CBO Questions for EPA regarding
H.R. xxxx, the HONEST Act of 2017
Marked up in House Science and Technology Cmte on 3/9/2017

- Responses in **black** below were provided by EPA on May 28, 2015 regarding S. 544 ([link to CBO estimate](https://www.cbo.gov)), the Secret Science Reform Act of 2015.

- The HONEST Act of 2017 and S. 544 are substantially similar. CBO has [highlighted](https://www.cbo.gov) the .pdf file of the HONEST Act to indicate language additions that were not in S. 544

- **CBO has prepared new questions in red below for the HONEST Act** and left EPA’s old responses in black regarding S. 544 for context

**Overview:** We do not think the committee report [for S. 544] would change the estimated cost of the S. 544/H.R. 1030 bill, currently estimated at “$250 million a year for the next few years” by the Congressional Budget Office. Do you think that EPA would implement the bill as suggested in the draft report language?

**Overview:** Does EPA believe the stated intentions for the HONEST Act and its implementation, as expressed in the committee report backup for S. 544, would change the way EPA would implement the legislation compared to what the agency believed for S. 544? That is, does EPA still estimate that implementation would require “$250 million a year for the next few years,” as estimated by CBO for S. 544?

EPA strongly supports increasing access to data to better facilitate independent analysis. That is why EPA has a plan in place to make its federally-funded data in published reports available to the public. This plan will begin to achieve many of the stated goals of The HONEST Act while incurring no additional costs to taxpayers, protecting PII and CBI, and ensuring that EPA uses the best available science to protect human health and the environment. This plan is part of the Open Government Initiative, which directs federal agencies that conduct research costing over $100 million to develop plans ensuring data resulting from federally-funded scientific research are accessible to the public. EPA’s resulting **Plan to Increase Access to Results of EPA-Funded Scientific Research** was finalized in December 2016 and describes the steps EPA will take to meet those directives. The plan is available at [https://www.epa.gov/open](https://www.epa.gov/open), and EPA has also established a forum on Increasing Public Access to EPA Research to effectively and efficiently implement the plan. As for scientific data created or funded outside of the federal government, there is a growing movement for scientific journals to publish the underlying data. EPA’s plan, in combination with this scientific movement for data transparency, will begin to achieve the stated goals of the HONEST Act at no additional cost to taxpayers while also protecting PII and CBI and preserving EPA’s ability to protect public health and environment by using the best
available science. The HONEST Act, however, would add significant costs, would not protect PII and CBI, and, most importantly, would prevent EPA from using the best available science.

The HONEST Act Would Cost Taxpayers More Than S.544/HR 1030
The $250 million estimate came from CBO. EPA roughly estimated that S.544/HR 1030 of 2015 (The Secret Science Reform Act) would cost at least that much, but it could cost considerably more based on the number of studies used in assessments every year and whether all studies (vs. just key studies) would have to have the primary data made public.

The HONEST Act would cost more than S.544/HR 1030 because it creates a new, extensive process to redact information. In addition to spending dollars and staff time on requesting and getting data from study authors, creating IT infrastructure and a data management system to manage, store, and archive large volumes of data, and making the data available in a format that is useful and accessible to the public, EPA would also have to spend dollars and staff time combing through these extensive datasets to find and redact Personally Identifiable Information (PII) and Confidential Business Information (CBI). Additionally, the HONEST Act would require computer code and models involved in the creation and analysis of data to be publicly posted. These are typically not available for most studies and often include proprietary code from private companies. It would be extremely difficult and costly to make these codes and models available with information on how to use them, and it could significantly affect the business of private companies who allow EPA to use their proprietary models and code. The additional requirements of the HONEST Act would incur significant costs above and beyond S.544/HR 1030.

EPA would also like to note that these cost estimates do not include costs of paying the authors of non-federally funded science for their time in preparing and sending the data. Preparing data is a significant request, and EPA anticipates that many study authors will require compensation for their time.

