



Written Testimony of

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Joint Hearing on

***“How the Report on Carcinogens Uses Science
to Meet its Statutory Obligations,
and its Impact on Small Business Jobs”***

Before the

**House Committee on Science, Space, & Technology
Subcommittee on Investigations & Oversight**

and

**House Committee on Small Business
Subcommittee on Healthcare & Technology**

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INTRODUCTION

Chairman Broun, Chairwoman Ellmers, Ranking Members Tonko and Richmond, thank you for inviting me to testify on the *Report on Carcinogens*, which the National Toxicology Program attempts to publish biennially. I am Dr. Richard B. Belzer, president of Regulatory Checkbook, a nonpartisan and nonprofit organization whose mission includes the promotion of quality improvements in science, economics, and information quality. I have been president of Regulatory Checkbook since its founding in 2001.

Regulatory Checkbook does not lobby or take public positions on substantive legislation or rule making. Our sparsely populated niche is to seek improvements in the quality of scientific information, risk assessment and economic analysis used in support of regulatory decision-making, regardless of whether it tends to support or oppose specific regulatory actions.

No one has compensated Regulatory Checkbook or me for my testimony today.

In August 2011, I was asked by the Competitive Enterprise Institute (CEI) to conduct a short study of why the RoC has become so intensely controversial. CEI offered to pay Regulatory Checkbook an honorarium of \$5,000 for a completed, publishable paper. CEI put no substantive constraints on my work. Subsequently, Regulatory Checkbook supplied an additional \$5,000.

CEI published my report in January 2012. A longer, working paper written for future submission to a scholarly journal is available on my personal web site at rbelzer.com.

Before this hearing was scheduled, CEI arranged for a Capitol Hill briefing on chemical policy and regulation. The briefing will include my monograph and two other papers. So, I will be back to talk about this subject again on Monday, April 30th, from 2:00 to 3:00 p.m. in Room 2322. Obviously, if Members still have questions at the end of today's hearing and the time to stop by, I would be honored to answer them in that less formal setting. As I understand it, there will be free snacks and refreshments, so the room may be full of staff.

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The Results of My Research

My research shows that the RoC is not a high-quality scientific work product. There are two major reasons why.

First, when Congress wrote the RoC's authorizing legislation in 1978, it asked for a scientific compendium of substances carcinogenic to humans but it did not ask for this in scientific language:¹

The Secretary shall publish a biennial report which contains—

- (A) a list of all substances
 - (i) which either are known to be carcinogens or may reasonably be anticipated to be carcinogens and
 - (ii) to which a significant number of persons residing in the United States are exposed;
- (B) information concerning the nature of such exposure and the estimated number of persons exposed to such substances;

Figure A: Statutory Directive for the Report on Carcinogens

This disconnect set the stage for today's hearing. Science does not "know" or "reasonably anticipate" things. Science cannot tell you whether a number is "significant." These are not scientific words. They are the words of lawyers.

Second, given the opportunity, the NTP has happily exchanged the starched white lab coat of science for the bureaucratic imperative of maximizing the number of substances listed. The NTP has achieved this by maximizing its flexibility to use (or reject) scientific information however it sees fit. Thus, while the NTP's listing determinations have scientific content, they are not scientific determinations.

¹ 42 U.S.C. § 241(b)(4)(A)(i)-(ii).

To start, the NTP had to create its own criteria for listing substances in the RoC, and the way it did so made sure that science would always be the junior partner.

The NTP defines a “known” human carcinogen as follows:

There is sufficient evidence of carcinogenicity from studies in humans,* which indicates a causal relationship between exposure to the agent, substance, or mixture, and human cancer.

*This evidence can include traditional cancer epidemiology studies, data from clinical studies, and/or data derived from the study of tissues or cells from humans exposed to the substance in question, which can be useful for evaluating whether a relevant cancer mechanism is operating in humans.

Figure B: "Known human carcinogen"

People get distracted by the footnote. Let’s ignore it and focus on what is really important: the comma midway through the first sentence:

There is sufficient evidence of carcinogenicity from studies in humans,* which indicates a causal relationship between exposure to the agent, substance, or mixture, and human cancer.

*This evidence can include traditional cancer epidemiology studies, data from clinical studies, and/or data derived from the study of tissues or cells from humans exposed to the substance in question, which can be useful for evaluating whether a relevant cancer mechanism is operating in humans.

