeting the bill’s criteria. This language produces the perverse result that EPA would be barred from publishing on its website—or indeed even in the Code of Federal Regulations— *prior and existing* regulations, reports, guidance, risk, exposure or hazard assessments that relied on scientific and technical information before the draft bill’s consideration. This results in a reckless retroactivity and censorship of duly enacted regulations and agency reports that one cannot imagine even the draft legislation’s authors intended. (Of course, prohibiting EPA from disseminating adopted regulations would not cause those regulations to be repealed; it would just make it immeasurably harder for anyone to find and follow the law.) But that is the consequence of the plain language of the draft bill, and such a “dissemination” prohibition would result in the massive censorship of valuable public health and safety information.

Illegal Delay and the Circular Problem of “Reproducibility”

The draft bill prohibits EPA from taking any covered actions unless all scientific and technical information relied on is “publicly available in a manner that is sufficient for independent analysis and substantial reproduction of research results.” The perverse problem with this language is that it could be read to mean that the only way to know with any certainty whether information is sufficiently reproducible is to allow time for independent parties to attempt to reproduce those research results. We know from experience that this can take years and involve great expenses.

The draft bill’s prohibition thus would prevent EPA from complying with statutory deadlines created by Congress under numerous federal laws. Before EPA may even propose or finalize a regulation to meet a statutory deadline, the agency would need to await confirmation of reproducibility, or else face constant anti-regulatory attacks from the earliest stages of a rulemaking that some scientific or technical information is not reproducible. This dynamic would poison EPA rulemakings either with massive delay or inescapable uncertainty, fundamentally obstructing EPA’s responsibilities under its various statutes to protect human health and the environment.

Moreover, this provision could actually create a perverse incentive for regulated industries with the financial means to do so either to (1) not undertake efforts to reproduce research results, so they may continue to charge that results are not reproducible; or (2) withhold from EPA research results that do prove the information is reproducible. And of course members of the public that lack the resources to conduct such reproduction studies, that want EPA to protect public health and the environment, will be unable to clear this hurdle in the draft bill.

Regulations Granting Industry Flexibility or Regulatory Relief

Industry sometimes appeals to EPA during the course of proposed rulemakings, or even prior to the initiation of rulemaking, to loosen the rigor of agency regulations, accord industry operational flexibilities, extend compliance deadlines or take other actions to reduce alleged

regulatory burdens. Frequently industry does so by submitting information particular to a specific company or industry sector; a particular chemical or product formulation; or a particular process unit or manufacturing process. These submissions frequently are accompanied by claims that information is CBI, due to the company-specific or industry-specific nature of information that may be proprietary, confidential or trade secrets. Industry parties sometimes submit health studies or risk assessments they have conducted that may contain confidential clinical data or other information that they do not wish to make publicly available.

The draft legislation would create a dynamic in which EPA is unable to consider that CBI or otherwise confidential health or risk data in deciding whether to adopt regulations or issue guidance that grants industry the requested regulatory flexibilities. When EPA exercises its regulatory authorities, at least, the draft bill also constrains the agency's ability to be flexible or relieve regulatory obligations, precisely where it might be needed most: by being responsive to particular demonstrations made by specific companies based on persuasive information that also happens to be CBI. It does not appear that the draft bill's co-sponsors could have intended this outcome.

Proprietary Models

The bill prohibits EPA from taking covered actions to enforce the law and protect the public if doing so involves relying on "computer codes and models" for creating and analyzing scientific and technical information. Section 6(b)(3)(B). This provision has the perverse effect of barring EPA from relying on proprietary models or computer programs whose software, design features and other inputs were created by and are owned by the private sector. There are undoubtedly numerous proprietary models used by EPA,¹ but a widely used model under the Clean Air Act serves as a useful example to highlight the bill's irresponsible—and probably unintended—consequences.

The Integrated Planning Model (IPM) is the most widely used model "to analyze the impact of air emissions policies on the U.S. electric power sector."² It is employed by EPA, state governments, the private sector and public interest organizations, and was developed by ICF Consulting, Inc., which owns the rights to the model and its utilization. EPA explains the purpose of the IPM and its value thusly:

EPA uses the Integrated Planning Model (IPM) to analyze the projected impact of environmental policies on the electric power sector in the 48 contiguous states and the District of Columbia. Developed by ICF Consulting, Inc. and used to support public and

¹ For other examples of proprietary models employed by EPA, see http://www.epa.gov/pesticides/science/models_pg.htm. The agency has said that "EPA prefers using non-proprietary models when available. However, the Agency acknowledges there will be times when the use of proprietary models provides the most reliable and best-accepted characterization of a system." http://www.epa.gov/crem/library/cred_guidance_0309.pdf, at 31. We respectfully submit that EPA should be asked to identify all proprietary models used by the agency, and how restrictions on their use would impede the agency's ability to enforce the law and protect public health and the environment.