The HONEST Act Would Fail to Protect PII and CBI
The redaction requirements of the HONEST Act would not solve concerns regarding privacy of personal and business information. This is because in Section 2, lines 18-22, the HONEST Act states that anyone can gain access to this redacted information if they sign a confidentiality agreement with the EPA Administrator. As written, a mere signature would be sufficient to grant anyone access to medical records and trade secrets. EPA is also concerned that the HONEST Act requires an agreement with the Administrator and not with EPA, as this may have certain legal implications. The HONEST Act simply does not protect PII and CBI.

The HONEST Act Would Prevent EPA from Using the Best Available Science
The HONEST Act would not protect PII and CBI, and this would strongly discourage industry and academia from working with EPA. Many scientists, including those from the private sector, would not be willing to provide their data because EPA could not guarantee to protect their information, such as their trade secrets, intellectual property, or their study participants’ medical records. Scientific research is a competitive field, and it is likely that not all investigators from the private sector, or academia, will be willing to make their underlying data available – at least not immediately. In some instances, EPA might be precluded from using the best available
science if the underlying data is not made available or is embargoed for a period of time. Therefore, in accordance with the HONEST Act, EPA could not use these studies to help protect health and the environment. This would impede EPA’s ability to use the best available science, because it is presumptively not the best available science if you cannot access all the science.

Because the HONEST Act might prevent EPA from using the best available science, scientific experts who review EPA documents (i.e., the covered actions) would question the completeness, validity, and credibility of analyses conducted by the EPA when large amounts of data are excluded due to the provisions stated in the bill. This would, in turn, cause the public to question the likelihood that such assessments would protect their health and the environment.

It is also important to note the role that industry-sponsored data plays in both the pesticide registration and pesticide registration review programs. Generally, a company does not make data on a new pesticide publicly available prior to its registration. This is to protect the company’s intellectual property. The company gives EPA its data to help make a safety determination, but again, these data are rarely made public. Under the HONEST Act, EPA could not use these private industry data during the pesticide registration and review process, which means that it would be nearly impossible to make a safety determination for new products, including those that address public health.

The HONEST Act Would Prevent EPA from Using Data to Respond to Emergency Events

Additionally, in the event of emergencies, EPA needs to conduct exposure, hazard, and risk assessments to protect the American public. In these time-critical situations, EPA and its state and local partners often need to base their decisions on information that is not immediately publicly available. If the HONEST Act prevented decision makers from using this valid scientific information because it wasn’t public, there could be disastrous consequences to the health and well-being of the American people. These data allow the Agency to respond to an emergency event and work with State authorities to gather information to make an informed decision. The HONEST Act would block EPA’s ability to use these data to implement a decision that would protect the health of Americans until further studies could be conducted and made public. Blocking the use of such data can have a serious impact on the health and wellbeing of the American public and the environment.

The HONEST Act Would Prevent Implementation of the Recently Amended Toxic Substances Control Act (TSCA)

Provisions under the newly amended Toxic Substances Control Act (TSCA), signed on June 22, 2016 would be significantly impacted by the HONEST Act. First, a number of provisions in section 26 could not be upheld under the HONEST Act. Section 26(h) requires the Agency to “use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with best available science.” As explained above, the HONEST Act would not allow EPA to use the best available science. Section 26(i) requires the Agency to use the “weight of scientific evidence” in making decisions under TSCA, and EPA believes this would not be possible given that the provisions of the HONEST Act would prohibit the use of some data. Finally, section 26(k) requires the Agency to “take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available.” EPA would be in
violation of the HONEST Act when upholding these provisions under TSCA, namely instead of using the best available science and all reasonable available data for chemical evaluations, EPA would be restricted to selecting information based on availability. This approach would introduce research bias that would compromise the quality of the Agency’s work.

Secondly, under TSCA EPA must evaluate new and existing chemicals to determine potential unreasonable risk to humans and the environment. Much of the information submitted by manufacturers is CBI, and, as stated, EPA does not believe the HONEST Act protects CBI. Because of this EPA, would not meet the new and existing chemical responsibilities under TSCA if EPA were limited to the data required under the HONEST Act. If CBI could not be used in chemical evaluation, these chemical programs would grind to halt, greatly hindering manufacturers’ and industries’ ability to get their chemicals approved for use in commerce.

