REGULATORY CHECKBOOK

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Comments on Proposed Revisions to the Process for the 13th Report on Carcinogens

Dear Dr. Lunn:

I am pleased to provide the following comments on the National Toxicology Program's proposed changes to the listing process for the 13th edition of the *Report on Carcinogens*.[1] According to the *Federal Register* notice, the NTP is proposing these changes "to enhance transparency and efficiency and to enable the NTP to publish the RoC in a timelier manner" while "maintain[ing] critical elements of the existing process including external scientific and public involvement, scientific rigor, and external peer review."[2]

These are worthy goals, but it does not appear that the proposed changes would do very much to achieve them. As currently written they do not add any discernable transparency and it appears more likely that they would reduce it. Their potential to improve "efficiency" within the Office of the Report on Carcinogens (ORoC) is far from obvious. The most likely improvements in "efficiency" would come from further undermining the quality of peer review, significantly reducing the already limited opportunity for meaningful public participation, and eliminating the desirable practice, adopted the first time for the 12th RoC, of responding to public comment.

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[1] National Toxicology Program (2011a).

[2] The NTP is not clear what it means by "efficiency." By definition, it cannot include "enabl[ing] the NTP to publish the RoC in a timelier manner" because that goal is separately listed. Moreover, improvements in ORoC *efficiency* that come at the expense of transparency cannot be justified. Therefore, I assume that *efficiency* in this context means "reducing unproductive activity within ORoC that does not (or could not) improve scientific quality."

These changes are fundamentally inconsistent with the NTP's stated commitment to "maintain critical elements of the existing process including external scientific and public involvement, scientific rigor, and external peer review." Meaningful public participation and rigorous peer review enhance scientific rigor because they force accountability.

Because the proposed changes would not address the fundamental issues that cause the RoC to be scientifically controversial, it also seems highly unlikely that they could enable the NTP to publish the 13th RoC in a timelier manner—unless the NTP intends to be even less responsive than it has been in the past to scientific concerns raised by bona fide peer reviewers and the public.

The *Federal Register* notice indicates that the NTP intends to "carefully review both the written and oral comments received," "consider what changes, if any, might be needed," and "present [the revised process] at the next NTP Board of Scientific Counselors meeting on December 15, 2011."[3] Given the obvious problems apparent in the draft proposal, plus the strong opposition voiced by every participant in the NTP's November 29 "listening session," it is simply impossible for the NTP to meet this schedule without intentionally disrespecting public concerns and thereby confirming the suspicion voiced by many that the NTP's process is merely a sham. Moreover, should the NTP ignore these concerns and present the draft revised process to the BSC for ratification on December 15, the NTP will seriously damage the BSC's credibility and the professional reputations of its members.

What Changes Are Missing from the Proposal?

Although the NTP proposes to change some terminology, the general outline of the proposed new process is very similar to the existing process. Similarities include at least the following items:

1. <u>The contents of draft background documents and draft substance profiles (now combined and called RoC Monographs) would continue to be just as susceptible to scientific controversy as they are today</u>. One source of controversy has been the NTP's refusal to correct scientific errors identified by public commenters prior to peer review. Nothing in the proposed changes reduces the NTP's propensity to commit scientific error or increases the likelihood that it will correct the errors it commits.
2. <u>Like existing ORoC work products, RoC Monographs would continue to ignore important statutory responsibilities that the NTP refuses to fulfill</u>. The NTP is required by law to determine whether "a significant number of

[3] National Toxicology Program (2011a, p. 67200).

persons residing in the United States are exposed," and provide "information concerning the nature of such exposure and the estimated number of persons exposed."[4] In lieu of complying with the law, it is the NTP's practice to report estimates of production volumes and similar statistics unrelated to human exposure (much less dose). No estimates are reported of the numbers of persons residing in the United States who are exposed, whether these exposure levels pose anything greater than a de minimis cancer risk, or whether the number of persons exposed to greater than de minimis cancer risk is significant.

3. Public disclosure of draft RoC Monographs would occur only after the NIEHS and its "federal partners" had secretly weighed in. A key defect of the existing process is that "federal partners" have an early and privileged opportunity to influence the scientific review, and do so in secret.