² <http://www.epa.gov/powersectormodeling/>.

private sector clients, IPM is a multi-regional, dynamic, deterministic linear programming model of the U.S. electric power sector. It provides forecasts of least-cost capacity expansion, electricity dispatch, and emission control strategies for meeting energy demand and environmental, transmission, dispatch, and reliability constraints. IPM can be used to evaluate the cost and emissions impacts of proposed policies to limit emissions of sulfur dioxide (SO₂), nitrogen oxides (NO_x), carbon dioxide (CO₂), hydrogen chloride (HCl), and mercury (Hg) from the electric power sector.

The IPM relies on computer codes and model characteristics whose content, features, inputs and other elements are not “specifically identified” and “publicly available in a manner that is sufficient for independent analysis and substantial reproduction of research results.”

Thus, the draft bill would prohibit EPA from proposing, finalizing or disseminating covered actions if it relied on the IPM, or it would require EPA to abandon use of the IPM altogether. This would produce the following harmful outcomes:

- When proposing or finalizing regulations, regulatory impact analyses or other covered actions, the draft bill would prohibit EPA from using the sophisticated IPM to analyze the projected impact of its power plant regulations on the electricity grid and its reliability, transmission lines, dispatch, jobs in the power and coal mining sectors, emissions control and retirement decisions, among other information generated by the IPM;
- The draft bill would prohibit EPA from “disseminating” to Congress, the public, industry officials and state and local government any covered action (such as a regulatory impact analysis) that contained or relied upon any information generated from the proprietary IPM;
- The draft bill would prohibit EPA from proposing or finalizing regulations to lessen regulatory impacts on the power sector, adopt exemptions or issue flexibility guidance to the extent that EPA relied upon the proprietary IPM;
- The draft bill would prohibit EPA from conducting risk, exposure or hazard assessments at the request of Congress to analyze the impact of proposed Clean Air Act legislation or EPA regulations on the power sector, or “disseminating” such results to Congress, to the extent that EPA relied on the IPM;
- Had the draft bill been enacted into law at the time, the Bush administration would have been unable to supply members of Congress or the public with all the useful IPM results generated to assess the impacts of Clear Skies legislation in the House and the Senate, as well as the Bush administration’s Clean Air Interstate Rule and Clean Air Mercury Rule.³ Indeed, members of Congress, President Bush and administration officials drew heavily upon these IPM results in promoting the Clear Skies bills during congressional deliberations and in statements from their offices.⁴

³ Information still available on EPA’s website demonstrates the vast extent to which the Bush administration relied upon the IPM to analyze the Clear Skies bills as well as EPA’s related regulatory actions. See, e.g., http://www.epa.gov/clearskies/tech_adden.pdf; http://www.epa.gov/clearskies/tech_addendum.pdf; & <http://www.epa.gov/clearskies/clearskiessummary04-11.pdf>.

⁴ See, e.g., <http://yosemite.epa.gov/opa/admpress.nsf/6427a6b7538955c585257359003f0230/c1b111b0d87d>

Another example of an EPA model that the draft legislation likely would render unavailable is the agency's use of various physiologically based pharmacokinetic (PBPK) models to conduct chemical assessments under the Integrated Risk Information System (IRIS). EPA says that "these models represent an important class of dosimetry models that are useful for predicting internal dose at target organs for risk assessment applications."⁵ It is likely that some widely-employed PBPK models would not pass muster under this draft legislation, due to their proprietary nature, the public unavailability of information or the inability to sufficiently reproduce model results.

In one recent example, EPA relied upon a PBPK model to propose non-cancer risk estimates for methanol at, or nearly at, an order of magnitude weaker than those proposed previously. The draft legislation could prohibit EPA from relying upon this PBPK model to lower the risk estimates for methanol. Moreover, any other attempt by industry to persuade EPA to weaken risk assessments for chemicals in IRIS could not rely upon PBPK models failing to meet the draft bill's criteria. Nor could those industry efforts rely upon health studies, risk assessments, research, product or process information or business information claimed by industry to be confidential. The draft bill would make this true for all risk, hazard and exposure assessments under IRIS and other EPA programs.

Finally, the draft bill is so poorly drafted that it could conceivably prevent EPA from using commercially available software to carry out basic computing functions, because the computer codes behind that software are proprietary and not publicly available. Again, we do not believe this absurd result was intended by the authors of the draft legislation, but this is the plain reading of its language.