Finally, a new requirement in section 4(h) of TSCA requires the Agency “to reduce and replace to the extent practicable, scientifically justified, and consistent with the policies of this title, the use of vertebrate animals in the testing of chemical substances or mixtures.” The movement away from animal testing utilizes among other methods, high-throughput screening methods, as highlighted in TSCA. It is not clear that the HONEST Act would allow the use of these approaches in chemical evaluations.

**In Summary**

EPA supports access to data and is already on a path to make data public and transparent. EPA will do this at no additional cost to the taxpayer. EPA will do this while protecting PII and CBI. EPA will do this while preserving its ability to use the best available science. And EPA will do this while retaining its ability to respond quickly to emergency events. EPA strongly opposes the HONEST Act because it does none of these things and will significantly impede EPA’s ability to protect the health and the environment of Americans.

**Repeat Question: Do you think that EPA would implement the bill as suggested in the committee report language?**

EPA’s previous response to this question regarding S. 544/HR 1030 (below) is applicable to the HONEST Act. However, the HONEST Act would place additional burdens on EPA above and beyond S 544. These are described in the answer to the first question (above).

**Old Answer:**

No. The committee report for S. 544/H.R.1030 suggests at the top of page 3 that EPA would implement the bill by basing actions only on information that is publicly available in a manner sufficient for independent analysis and substantial reproduction of research results, rather than taking steps to collect, reproduce, disseminate, etc. any scientific or technical information covered in the bill. This would mean that EPA would be unable to develop policies, guidance or regulations using the best available science. Instead of using the best-available research for their assessments, EPA would be restricted to selecting studies based on their data availability. This
approach would introduce potential research bias that could compromise the quality of the agency’s work.

The requirement to use only data and studies that are publicly available in a manner sufficient for independent analysis or substantial reproduction prevents the Agency from using many peer-reviewed health studies because they often contain private patient information or CBI. Further, although the report text refers to the Data Access Act and OMB Circular A-110\(^1\) on page 2, the bill specifically states “all scientific and technical information” and does not limit its scope to information covered by the Data Access Act and OMB Circular A-110.

Use of other independently funded and produced, peer-reviewed studies in rule-making would not be allowed without further steps to answer the bill’s requirement for public availability of all “(i) materials, data, and associated protocols necessary to understand, assess, and extend conclusions; (ii) computer codes and models involved in the creation and analysis of such information; (iii) recorded factual materials; and (iv) detailed descriptions of how to access and use such information.”

For the Agency to rely solely on information that would already meet the bill’s requirements would compromise EPA’s ability to protect the health of Americans as required under a variety of existing laws.

**Legal Question:** Current law—and the HONEST Act—require that EPA use the “best available science” when setting regulatory standards. EPA contends above that meeting the bill’s requirements for full data transparency would, as a function of feasibility, shrink the universe of studies that EPA could draw from, and as a result, would compromise EPA’s mandate of using the “best available” science.

1. Is “best available science” a legal standard that could be enforced? Or is it more of a broad concept that is flexible and open to interpretation?

The scientific community considers best science to be the highest quality research that objectively provides quantitative or qualitative information for decision making. If it has been conducted, peer-reviewed, and published, it is available. Best available science is not defined by conditions set upon EPA by the HONEST Act. And the HONEST Act will significantly limit the Agency’s ability to use science in replacing default assumptions in species extrapolation and cancer risk assessment.

By limiting the pool of science EPA can use, the HONEST Act would prohibit EPA from using the best available science and wastes federal research dollars that have already been expended on previous studies where the data, for any reason, may not be available to the EPA.

\(^1\) Note that OMB Circular A-110 has been superseded in accordance with 2 C.F.R. § 200.104.
a. For example, EPA draws from roughly 50,000 scientific studies per year. If meeting this bill’s requirements shrunk the number of studies EPA could use to 20,000, could EPA be challenged in court for using procedures that violate the standard of “best available” science? OGC should answer this.

2. Or could EPA argue that, in its judgement, those 20,000 represent the best available science? (Certainly many would challenge this… but is it within the agency’s discretion to make the determination as to what constitutes the “best available science”?) OGC should answer.