4. Consistent with current practice, comments provided by the "federal partners" provided during the stage denoted "Scientific Evaluation of Candidate Substances" would not be publicly disclosed." There is a legitimate basis for protecting interagency *policy* deliberations from public disclosure, but there is no public interest served by extending that protection to the sharing and review of *scientific* information. For the comments of "federal partners" to be germane to the "scientific evaluation," they must be strictly scientific. Thus, there is no justification for keeping them confidential.

5. To the extent that listing decisions are informally made at the "Scientific Evaluation" stage based on undisclosed, nonscientific comments of the "federal partners," the proposed changes cannot improve the transparency of the RoC process or improve the scientific quality of the RoC. The November 29 "listening session" clearly shows that nongovernmental stakeholders believe that the NTP decides whether to list a substance prior to the scientific review stage. Nothing in the proposed process changes would rebut that belief.

6. The NTP would continue to "consider" public comments, but it would not accept any responsibility to actually respond to them or rebut the scientific arguments they contain. In the 12th RoC, the NTP for the first time responded to public comments.[5] This document addresses a small subset of the scientific issues raised by public commenters and often represents those issues in ways that are inconsistent with the commenters themselves. The document is strikingly bereft of actual rebuttal evidence. That it falls woefully short of a

[4] See 42 U.S.C. § 241(b)(4)(A)-(B).
[5] National Toxicology Program (n.d.).

proper response is self-evident when one considers whether the editor of a scholarly journal would accept it as sufficient to overcome negative peer reviews.

7. BSC reviews, if any,[6] would continue to be guided by a charge that primarily seeks ratification of the NTP's proposed policy decisions rather than validation of the scientific information contained in ORoC work products. Under the current process, the BSC is asked to merely opine on the adequacy of ORoC work products for the narrow and nonscientific purpose of validating NTP policy decisions, not conduct a genuine scientific review. Nothing in the proposed changes would remedy this fatal procedural defect.

8. BSC reviews would be continue to be functionally controlled by NTP staff, and their reports would be summarized by NTP staff. BSC reviews are conducted as colloquies between BSC members and NTP staff, whose role is to advocate for their work. There is no advocate for opposing views, nor does the process include even the pretense of intellectual balance.

9. Consistent with the existing process, the proposed revision lacks clarity concerning the timing of each of the process elements. For example, no number of public comment periods is sufficient if the amount of time provided is unreasonably short (e.g., less than 60 days). Similarly, it would be cynical to suggest that peer review panels can take account of public comments if they are not provided enough time to review them, or if the review setting makes that infeasible or inconvenient, or if the NTP staff provide install themselves as barriers to effective communication between public commenters and peer reviewers.

10. Like the current process, the revised process has no provision for affirmative compliance with applicable information quality standards (e.g., transparency, reproducibility, and objectivity), particularly the requirement for pre-dissemination review of ORoC work products, as required by government-wide and Departmental information quality guidelines.[7] These guidelines have been in place for more than nine years.

This list of commonalities between the current and proposed review processes is extensive. In each case, the NTP has missed an opportunity to revise the process in ways that would enhance transparency, reduce ORoC inefficiency, and

[6] The proposed revision would permit the NTP to bypass BSC review in favor of "expert panels." In the text of the proposed process change, these "expert panels" would have unspecified character, composition, independence, and charge.

[7] Office of Management and Budget (2002) and U.S. Department of Health and Human Services (2002).

improve the timeliness of publication. I urge the NTP to reconsider its implicit decision not to make any improvements in these areas. The NTP will have a difficult time persuading its stakeholders, the Administration, and the Congress that its efforts are serious if it fails to do so.

What Changes Are Included in the Proposal?

The next question is whether the proposed changes would perceptively advance any of the NTP's stated goals. Unfortunately, the answer is a resounding "no." The changes proposed are highly unlikely to make any positive contribution to transparency. To the extent that they improve ORoC "efficiency" (narrowly construed), they would do so by undermining transparency. None of the proposed reforms would reduce the propensity of the NTP to generate scientific controversy, so it is hard to imagine how they would make publication timelier unless the NTP intends to be even more dismissive of public participation and genuine peer review than it is today.