Figure C: "Known human carcinogen"

In English grammar, everything that follows this comma is called a “parenthetical element.” It can be removed from the sentence without changing the sentence’s meaning.² Therefore, the NTP’s definition for a

² U.S. Government Printing Office Style Board. Style Manual: An Official Guide to the Form and Style of Federal Government Printing Washington, D.C.: U.S. Government Printing Office, 2008, 201, Rule 8.40 on comma usage [“to set off parenthetical words, phrases, or clauses”].

“known” human carcinogen can be shown much more succinctly, as follows:

There is sufficient evidence of carcinogenicity from studies in humans,* which indicates a causal relationship between exposure to the agent, substance, or mixture, and human cancer.

*This evidence can include traditional cancer epidemiology studies, data from clinical studies, and/or data derived from the study of tissues or cells from humans exposed to the substance in question, which can be useful for evaluating whether a relevant cancer mechanism is operating in humans.

This definition is tautological and utterly opaque. It is tautological because it must be true: it goes without saying that for every substance deemed a “known” human carcinogen by the NTP, the evidence was at least “sufficient.” It is utterly opaque because no one outside the NTP knows what makes evidence “sufficient.”

We do not know if the NTP requires evidence of human carcinogenicity to be “beyond a reasonable doubt” (say, $\geq 95\%$), or whether a “preponderance of the evidence” will do, a likelihood greater than 50%. Indeed, the NTP’s evidentiary standard could be well below a 50% likelihood. For all we know, the NTP might be applying a “beyond reasonable doubt” standard in which the null hypothesis is the substance is presumed to be a carcinogen, and thus it is the duty of negative evidence to show that there is less than 5% chance that the substance is not a carcinogen. Or maybe even a 1% chance.

A similar story can be told regarding the definition of a “reasonably expected” human carcinogen. The definition has the same comma located in the same place. Everything following the comma is a parenthetical element, and it may be deleted without changing the meaning of the definition.

“Sufficient evidence,” “limited evidence,” “less than sufficient evidence”—all these terms used by the NTP are legal terms, not science. What the Congress seems to have asked for was a scientific compendium. What the NTP produces is legislative determinations. It produces these legislative determinations in a way that looks

scientific—biology words are often used, for example—but the determinations themselves cannot be scientific because the definitions have no scientific content.

The NTP Does Not Comply with a Crucial Element of the Law

Return with me for a moment to my second slide, the one showing the statutory directive the NTP is supposed to implement:

The Secretary shall publish a biennial report which contains—

- (A) a list of all substances
 - (i) which either are known to be carcinogens or may reasonably be anticipated to be carcinogens and
 - (ii) to which a significant number of persons residing in the United States are exposed;
- (B) information concerning the nature of such exposure and the estimated number of persons exposed to such substances;

Figure D: Statutory Directive for the Report on Carcinogens

So far, we have discussed only the first clause in subparagraph (A). To be listed, a substance also must satisfy the test in the second clause: “a significant number of persons residing in the United States” must be exposed to it.

The text refers to human exposure, so to comply with the law, the NTP must investigate and estimate the extent of human exposure in the United States. This cannot be done merely by estimating the mass or volume of production or use. It also cannot be done by relying on historical data (such as “persons who were exposed sometime in the past”) or data from another country (such as “persons exposed in China”). The law is clear: It must be actual human exposure, occurring now, in the United States.

1. Define “a significant number of persons residing in the United States”;
2. Define a *de minimis* cancer risk level; and
3. Estimate for each candidate substance the number of persons in the United States exposed above the *de minimis* cancer risk level.

Figure E: Steps Required to Implement 42 U.S.C. § 241(b)(4)(B)

This text box shows the steps that must be taken to implement clause (B). Two of the three steps are strictly policy determinations—the definition of a “significant” number of persons, and the definition of a *de minimis* cancer risk level. The third—estimation of the number of persons residing in the United States actually exposed above the *de minimis* cancer risk level—is strictly scientific.

To the best of my knowledge, the NTP has performed none of these tasks. Indeed, the NTP appears to functionally ignore this requirement for listing.³ It would be an interesting research project to determine how many of the 240 listed substances do not meet the statutory test for listing because actual human exposure in the United States is lacking.

For those substances that pass both prongs of the statutory requirement for listing, the law requires the NTP to include “information concerning the nature of such exposure and the estimated number of persons exposed to such substances.”⁴ The NTP does not perform this task, either. I am unaware of any substance listing that includes an objective estimate of the number of persons exposed and at what level.