3. In other words, to what extent does this standard (or other standards in environmental laws) legally bind EPA or control its processes? OGC should answer.

New Question: The bill states that “Nothing shall be construed as requiring the Administrator to disseminate scientific and technical information”

Suppose that EPA were to only use studies that are already publicly available at the time of promulgating a “covered action”…

1. How many studies per year might EPA expect to draw from? Note that for S. 544, EPA reported that the agency relies on approximately 50,000 studies per year to perform its mission. Would EPA expect a 50% reduction, 80%?

   It is difficult to estimate how many articles with sound scientific information would be considered unusable given the provisions of the HONEST Act, but it would certainly limit access to the majority of studies currently in the peer reviewed literature. It’s not just the number of studies but the type of studies and the integration of the results of these different types of studies that inform the underlying scientific basis of EPA’s decisions. The most informative studies include large comprehensive datasets, such as epidemiology studies, and animal toxicology studies from the open scientific literature, generally do not have all necessary information available on publication. With no new resources, the number of studies that EPA would be able to draw from would be greatly reduced – EPA roughly estimates it could be reduced by approximately 95% given the stated data-availability requirements and processes in this bill. And for industry-sponsored data submitted for pesticide registration, little to no data may be publicly available prior to a new registration.

2. Out of that fraction of studies, what percentage does EPA expect would already have ALL necessary information publicly available (including all data, models, code, etc.) that would allow an independent researcher to re-produce the study?

   Few peer-reviewed studies published in scientific journals meet the requirements described in this bill. Therefore, EPA roughly estimates that less than perhaps 5% would have all of the information publicly available to independently confirm the study details as required under this bill.
a. My understanding from speaking with researchers is that the vast majority of scientific journals do not publish underlying data. One generally must request it from the author. And if one does request it, the data is likely not in a format that would immediately allow for reproduction of the study (e.g., the author might provide some data but not the model/code)

It is true that one must request study data (for data not owned by EPA) from the author if the journal did not publish it, and it is also true that generally the data are not in a format that would immediately allow for independent confirmation of study results. Moreover, for some studies, the raw data may no longer exist. Most scientific journals do not currently publish underlying data, but there is growing momentum for journals to make underlying data available, often as a prerequisite for publication. This practice is increasing. Some funding agencies, such as NIH, also mandate that underlying data be submitted. In the coming years, more and more studies will include such data, and, as noted in the answer to the first question, the EPA’s Plan to Increase Access to Results of EPA-Funded Scientific Research Plan is a more cost-effective approach to ensuring that the data from prospective studies are made available. However, the HONEST Act also applies to research conducted in the past, so there will be many situations where EPA will need to negotiate with the data owner and may not be successful. While the HONEST Act includes text suggesting its requirements do not apply to existing regulations, EPA is required by law to revisit specific rules after several years (e.g. EPA must review the National Ambient Air Quality Standards every five years). This means that previous studies used to support existing legislation would in fact be affected by the HONEST Act when EPA revisits legislation as required by law.

3. If such information was not publicly available…

a. How likely is it that EPA could work cooperatively with a study’s authors to get them to post such information publicly?

EPA has requested underlying data or lab records for very few key studies in recent years. In each instance the level of effort was very substantial and took many weeks of investigator time over many months. The computer code was rarely included. In addition, most study authors do not have the resources to maintain a public archive of all data, models, and computer code indefinitely and would be unlikely to do it for EPA without compensation.

b. If the study’s authors did not want to cooperate, would EPA likely just choose to not include the study as part of its analysis?

EPA would not be allowed to include the study as part of its analysis according to the HONEST Act, placing the Agency in conflict with best available science requirements.

c. If EPA determined that it needed to post the information for a study itself, what steps would the agency need to take to actually do this—sign a contract, recollect data, construct database and website?
EPA would have to create and implement a new and significant infrastructure to manage the use, availability, and access to these data. This new infrastructure will also likely need to be shaped differently under different legal authorities – for example, when registering pesticides, registrants provide CBI data that EPA must protect. FIFRA also prohibits disclosure of information submitted by a pesticide registrant to any employee or agency of any multinational business. As a result, it is not clear how the required public disclosure in the HONEST Act would/could apply to information submitted under FIFRA. The new TSCA has similar provisions.

d. To what extent would EPA’s existing online infrastructure (regulations.gov dockets, for example) be able to house such information?