My reasons for concern are summarized below:

1. The content of the new "concept papers" that ORoC would prepare in support of advancement to scientific review (now called "scientific evaluation") is ambiguous. A few hints are provided in the text, but they are insufficient to evaluate the merits of the proposal. Either the NTP has not though through the "concept paper" idea or it has declined to fully disclose what it intends to do.
2. "Concept papers" would be reviewed by the BSC, but the proposal does not explain the nature and scope of their charge. No standards for scientific rigor are proposed, so there would be no criteria for judging the quality of a BSC review. This defect is in part the necessary consequence of ambiguity concerning what "concept papers" would contain. Unless this is resolved, however, there is no reason for confidence that early BSC review would have significant value.[8]
3. The NTP proposes to seek public comment on "concept papers," but it would exclude these comments from the BSC review. To the extent that public commenters identify crucial scientific issues, the BSC would not have any reason to know about it. If for some reason BSC members did become informed, they would not have sufficient opportunity under the charge to do

[8] If the NTP intends early BSC review to insulate it from charges that its reviews are systematically biased, this change should be withdrawn. The purpose of the BSC is to provide scientific advice, not to protect the NTP from legitimate criticism.

anything about it, especially if (as under current practice) comment periods close immediately prior to BSC meetings. The exclusion of public comments from BSC review, with an adequate amount of time for the BSC to review them, is a fatal defect of the existing review process that the proposed changes would do nothing to remedy.[9]

4. The current practice of seeking public comment on draft background documents prior to the first round of peer review appears to be eliminated. This change could improve ORoC efficiency but only at the expense of reduced transparency, and with dubious effects on scientific quality.

5. The revised process would permit the NTP to bypass the FACA-chartered BSC in favor of review by ad hoc "expert panels" of unknown character, composition, independence, transparency, and charge. The text of the proposed process revision says nothing about the procedures that would govern these ad hoc panels. During the November 29 "listening session," the NTP's Mary Wolfe stated that ad hoc reviews would be fully compliant with FACA. This change needs to be clearly stated in the text of the process description. The NTP also must provide much more information concerning exactly how it would implement ad hoc reviews to ensure that panels are comprised of subject matter experts without financial or intellectual conflicts of interest, fully independent of the NTP, and charged with conducting rigorous scientific peer review without being controlled by NTP staff, who are inherently conflicted.

6. The revised process would be "tailored" to permit the NTP to rely on a variety of nonstandardized inputs without any safeguards in place to ensure transparency and meaningful opportunities for public participation. At the same time that "tailoring" may be helpful because it is adaptive, it also is likely to make substance reviews less transparent and reproducible, and more susceptible to favoritism.

7. Some of the proposed nonstandardized inputs in this "tailored" process have dubious merit. One example is the "listening session." This certainly serves a therapeutic purpose by providing interested parties an opportunity to vent their frustrations (see, e.g., the November 29th "listening session"). But the NTP accepts no responsibility to respond to what is has listened to. For

[9] The proposed BSC review of "concept papers" would occur along with public comment on proposed nominations for review (now called "proposed substances for evaluation"). Because the BSC is a FACA-chartered advisory group, an opportunity for public comment is required by law.

public participation to be meaningful, the NTP must actually engage with the public.

8. Nothing in the proposed revision would prevent the NTP from accepting and even relying upon nonscientific input, including nonscientific input of a frankly political nature.[10] This is obvious because of the early and privileged access given to the "federal partners" combined with the fact that the substance of their participation would be kept secret even though it is supposed to be strictly scientific.

Would any of the proposed process changes improve transparency?

It is not self-evident that any of the proposed process changes would be improve transparency. Reducing opportunities for meaningful public comment surely do not, nor does compressing public comment at the end of the process, long after listing decisions may have been made informally.

Opening the door to a host of nonstandard inputs, only some of them scientific, also does not enhance transparency. Without a consistent set of standards for the admissibility of scientific (and only scientific) evidence, consistently applied, transparency is almost certain to be materially diminished rather than enhanced. Where the NTP sees advantages in an approach that "is tailored to enable ORoC to use the most appropriate mechanism(s)," skeptics reasonably see utter opacity and ad hockery, with expanded opportunities for mischief. Even if this procedural flexibility could be assured of improving the scientific quality of the 13th RoC, it is bound to undermine public confidence about procedural fairness and predictability unless much greater attention is paid to process integrity, predictability, and basic fairness.

Which proposed process changes could improve ORoC efficiency?

It is not self-evident that any of the proposed process changes would improve ORoC efficiency, though it depends somewhat on how the term *efficiency* is defined, which neither the *Federal Register* notice nor the text of the proposal do. Given the sentence construction, it is unreasonable to infer that *efficiency* in this context means "publishing the RoC in a timelier manner" because that goal is stated separately. Presumably, *efficiency* in this context means avoiding duplicative effort and process delays that lack value for improving the potential scientific quality of the RoC.