³ In the 12th RoC, the NTP acknowledges that “[t]he RoC is required to list only substances to which a significant number of people living in the United States are exposed” (p. 4). The NTP defends its continued inclusion of substances for which actual U.S. exposure is unambiguously trivial because “people who were previously exposed remain potentially at risk or because these substances still are present in the environment.” Both justifications are contrary to the plain text of the law, which says nothing about risk and requires listings to be limited to where the number of actually exposed persons residing in the U.S. is “significant.”

⁴ 42 U.S.C. § 241(b)(4)(B).

What Can Congress Do?

An obvious starting point is to figure out a way to compel the NTP to perform all of the tasks set forth in statute—to limit listings to substances “to which a significant number of persons residing in the United States are exposed,” and to objectively estimate the numbers of persons exposed. The NTP would comply in a New York minute if the public had standing to challenge its listing decisions, a right that to the best of my knowledge it does not have.

More generally, if Congress wants the RoC to become a useful scientific compendium about human carcinogens, it will need to upgrade the statutory language to make it scientific. I present six ideas in my monograph:



1. **Direct the NTP to make its determinations conditional on exposure or dose.** The NTP completely ignores exposure or dose in making its determinations. That severely undermines the practical utility of the RoC and arguably renders its determination useless or misleading.
2. **Direct the NTP to include potency in its listing decisions.** The NTP makes no distinction between strong and weak carcinogens. Relative potency matters. It is misleading to report substances with the same carcinogenicity label when their capacity to cause cancer—at the same dose—varies by orders of magnitude.
3. **Replace problematic risk descriptors or provide guidance concerning how to interpret them.** Congress should abandon its reliance on nonscientific descriptors such as “known” and “reasonably anticipated.” If you want a scientific compendium, ask for one in the language of science, not law.
4. **Direct the NTP to establish a strictly scientific weight of evidence (WoE) scheme.** Nobody knows how the NTP weighs evidence because the NTP won't tell us. Enough. Direct the NTP to devise a new WoE scheme that is transparent, reproducible, and strictly science-based. Give the public the right to challenge it in court if it's not strictly scientific.
5. **Sunset listings to encourage revision.** The current process is anti-scientific because it encourages the NTP to review each substance once, then bolt the door to prevent the intrusion of inconvenient, new scientific knowledge.
6. **Direct the NTP to affirmatively comply with applicable Information Quality Guidelines.** The information quality framework requires information to be objective and presented in an objective manner. The NTP doesn't comply. Petitioning for correction is ineffective because there is no penalty for noncompliance. Give the public the right to challenge

These reforms would help restore the NTP as a scientific agency and get it out of the business of legislating policy through the back door.

Conclusion

Last fall, a real scientific controversy arose because a team of physicists using the Large Hadron Collider at the European Center for Particle Physics reported that they had measured neutrinos moving slightly faster than the speed of light.⁵ So what's the big deal? Well, if

⁵ T. Adam, N. Agafonova, A. Aleksandrov, O. Altinok, P. Alvarez Sanchez, A. Anokhina, S. Aoki, A. Ariga, T. Ariga, D. Autiero, A. Badertscher, A. Ben Dhahbi, A. Bertolin, C. Bozza, T. Brugièrè, R. Brugnera, F. Brunet, G. Brunetti, S. Buontempo, B. Carlus, F. Cavanna, A. Cazes, L. Chaussard, M. Chernyavsky, V. Chiarella, A.

it was true, then Albert Einstein was wrong. And that would be a big deal.

Certain of Einstein's theories are believed to be true—let's call them "known"—because they have been subjected to countless experiments and never been refuted. Until now, apparently. As *Time's* Michael Lemonick wrote:

Physicists have a stock phrase they trot out whenever someone claims to have made an astounding new discovery about the universe. "Important," they say, "if true."⁶

This group of scientists behaved as if their result was true and that obtaining credit for their discovery was the most important thing. (This is a phenomenon we see all the time, when a research group, a university, or a scholarly journal rushes to issue a press release in order to garner headlines.)