EPA’s existing infrastructure would not be able to house the information. EPA would have to create and implement a new and significant infrastructure to manage the use, availability, and access to these data. This new infrastructure will also likely need to be shaped differently under different legal authorities – for example, when registering pesticides, registrants provide CBI data that EPA must protect. The new TSCA has similar provisions.

e. Altogether, how much does EPA estimate it would cost to make a typical study and all necessary data/materials publicly available? Note: EPA reported for S. 544 that its estimate was $10,000 - $30,000 per study

EPA estimated that it would cost $10,000-$30,000 per study for S.544, but some studies may cost closer to $1 million. This estimate would be higher for The HONEST Act because EPA would also need to publish models and code and create a process to comb through extensive datasets to find and redact PII and CBI.

i. Can EPA provide a rough breakout, by percentage, of how much of that cost comes from different components? For example:

EPA would need to conduct a sophisticated analysis to come up with accurate numbers, but we roughly estimate it would take:

1. 70% staff time (significant staff and management time required to obtain and evaluate data and models, redact and provide description of how to access and use such information)
2. 20% contract overhead
3. 10% IT costs for database construction

Note this rough estimate breakdown does not include costs to create and enhance infrastructure. It also assumes that resources would not be available to do this primarily via a contract, so staff would have to perform the bulk of these tasks.

Does the draft report language from your vantage point conflict with the bill language?

The language the committee cites from the Data Access Act (otherwise known as the Shelby Amendment), 2 C.F.R. § 215.36(d), and Circular A-110 (page 2) states that scientific and technical information that is federally funded and used by the Federal government in developing
an Agency action that has the force and effect of law would have to be made publicly available if an Agency received a FOIA. This does not encompass the full scope of the bill language, which requires all scientific and technical information to be publicly available.

Using this to argue that many studies that EPA relies on are already publicly available, so it would not cost the agency, is inapposite. The fact that information could be subject to a FOIA request and would have to be released in response to a FOIA request is not the same as the bill’s affirmative requirement that all information be “publicly available online in a manner that is sufficient for independent analysis and substantial reproduction of research results.”

Further, the bill text’s broad definition of “scientific and technical information” is inconsistent with the report text’s argument that complying with the bill can be accomplished without imposing unnecessary burdens, discouraging research, or raising confidentiality concerns. For example, “materials, data…to understand, assess, and extend conclusions,” “computer codes and models,” and “recorded factual materials” must all be reviewed for CBI, personal privacy, or intellectual property concerns prior to their being made publicly available. This review would impose substantial resource and technical burdens on researchers and the Agency, despite the availability of “statistical and technical approaches” referred to on page 3.

Additional Comments:

- The Committee’s discussion of the NIH Principles and Guidelines for preclinical and clinical trials (page 2, last paragraph) to enhance reproducibility does not appear to be applicable to the vast majority of EPA-cited research which is not clinical or pre-clinical. Therefore, this does not provide a way to reduce the estimated costs of the bill for EPA.

- The Committee states that the bill does not create expectations for EPA to itself collect or disseminate any information (page 3, last paragraph). However, even if EPA does not need to collect or disseminate information from the studies, it would need to confirm that data from all cited studies are available, which in itself would be a major undertaking.

**New Question:** If EPA was only going to use data from existing publicly available studies, and was just going to confirm that the data was available online from the authors, how much would it cost the agency, per study, to undertake that confirmation?

In the simplest sense, this would only be confirmation of data availability, not computer code, models, information on how to use the code, etc. That might include correspondence with author and checking of websites and could be as little as $1000 per study based on 8 hour workday at $125 per hour loaded cost. However, it could be much greater to confirm availability of data for complex studies.

(And if authors refuse to make data available, EPA would either need to itself collect and disseminate any information or remove the study from its assessment.)