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[10] It is plausible that this proposed "change" is actually an attempt to codify in the formal process what the NTP actually does.

But the proposal does not provide evidence for the proposition (or even assert) that certain elements of the existing process meet that definition. Thus, there is no way for the public to provide informed comment on the extent to which any of the proposed changes would improve "efficiency."

How would the proposed process changes enable the NTP to publish the RoC in a timelier manner?

It is not self-evident that any of the proposed process changes would enable the NTP to publish the RoC is a timelier manner. The NTP does not provide an analysis explaining why it took seven years to publish the most recent biennial report. If expediting publication is understood to be consistent (and not in conflict) with enhanced transparency and ORoC efficiency, then it is hard to know what the NTP believes to be the problem that needs to be solved. For that reason, there is no way for the public to provide informed comment on the extent to which any of the proposed changes would "solve" them.

An objective analysis of the reasons why the 12th RoC took more than three times the statutorily allowed two years is a prerequisite to the design of proposed solutions. Well-posed problems sometimes admit to solution, but solutions derived from a poorly formed problem definition are virtually guaranteed to fail. The NTP should take a step back and provide such an analysis for public comment before attempting to devise solutions.

Abandoning the response to public comments is a major step backwards

Finally, the proposed revision does not include an important provision contained in but poorly implemented in the current review process: the NTP's commitment to respond to public comments. The NTP's response to public comments for the 12th RoC was largely a recitation of previously stated positions without any effort devoted to rebuttal.[11] The NTP committed to "assess the merit of responding to public comments following completion of the 12th RoC and determine whether any change is needed in the review process with regard to this practice.[12] No such assessment is provided along with the NTP's proposal to abandon this practice. It is unclear why the NTP decided that the very limited accountability provided by having to respond to public comments was too great a burden to bear.

[11] National Toxicology Program (n.d.).

[12] See National Toxicology Program (2011b, footnote 9).

This is nontrivial backsliding from the 12th RoC process, but it is not surprising given that the NTP only agreed to respond at all under duress.[13] It is easy to see how abandoning the discipline of responding to public comment could improve the narrowest, most self-interested interpretation of "ORoC efficiency." Defined this way, however, improvements in efficiency are contrary to the public interest.

A Plausible Explanation for Low Quality, Perpetual Controversy, and Publication Delay

From the perspective of a disinterested third party without a stake in listing decisions, it appears that there are three dominant reasons why the RoC program has largely failed to achieve its statutory mission.[14] First, the NTP's listing criteria consist of a set of checkboxes informed by inherently inscrutable, nonscientific policy judgments, all of which lead to the fallacy of tautological argument. The NTP deems a substance a *known* human carcinogen if it judges the evidence from human studies to be *sufficient*. But what makes the evidence sufficient? How many studies are required? How strong must be the associations? What if there are studies with negative or equivocal evidence? Does it matter if there is no known mechanism of action? The NTP criteria answer none of these questions. They are accompanied by no publicly-disclosed weight-of-evidence scheme, they do not yield transparent and reproducible decisions, and they include no scientific means for rebutting default assignments that are by now quite obviously arbitrary. A substance is deemed to be a *known* human carcinogen if the evidence is *sufficient*, but the evidence is per se *sufficient* if the NTP deems the substance a *known* human carcinogen.

Second, the listing criteria are written in a way that enables the NTP to evade its implied statutory responsibility to demonstrate causality. The statutory categories—*known* and *reasonably anticipated* human carcinogens—describe

[13] Graham (2004, p. 1): "To fully realize the value of the comment process, NTP should prepare and disseminate a response-to-comments document before completion of a substance's review. This document would improve the transparency of the process and assure the public that their perspectives have not only been sought but also considered. Moreover, the discipline of preparing this document will ensure that the scientists responsible for the Report on Carcinogens have systematically considered and addressed all the significant scientific comments that NTP has received. It would also be desirable for this document to be made available before an NTP review committee evaluates a particular substance. With this structure, the members of these important committees will also have the benefit of both the insights of the public and the NTP's responses to these comments."

[14] See Belzer (2011) for a working paper that elaborates on these points.

different levels of confidence that a causal relationship exists between exposure (or dose) and cancer.[15] To ascribe either the higher (*known*) or lower (*reasonably anticipated*) level of confidence requires a demonstration of causality that is presumably stronger for the former than for the latter. But the NTP does not make a demonstration of causality a predicate for listing under either criterion. The NTP merely assumes that causality is demonstrated by the act of listing.