Obstructing Clean Air Act Enforcement

The draft legislation, coupled with the unwarranted subpoena steps by the Committee majority, plainly is targeting a few clean air health studies that show causal associations between fine soot pollution (PM_{2.5}) and premature mortality. One of the draft bill's co-sponsors has suggested that the massive body of scientific evidence showing a causal association between soot pollution and mortality comes down to "secret" data from just two studies.⁶ This is incorrect. A much broader body of scientific studies examines and reaffirms the causal association between fine soot pollution and mortality. These studies post-date the so-called "Harvard Six Cities" and

591385256c0500625054!OpenDocument; <http://www.inhofe.senate.gov/epw-archive/press/bchairman-inhofe-introduces-the-administrations-clear-skies-initiative/b;> & [http://www.epw.senate.gov/107th/smi_061202.htm;](http://www.epw.senate.gov/107th/smi_061202.htm) <http://georgewbush-whitehouse.archives.gov/news/releases/2002/02/20020214-5.html>.

⁵ <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=135427>.

⁶ Rep. Lama Smith, "The EPA's Game of Secret Science," The Wall Street Journal (July 29, 2013).

http://online.wsj.com/news/articles/SB10001424127887323829104578624562008231682?mg=r_eno64-wsj&url=http%3A%2F%2Fonline.wsj.com%2Farticle%2FSB10001424127887323829104578624562008231682.html.

"American Cancer Society" studies, some of them independently re-analyze the studies, and they consistently find the same causal soot-mortality relationship.⁷

Committee Chairman Smith has charged that the data in the Harvard and American Cancer Society studies "have not been subjected to scrutiny and analysis by independent scientists."⁸ This too is incorrect.

In December 2012, a seminal report entitled the 2010 Global Burden of Disease⁹ "estimate[d] over 2.1 million premature deaths and 52 million years of healthy life lost in 2010 due to ambient fine particle air pollution, fully 2/3 of the burden worldwide." Drawing upon a broad body of data and studies from around the world, the report examined the risks of premature mortality linked to soot pollution and independently affirmed the results of the Harvard Six Cities study. The Global Burden of Disease researchers found significant mortality impacts from fine particulate pollution. They concluded that "[t]he magnitude of disease burden from particulate matter is substantially higher than estimated in previous comparative risk assessment analyses."

As explained in a release¹⁰ by the esteemed Health Effects Institute, a contributor to the report, "[t]he 2010 [Global Burden of Disease report] was produced by a rigorous scientific process involving over 450 global experts and led by the Institute of Health Metrics and Evaluation (IHME) at the University of Washington along with its partner institutions: the World Health Organization, the University of Queensland, Australia, Johns Hopkins University, and Harvard University."

Similarly, in July 2000, the Health Effects Institute issued a special report¹¹ entitled "Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality." The explicit goal of that study was "to conduct a rigorous and independent assessment of the findings of the Six Cities and ACS Studies of air pollution and mortality." (p.ii) To accomplish this goal, the team of researchers had "access to the original data" once they entered into contractual agreements and a Memorandum of Understanding to ensure that confidentiality was protected. (p.4). The report concluded that

⁷ In revising and updating National Ambient Air Quality Standards (NAAQS) for fine particulate matter, EPA devotes an entire chapter of its Regulatory Impact Analysis (RIA) to cataloguing and reviewing updated health effects studies, and explaining how they were incorporated into the agency's 2012 standards review. See, e.g., <http://www.epa.gov/ttn/ecas/regdata/RIAs/finalria.pdf> (at pp. 5-7 to 5-8 listing 5 updates from the proposed 2012 RIA; fig 5-4 at p. 5-73; pp. 5-31 to 5-35).

⁸ *Supra* note 6.

⁹ [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(12\)61766-8/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(12)61766-8/fulltext).

¹⁰ <http://www.healtheffects.org/International/GBD-Press-Release.pdf>. The Health Effects Institute is "a nonprofit corporation chartered in 1980 as an independent research organization to provide high-quality, impartial, and relevant science on the health effects of air pollution." Funded jointly by the federal government and industry, it is an honest broker that has garnered widespread respect for its scientific expertise, integrity and research excellence.

¹¹ <http://pubs.healtheffects.org/getfile.php?u=274>.

“reanalyses assured the quality of the original data, replicated the original results, and tested those results against alternative risk models and analytic approaches.” (pp.iii-iv).