**New Question:** The choice of whether to pursue collection/dissemination of information for a study or to remove it from EPA’s assessment is a critical one. Similar to the question above
about the legal standard for “best available science,” what factors would EPA consider when determining whether to include or exclude a study?

1. Are there any studies that EPA would be legally required to include so to meet the “best available” standard?

2. Presumably, EPA would try to strike a balance between incorporating the “best” studies vs. expending resources (subject to their availability) to incorporate studies that are not yet in a format that would meet the bill’s transparency requirements.

New Question: CBO estimated for S. 544 that implementation of the bill might cost $250 million per year for several years, and that thereafter costs would decline as EPA completed putting data infrastructure in place and became more adept and efficient at working with researchers.

That estimate assumes that the EPA would reduce the number of studies it relies on by half (to 25,000/year) and that the Congress would provide appropriations at a level sufficient to meet the agency’s needs. Given the significant uncertainty as to appropriations levels and the extent to which EPA would ultimately implement by reducing the # of studies vs. investing resources to upgrade the data transparency of studies, it is useful to ask the following question:

If EPA was limited to $100 million/year to implement this bill, can EPA describe what activities it would spend those funds on over the first 5 years?

There are legal requirements under the Clean Air Act to review the criteria air pollutants every 5 years and to review residual risks of hazardous air pollutants. The Toxic Substances Control Act (TSCA) will require EPA to be evaluating at least 20 chemicals at all times. The Pesticide Registration Improvement Act (PRIA) mandates specific deadlines for new registration decisions, and FIFRA requires EPA to re-evaluate the safety of all pesticides every 15 years. These would be highest priority due to these legal requirements. But to focus on those activities alone would hamstring the implementation of Superfund, Safe Drinking Water, and other required environmental protection efforts.

The CBO estimates that new “covered actions” would cost between $10,000 to $30,000 for each scientific study used by the Agency. Recall that EPA risk assessments, for example, typically cite hundreds or even thousands of studies (the reference list for the Integrated Risk Information System (IRIS) Trichloroethylene (TCE) assessment is 107 pages). For EPA to confirm the availability of data, model code, etc. for each cited study in each assessment would require substantial staff time and resources as well as considerable funding, much more than the $1,000,000 per fiscal year limit included in the Act.

The Committee argues that it does not intend for EPA to duplicate public access to scientific data that are already provided by others and states that most scientific journals
are available online directly or through one of these databases. However, access to journal articles and databases does not necessarily mean access to the underlying scientific and technical information. EPA would still be responsible for making sure this information is available.

- The Committee presents the findings of the Panel on Data Access for Research Purposes of the National Research Council that stated: “Nothing in the past suggest that increasing access to research data without damage to privacy and confidentiality rights is beyond scientific reach.” The Committee report does not convey how the findings of the Panel could be implemented without increasing the estimated costs to the EPA.

Note: the new additions in the HONEST Act language (see PDF) concern information redaction. The language requires that any personally identifiable information, trade secrets, or commercial/financial information obtained be redacted prior to public availability. In EPA’s estimate of $10,000 - $30,000 per study, are the costs of grooming the research data to comply with privacy and confidentiality rights included in that range?

No. The addition of the privacy and confidentiality rights would make it cost more. The HONEST Act would require EPA to create and implement a new, extensive process to redact information. In addition to spending dollars and staff time on requesting and getting data from study authors, creating IT infrastructure and a data management system to manage, store, and archive large volumes of data, and making the data available in a format that is useful and accessible to the public, EPA would also have to spend dollars and staff time combing through these extensive datasets to find and redact Personally Identifiable Information (PII) and Confidential Business Information (CBI). Additionally, the HONEST Act would require computer code and models involved in the creation and analysis of data to be publicly posted. These are typically not available for most studies and often include proprietary code from private companies. It would be extremely difficult and costly to make these codes and models available with information on how to use them, and it could significantly affect the business of private companies who allow EPA to use their proprietary models and code. The additional requirements of the HONEST Act would incur significant costs above and beyond S.544/HR 1030.