Third, the NTP exaggerates the contributions made by science to avoid accountability for its underlying policy decisions.[16] Outcomes are made to appear as if they are founded on science but in fact are grounded on undisclosed policy judgments and ratified by scientific experts who are required to shoehorn their scientific determinations into these policy judgments. This process cannot help but engender scientific controversy and conflict.

These three fundamental issues are the real source of ORoC inefficiency and publication delay. They create, exacerbate, and then magnify interagency and public conflicts that take considerable time to overcome.[17] The NTP professes to make decisions based on science, but science is demonstrably the junior partner in NTP decision-making. Much of the internal ORoC inefficiency and publication delay results from the time-consuming burden of having to conscript science to support policy decisions made for nonscientific reasons. Unless these issues are addressed, every effort to improve ORoC efficiency and reduce publication delay will come at the price of reduced transparency, increased procedural unfairness, and ever-expanding controversy.

The checkbox approach to listing might have been acceptable in the late 1970s. At that time, the scientific understanding of the mechanisms of carcinogenesis, particularly as they differ across species and doses, was truly limited. In the absence of knowledge, precautionary assumptions were made that humans were as sensitive as the most sensitive rodent species tested in the laboratory, and low dose effects were extrapolated linearly from extraordinarily

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[15] Known and *reasonably anticipated* do not imply weaker intensities of human carcinogenic effect (i.e., potency). The statute neither requires nor proscribes the assessment and reporting of relative human carcinogenic potencies. The RoC would have much more practical utility for decision making if it included this information.

[16] Wagner (1995).

[17] Public conflicts may be overcome but are not resolved. A similar pattern likely exists among the "federal partners," with consensus achieved either by exhaustion or the exercise of raw power.

high doses. The NTP's criteria still assume that there are only two alternative states of the world for a substance: it's either a human carcinogen or it's not.[18]

Scientific understanding of carcinogenesis has advanced by leaps and bounds over the past four decades, but hardly any of it is relevant to the NTP's scientific review, which is stuck in the '70s. Whole animal bioassays and similar laboratory experiments, none of which were designed for estimating low-dose human cancer risk, continue to dominate the NTP's mindset. There's an obvious reason for this: as the agency that performs these laboratory experiments, it has a fatal conflict of interest with respect to the fair review of scientific information. To give these studies a reduced role commensurate with their scientific status as methodological relics is tantamount to admitting that hundreds of past NTP determinations are scientifically suspect. It would require a confident organization with brave leadership to make these admissions and chart a new course for the RoC program.

If the NTP applied information technology the same way it uses environmental science, it would be analyzing data using a mainframe computer housed in a small, refrigerated industrial building. It would be programming the computer with massive stacks of punch cards, and producing the RoC text using a battery of IBM ® Selectric typewriters. Unless and until the NTP abandons its '70s-vintage understanding of its statutory responsibility, and overcomes its internal conflict of interest with respect to the weight given to its own laboratory studies, it will continue to provoke scientific controversies that inevitably reduce ORoC efficiency, delay publication, and undermine public confidence that the RoC program deserves to continue.

Better Process Reforms

The NTP might counter that its hands are tied by the statutory text, but this is unpersuasive. First, the NTP does not fully implement the statutory text, mostly notably with respect to exposure, as noted above. It cannot be true that the NTP's hands are tied by some of the statutory text when it has no qualms about simply ignoring other parts of it.

Revise the listing criteria to make them compatible with 21st Century scientific knowledge

Second, nothing in the statutory text requires the NTP to act as if it is frozen in time along with bell-bottoms and disco. The NTP could—and, if it wants to remain relevant in a time of budget austerity, it should—revise its listing criteria to make

[18] The distinction between a *known* and a *reasonably anticipated* human carcinogen concerns only the NTP's view of the strength of evidence. It does not describe alternative states of scientific knowledge.

the words in the statutory text correspond to probabilistic descriptions, as the public understands them. To be concrete, the NTP should begin by revising the definition of a *known* human carcinogen so that classification means that there is at least a 95% chance that the substance actually causes cancer in humans at average environmental or occupational exposures or doses now occurring in the United States. Similarly, it should revise the definition of a *reasonably anticipated* human carcinogen so that classification means that there is a high probability (e.g., 67%) that it causes cancer in humans at average environmental or occupational exposures or doses now occurring in the United States.[19]

The NTP makes neither of these distinctions today despite their obvious importance if the RoC is going to have practical utility for informing decision-making. Continuing to avoid making these distinctions sows doubt whether producing a new edition every two (or seven) years is a worthwhile governmental activity.