EPA's Integrated Science Assessment¹² for the PM_{2.5} standards explained (p. 7-95) that the Harvard and ACS studies have “undergone extensive independent reanalysis,” and “were based on cohorts that were broadly representative of the U.S. population.” Reviewing this assessment and the broader body of epidemiological and toxicological studies, EPA's official Clean Air Science Advisory Committee (CASAC) recommended “‘upgrading’ the causal classification for PM_{2.5} and total mortality to ‘causal’ for both the short-term and long-term time frames.” CASAC further found “[t]here are epidemiological studies showing a positive association of all-cause mortality with PM_{2.5}.”

Despite this extensive body of evidence, thorough re-analysis, and reaffirmation by governmental scientific advisory bodies, the draft bill is founded on an obvious agenda to deny EPA the ability to rely upon peer-reviewed medical studies that involve commitments to patient confidentiality, when the agency carries out its statutory responsibilities to safeguard public health and clean air. The truth is there is a basic difference between “secret science” and confidential patient data subject to confidentiality agreements reached to conduct important medical research. The American people understand this difference. The legitimate researchers and reanalysis initiatives that committed to the confidentiality policies of the relevant research institutions, as HEI and the Global Burden of Disease teams did, were able to access the patient data.

EPA has squarely rejected the effort to create doubt through secrecy charges concerning these same health studies:

The EPA is transparent with regard to the scientific bases of agency decision making and disagrees with assessments and your assertion that the agency relies on ‘secret’ data in regulatory actions and of health benefits. In setting the National Ambient Air Quality Standards (NAAQS) and in assessing health benefits anticipated from air pollution regulations, the EPA relies on the scientific studies that are published in the peer-reviewed literature. The EPA provides the information used in regulatory decisions, including the epidemiological studies, in the publicly available docket accompanying each rulemaking.¹³

The Committee has now gone so far as to use its unfounded charges to write a bill that would block the use of a breathtaking range of science that has long been used to safeguard the public.

Technology-Based Emission Standards

The draft legislation would thwart EPA’s responsibility to carry out health safeguards required by Congress under the Clean Air Act and Clean Water Act. For example, both of these statutes contain “technology-based” emission standards for industry based on emissions

¹² <http://cfpub.epa.gov/ncea/CFM/recordisplay.cfm?deid=216546#Download>.

¹³ <http://switchboard.nrdc.org/blogs/jwalkc/04-10-13%20EPA%20letter%20to%20Senator%20Vitter.pdf>.

reductions deemed achievable by state-of-the-art technology.¹⁴ EPA sometimes solicits from corporations information about an industrial sector's pollution control technology, process units and other types of regulated or potentially regulated equipment. Industry requests that some of the information it submits to EPA be treated as CBI. Similarly, when industry representatives submit comments in response to proposed technology-based emissions standards, these commenters request that various information contained in those comments be treated as CBI.

The draft bill would create a perverse dynamic in which corporate officials could thwart EPA's development of statutorily required technology standards, by designating as CBI information that is crucial to determining what emissions reductions are achievable by state-of-the-art technology. Indeed, the draft bill's design would particularly obstruct the implementation and enforcement of technology-based safeguards for air and water, because industry representatives could so easily seek to designate a wide variety of technology and process information to be CBI. Accordingly, even though the draft bill does not purport to amend the Clean Air Act or Clean Water Act, and even though your Committee lacks the jurisdiction to do so, the draft bill would have the effect of radically re-working and weakening the purpose and effectiveness of these laws.

Toxic Substances Control Act

The draft bill would fundamentally obstruct EPA's responsibility to protect the public by regulating toxic substances under the Toxic Substances Control Act (TSCA), which relies extensively upon industry claims of confidential business information.

For example, Section 8(e) of TSCA requires chemical manufacturers, importers and processors to report immediately to EPA whenever they obtain evidence "that reasonably supports the conclusion that [a substance or mixture] presents a substantial risk of injury to health or the environment."

Typically, these industry reports claim the information provided is protected confidential business information—including the identity of the chemical, the name of the company submitting the information, as well as health and safety studies about the chemical.¹⁵ The most recent list of section 8(e) studies from April 2013 shows just how pervasive these industry CBI claims are.¹⁶

Members of the public can only see the sanitized version of the 8(e) reports, which might show the results of lab testing for human or aquatic toxicity and which "reasonably support the

¹⁴ See, e.g., Clean Air Act section 112(d) (Maximum Achievable Control Technology (MACT) standards).

¹⁵ EPA has allowed these CBI claims to be asserted even though TSCA section 14(b) does not allow it. The current abuse of CBI under TSCA is a widely recognized problem. EPA is not required even to review all CBI submissions for their validity. There is no up-front justification requirement that must accompany CBI claims. Once CBI status is granted under TSCA it has no sunset and is rarely if ever re-opened. This has resulted in massive overuse and abuse of the CBI designation. For more information, see, e.g., <http://blogs.edf.org/health/2010/02/12/worse-than-we-thought-decades-of-out-of-control-cbi-claims-under-tsca/>.