The new language that requires the Administrator to sign a confidentiality agreement before releasing redacted data does not consider the legal authority of the Administrator to enter into such an agreement. Release of personal identifying information is determined by human subjects research protections and institutional review boards, HIPPA, and the privacy act. In order for the Administrator to release such information under a confidentiality agreement, re-approval by IRBs would be required. In many cases individual participants may need to be re-consented, which would incur additional costs to locate them and complete and manage the require paperwork. Since not all individuals would likely provide consent, the data set released would be inconsistent with the published research data. This could affect any attempted “substantial reproduction of research results,” which is an objective of the HONEST Act.

The redaction requirements of the HONEST Act would not address privacy and confidentiality rights. This is because in Section 2, lines 18-22, the HONEST Act states that anyone can gain
access to this redacted information if they sign a confidentiality agreement with the EPA Administrator. A signature would grant anyone access to medical records and trade secrets. The HONEST Act simply does not protect PII and CBI.

The bullets below are old responses and might not be applicable to the new bill.

- Of the three examples in footnote 5, two are requests for clarification of published results and one is an (apparently unanswered) request for data. It is unclear how these support the committee’s statements about the low cost of the proposed bill.

- The analysis provided by CBO is based in part on discussions with EPA last year about the NAAQS process and EPA’s experience obtaining data necessary for reanalysis (for ozone, sulfur oxides) and also methanol, each of which was very resource intensive. Those studies were important, but they surely didn’t reflect the bill language to make "...all scientific and technical information used to support that action is publicly available in a manner that is sufficient for independent analysis and substantial reproduction of research results."

The EPW report language paints a very rosy picture of what is already being done and is easy to do. It also points to the NIH Principles and Guidelines website and states "The Committee deems any information and technical information published in a journal or other publication under conditions that meet NIH’s Principles and Guidelines to be information that is sufficient for independent analysis and substantial reproduction." EPA notes that the NIH website is targeted to a specific type of study - preclinical studies - which EPA rarely if ever uses, and it uses words like "recommends sharing of dataset" and "encourages...sharing of software...", which seems to be less onerous than the bill language to provide all data sufficient for reanalysis. However, these words make application of the NIH Principles and Guidelines less than definitive, which means less helpful than implied by the EPW report.

The EPA considers a very large body of evidence in drawing causal conclusions and conducting exposure, dose-response, risk, and other analyses and to suggest the NIH standards are sufficient has limited relevance to the large and diverse data the agency actually uses. If the language indicated acceptance of Any Studies in Any Publication is sufficient to meet the bill requirements for reanalysis, then we might be in a different position. But that’s not what the report indicates. By pointing to the NIH Principles for journals publishing preclinical studies, it is implied that that level of data access and transparency is the norm, which is simply not the case, now.

The inclusion in the bill language of the word "all" sets up a very significant requirement that the agency will provide via a computer system the data and software used by studies for reanalysis by others; this remains an absolutely enormous and paralyzing effort in ORD’s opinion.
I think the CBO original estimate remains reasonable (if anything it is a low estimate) and the resources to meet the bill requirements are not substantially affected by the report language.

- EPA points to the Ozone NAAQS review and what they describe in the quote below is generally limited to very specific questions, asking for additional information on the air quality concentrations in epidemiologic studies, or questions about specific results, not routine requests for access to data. Such questions will be focused on a subset of studies that are more informative for the NAAQS decision, not all studies. It is also not without FTE cost to do this kind of outreach and follow-up. As for “existing repositories”, EPA is skeptical that it’s a simple solution for protecting personal information collected in conducting human studies.

- “available in a manner sufficient for independent analysis and substantial reproduction of research results. This type of communication and interaction between EPA and researchers is a common practice at the Agency. For instance, during the recent development of the National Ambient Air Quality Standards for Ozone, the online rulemaking docket reveals examples of EPA officials engaging with researchers asking for clarification or access to data. If the researcher informs EPA the scientific or technical information is not public and EPA wants to rely on their study for a covered action then EPA, similar to the policies of the National Science Foundation (NSF), NIH, and the National Aeronautics and Space Administration (NASA), could encourage the researcher to share the information through existing repositories. “