Chukanov, G. Colosimo, M. Crespi, N. D'Ambrosio, G. De Lellis, M. De Serio, Y. Déclais, P. del Amo Sanchez, F. Di Capua, A. Di Crescenzo, D. Di Ferdinando, N. Di Marco, S. Dmitrievsky, M. Dracos, D. Duchesneau, S. Dusini, J. Ebert, I. Efthymiopoulos, O. Egorov, A. Ereditato, L.S. Esposito, J. Favier, T. Ferber, R.A. Fini, T. Fukuda, A. Garfagnini, G. Giacomelli, M. Giorgini, M. Giovannozzi, C. Girerd, J. Goldberg, C. Göllnitz, D. Golubkov, L. Goncharova, Y. Gornushkin, G. Grella, F. Grianti, E. Gschwendtner, C. Guerin, A.M. Guler, C. Gustavino, C. Hagner, K. Hamada, T. Hara, M. Hierholzer, A. Hollnagel, M. Ieva, H. Ishida, K. Ishiguro, K. Jakovcic, C. Jollet, M. Jones, F. Juget, M. Kamiscioglu, J. Kawada, S.H. Kim, M. Kimura, E. Kiritsis, N. Kitagawa, B. Klicek, J. Knuesel, K. Kodama, M. Komatsu, U. Kose, I. Kreslo, C. Lazzaro, J. Lenkeit, A. Ljubcic, A. Longhin, A. Malgin, G. Mandrioli, J. Marteau, T. Matsuo, N. Mauri, A. Mazzoni, E. Medinaceli, F. Meisel, A. Meregagli, P. Migliozzi, S. Mikado, D. Missiaen, K. Morishima, U. Moser, M.T. Muciaccia, N. Naganawa, T. Naka, M. Nakamura, T. Nakano, Y. Nakatsuka, V. Nikitina, F. Nittia, S. Ogawa, N. Okateva, A. Olchevsky, O. Palamara, A. Paoloni, B.D. Park, I.G. Park, A. Pastore, L. Patrizii, E. Pennacchio, H. Pessard, C. Pistillo, N. Polukhina, M. Pozzato, K. Pretzl, F. Pupilli, R. Rescigno, F. Riguzzia, T. Roganova, H. Rokujo, G. Rosa, I. Rostovtseva, A. Rubbia, A. Russo, O. Sato, Y. Sato, J. Schuler, L. Scotto Lavina, J. Serrano, A. Sheshukov, H. Shibuya, G. Shoziyoev, S. Simone, M. Sioli, C. Sirignano, G. Sirri, J.S. Songa, M. Spinetti, L. Stanco, N. Starko, S. Stellacci, M. Stipcevic, T. Strauss, S. Takahashi, M. Tenti, F. Terranova, I. Tezuka, V. Tioukov, P. Tolun, N.T. Tran, S. Tufanli, P. Vilain, M. Vladimirov, L. Votano, J.-L. Vuilleumier, G. Wilqueta, B. Wonsak, J. Wurtz, C.S. Yoon, J. Yoshida, Y. Zaitsev, S. Zemskova, A. Zghiche, "Measurement of the neutrino velocity with the OPERA detector in the CNGS beam," ArXiv.org, November 17, 2011. Available at <http://arxiv.org/pdf/1109.4897v2.pdf>.

⁶ Michael D. Lemonick, "Was Einstein Wrong"? A Faster-than-Light Neutrino Could Be Saying Yes," *Time*, September 23, 2011. Available at <http://www.time.com/time/health/article/0,8599,2094665,00.html>.



But the physics community insisted on determining first whether the claims were true before discarding Einstein and virtually everything learned since his day. They reviewed the experiment that yielded the astounding result. They performed more experiments. They did this over and over. And they discovered that the astounding result purportedly overturning Einstein was the result of a loose cable. In late March, the leading physicists responsible for claiming to have refuted Einstein have resigned, their careers left in ruins.

Human carcinogenesis is much less certain. Hardly anything at all is “known” in the way Einstein’s special theory of relatively is “known.” So if the NTP applied a scientific standard of confidence for the definition of a “known” human carcinogen, the RoC would be a very thin pamphlet. And every few years, one of the few “known” human carcinogens would have to be removed from the pamphlet because new scientific knowledge rendered the previous conclusion scientifically untenable.

For the RoC to ever produce useful information about human carcinogens, the authorizing statute will have to be changed. Legalese will have to be replaced with the language of science. The NTP must be directed to stick to science, and its incentives to practice bureaucratic self-aggrandizement must be eliminated. Only then will it be possible for the RoC have any practical value for informing decisions.

I look forward to answering any questions you might have.