¹⁶ <http://www.epa.gov/oppt/tsca8e/pubs/8emonthlyreports/2013/8eapr2013.html>.

conclusion that [the substance] presents *a substantial risk of injury* to health or the environment.” (emphasis added). Although the public will not have access to this information, EPA will, and they use 8(e) reports to prioritize chemicals for greater reporting, or testing, potential regulation, potential voluntary agreements with companies to restrict or phase out the use of particular substances, as well as possible enforcement actions.

A very similar function occurs under the new chemicals program of TSCA (Section 5). Industry officials submit Pre-Manufacturing Notices and claim that information about their proposed new chemicals is CBI. This includes health and safety studies that should not be eligible for treatment as CBI under TSCA, but that EPA routinely treats as CBI anyway. While the public does not see information submitted as CBI, the agency does, and can use that information to take several steps: (1) reject a PMN, for example if the new substance is persistent, bioaccumulative and toxic; (2) require additional testing under a TSCA section 5(e) consent order; or (3) restrict some uses of the new chemical using a Significant New Use Rule (SNUR).

The draft legislation irresponsibly prohibits EPA from taking or even proposing to take the aforementioned actions by relying on the submitted industry information to the extent that industry claims it to be CBI. This creates the perverse result that industry is allowed to prevent EPA from taking necessary steps to address “substantial risk of injury to health or the environment” caused or potentially caused by the industry’s own chemicals, based on the decision entirely within industry’s control to designate submitted information as CBI. And the particular perversity of the draft legislation is that information may well be CBI under current law; but current law does not restrict EPA from protecting the public simply because industry has legally protected interests over its CBI.

Consider the following example under TSCA. A chemical manufacturer submits a Pre-Manufacturing Notice for a new chemical under TSCA Section 5, and the notice contains data or information that the manufacturer claims to be CBI.

EPA has 90 days (plus an option for a 90-day extension) to review the notice and determine whether or not it wants to allow the new chemical to start being manufactured, whether it wants to require more testing, impose some restrictions, or stop the chemical entirely. If EPA takes *no action* on a PMN within the 90-day review period, the company submitting the notice can begin to manufacture the chemical. Once a new chemical is allowed to be manufactured, the chemical is then added to the TSCA inventory. This allows any other company to begin using the chemical for any other purpose (including in greater volumes than proposed in the original notice, and for different kinds of uses, including uses that may be much more dispersive and lead to greater human exposure, *e.g.*, in a flame retardant).

The definition of “covered action” in the draft legislation does not include *inaction* by EPA. Accordingly, the chemical manufacturer and other industrial users that follow-on may begin manufacturing new chemicals based upon the submission of CBI—“secret science” to use the nomenclature of the draft bill—all without any of that information needing to be publicly available or reproducible when EPA fails to take any action on receipt of the notice.

If EPA does have health and safety concerns, however, based in part on the information submitted as CBI, TSCA authorizes EPA to take several steps: (1) require the company to do

more testing; (2) impose restrictions on the original notice submitter; and (3) restrict other entities from using the chemical for different uses or different volumes.

The draft legislation treats all of *these* EPA actions under TSCA as “covered actions,” because they involved proposed or final regulations and/or the need for risk or hazard assessments. Accordingly, the draft bill prohibits EPA from taking any of these actions to protect the public, to the extent the agency needs to rely upon the industry CBI that raised the concerns in the first instance.

So the draft legislation is an irresponsible one-way ratchet: industry may proceed to manufacture new chemicals based on EPA’s consideration (or even non-consideration) of “secret” CBI. But EPA may not regulate identified dangers or risks to the public from those chemicals based on consideration of that same “secret” industry CBI.

Conclusion

In sum, this draft legislation would effectively amend numerous environmental statutes in a manner that would obstruct the development and implementation of health and environmental safeguards. It would do so in a fashion that would also restrict industry’s ability to inform EPA decision-making, potentially raising the costs of regulation. At the same time, the bill unfairly caters to industry by exempting permitting and other agency actions from its ambit and underscoring the CBI protections in existing law.

The Subcommittee ought to abandon this misguided project of chasing the phantom notion of “secret science.” With this draft bill, the Subcommittee has moved from reviving baseless charges about clean air science that were disproved over a decade ago to damaging EPA’s ability to use science for decades ahead. Surely there are more productive ways to spend its time.

Sincerely,

John Walke
Clean Air Director
Natural Resources Defense Council