Conduct pre-dissemination review as required by OMB and HHS information quality guidelines

Third, there is no evidence in the existing process that ORoC actually performs the pre-dissemination information quality review that is required by information quality guidelines published in 2002 by the Office of Management and Budget:

> As a matter of good and effective agency information resources management, agencies shall develop a process for reviewing the quality (including the objectivity, utility, and integrity) of information before it is disseminated. Agencies shall treat information quality as integral to every step of an agency's development of information, including creation, collection, maintenance, and dissemination. This process shall enable the agency to

[19] These probabilities are intended to stimulate debate, not advocate specific values, and they address only a first-order causality question. The 95% probability is intended to capture the notion that causality is proved beyond a reasonable doubt. The 67% probability is intended to capture a lay understanding of what it means to be *reasonably expected*, a lesser standard than *known* but a much stronger standard than *probable* or *possible.* Even if these figures closely approximated the likelihood of causality, more needs to be done so that the public does not incorrectly infer that exposure at current environmental or occupational levels means an individual's likelihood of getting cancer is 95% or 67%, respectively.

> substantiate the quality of the information it has disseminated through documentation or other means appropriate to the information.[20]

This directive is not optional, and it has been required since October 1, 2002. In the revised process, the NTP appears to be continuing to ignore it.

Overhaul the peer review process

Fourth, the NTP needs a major overhaul of its peer review process to protect the scientific integrity of the independent scientists who agree to participate in it. The current peer review process lacks that integrity. It has been widely (and legitimately) criticized as riddled with conflicts of interest and focused on ratifying NTP policy decisions, an illegitimate task for *scientific* peer review. The proposed changes would not address any of these defects, leading to the reasonable inference that the NTP *intends* for these defects to persist because it finds them bureaucratically useful.

Several participants on the November 29th "listening session" were highly critical of the way the NTP selects peer reviewers. In particular, it seems that the NTP has on occasion selected persons as peer reviewers with personal interests in the review, publicly expressed policy views related to the substance being reviewed, or both. There are no circumstances in which this practice can be construed as legitimate.[21]

The current peer review serves a policy rather than scientific purpose. The first round of reviewers is asked to "(1) to apply the RoC listing criteria to the relevant scientific evidence and make a recommendation regarding the listing status for the candidate substance and (2) to provide the scientific justification for that recommendation."[22] Both are *policy* tasks that may, but need not, be informed by

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[20] Office of Management and Budget (2002, p. 8459). The Department of Health and Human Services (2002) has publicly agreed to adhere to these guidelines.

[21] During the "listening session," several participants suggested that the NTP adopt the conflict of interest policy of the National Academies. It was said that the Academies' policy would not exclude scientists from peer review panels where they would be reviewing their own work. This appears to be a misunderstanding of the Academies' policy. The Academies' policy expressly states, "an individual should not serve as a member of a committee with respect to an activity in which a critical review and evaluation of the individual's own work … is the central purpose of the activity. See The National Academies (2003, PDF p. 5).

[22] National Toxicology Program (2011c). This review is said to be conducted by an "expert panel," language that obfuscates whether they are scientists or policy officials. That they are all representatives of the "federal partners" and that their

science. The second round of peer reviewers is asked "to determine whether the scientific information cited in the draft substance profile for a candidate substance is technically correct, clearly stated and supports the NTP's policy decision regarding its listing in the RoC."[23] But this is a mix of science and policy, and the BSC's charter limits it to providing scientific review. By combining science and policy within the BSC's charge, the NTP telegraphs that what it wants from the BSC is a ratification of its policy decisions.

Respond seriously to public comment

Fifth, instead of abandoning any effort to respond to public comments, the NTP should substantially invigorate it. Indeed, abandoning responding to public comments is not a credible path forward. It telegraphs to the world that the NTP cannot effectively rebut the scientific arguments made by many public commenters.

Abandoning the response to public comments also is inconsistent with the spirit of President Obama's 2009 Memorandum on Transparency and Open Government[24] and his January 2011 directive that Executive branch agencies (including the NTP) adopt and practice principles of open exchange:

> [E]ach agency, consistent with Executive Order 12866 and other applicable legal requirements, shall endeavor to provide the public with an opportunity to participate in the regulatory process. To the extent feasible and permitted by law, each agency shall afford the public a meaningful opportunity to comment through the Internet on any proposed regulation, with a comment period that should generally be at least 60 days. To the extent feasible and permitted by law, each agency shall also provide, for both proposed and final rules, timely online access to the rulemaking docket on regulations.gov, including relevant scientific and technical findings, in an open format that can be easily searched and downloaded…[25]

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work is not publicly disclosed exacerbates the perception that the "Scientific Evaluation" step is a misnomer.

[23] National Toxicology Program (2011c). This review is conduced by the BSC, which has expertise only with respect to science but historically has no qualms about giving policy advice, too.

[24] Obama (2009).

[25] Obama (2011, Section 2(b)). That listing determinations are not "rules" under the Administrative Procedure Act does not exempt the NTP from adhering to the spirit of the directive, which applies to any action in which notice and comment is practiced. The public comment period for the notice proposing to revise the review process did not comply with this directive.

Cass Sunstein, the Administrator of OMB's Office of Information and Regulatory Affairs, has distributed guidance to all Executive branch agencies explaining what is expected of them:

> **Public Participation**
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> Section 2 of Executive Order 13563 emphasizes the importance of public participation. It requires agencies to "afford the public a meaningful opportunity to comment through the Internet on any proposed regulation, with a comment period that should generally consist of not less than 60 days." This section complements a corresponding provision in Executive Order 12866,1 while also emphasizing the importance of public comment through the Internet. Section 2 aims to promote agencies' continuing efforts to use online technologies to facilitate greater participation in the rulemaking process, thus making that process simpler and more accessible—and less burdensome and costly—for all stakeholders.
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> Section 2 also requires an "open exchange" of information among government officials, experts, stakeholders, and the public. In this context, "open exchange" refers to a process in which the views and information provided by participants are made public to the extent feasible, and before decisions are actually made. Section 2 thus seeks to increase participation in the regulatory process by allowing interested parties the opportunity to react to (and benefit from) the comments, arguments, and information of others during the rulemaking process itself. In this way, Section 2 is designed to foster better and more informed agency decisions.[26]

The NTP's existing public comment process falls well short of these standards. It does not provide "at least 60 days" for each public comment period; it does not utilize these comments in a constructive manner to resolve scientific disputes; and it does not include any mechanism at all for open exchange. The NTP did not even adhere to the President's directive with respect to the public participation process for this request for comment, allowing only 30 days and scheduling review (and presumably rubber-stamp ratification) by the BSC about 45 days after proposal.

More disturbingly, the proposed changes would remedy any of these defects. Some proposed changes appear more likely to make the process less transparent, offer no improvement in ORoC efficiency, and continue to generate the breadth and depth of scientific controversies that inevitably impede timely publication. Why the NTP has rejected the President's clear directions is quite baffling. If the NTP believes it is (or ought to be) exempt, then it has an obligation to explain why.

[26] Sunstein (2011, pp. 1-2).

Conclusion

The NTP's proposed changes to the RoC review process appear highly unlikely to accomplish the agency's stated objectives. The effects of several of the proposed changes are hard to predict, but they could make the review process worse. At least one proposed change—the abandonment of any effort to respond to public commenters—is clearly a step backwards. A reasonable inference one takes away from this proposed change is that the NTP has decided that it cannot refute the scientific criticisms directed by the public, so public participation is a nuisance it would like to discourage.

The part of the RoC that is most critically in need of reform is the listing criteria. They are arbitrary in design, tautological in application, and generally indifferent to scientific knowledge gleaned since the 1970s. The NTP still provides no way for science to rebut a presumptive listing decision grounded in its antiquated checkbox mentality. A wholesale revision of the listing criteria to make them compatible with scientific knowledge is more urgently needed than the amendments to the review process proposed here.

Even if the NTP lacks sufficient courage to update its listing criteria for the 21st Century, there is no justification for its failure to fully disclose the weight of evidence framework it uses to make listing decisions. If transparency truly is the primary objective of this process revision, this should be at the top of the list of actions it should be undertaking. The NTP's refusal to so undermines public confidence that the NTP is serious about reform.

Sincerely,

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