

**Comments of Environmental Defense Fund, Earthjustice, Natural Resources Defense Council, Physicians for Social Responsibility, and Union of Concerned Scientists
On Candidates Under Consideration for Appointment to the
Toxic Substances Control Act, Science Advisory Committee on Chemicals**

Docket ID: EPA-HQ-OPPT-2020-0135

Submitted October 29, 2020

Introduction

Environmental Defense Fund, Earthjustice, Natural Resources Defense Council, Physicians for Social Responsibility, and Union of Concerned Scientists submit these comments on the list of nominees being considered for membership on the Environmental Protection Agency’s Toxic Substances Control Act (TSCA) Science Advisory Committee on Chemicals (SACC).¹ This committee is responsible for providing expert advice to EPA’s Office of Pollution Prevention and Toxics “with respect to the scientific and technical aspects of risk assessments, methodologies, and pollution prevention measures or approaches supporting implementation” of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act).

According to the Federal Advisory Committee Act (FACA) and EPA’s Peer Review Handbook, this committee must be both balanced and free of members who have actual or perceived conflicts of interest or an appearance of a loss of impartiality. EPA’s “selection criteria” for the SACC similarly include the “[a]bsence of financial conflicts of interest or the appearance of a loss of impartiality.” 85 Fed. Reg. 16,094-05 (Mar. 20, 2020).² We have reviewed the list of nominees under consideration for membership and are concerned about actual or potential conflicts of interest or appearances of a loss of impartiality (or both) with respect to many of the 61 nominees.

We believe the information we provide in these comments on 19 of the nominees – which is from public sources – is sufficient to find that actual or potential conflicts of interest or an appearance of a loss of impartiality (or both) exist. We therefore urge EPA not to add those nominees to the SACC.

¹ EPA’s memorandum opening the docket for comments on the nominees is available at <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2020-0135-0017>. Biosketches of the nominees are available at <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2020-0135-0018>.

² We note that in its earlier comments EDF criticized these criteria as too narrow. See: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2020-0135-0002>.

Our comments are not intended to challenge the scientific and technical expertise or impugn the integrity of these nominees, but rather to ensure that all SACC deliberations are able to be conducted without fear of conflict.

Background

In April, 2020, EDF submitted comments to EPA in response to its initial solicitation of SACC nominations.³ We incorporate those comments herein by reference. Salient points made in those comments that warrant reiteration here are:

- In addition to the current nominees, EPA needs to screen all existing members of the SACC and all ad hoc panelists for actual or potential conflicts of interest or appearances of a loss of impartiality; and
- EPA must rectify the lack of balance on the current SACC by prioritizing the selection of labor, public health, and public interest representatives.

To date, the SACC has reviewed only the first 10 draft TSCA chemical risk evaluations. However, as noted in the Federal Register notice, in the future the SACC may be called on to address broader, cross-cutting scientific issues:

Given the foundation provided by the SACC recommendations from these first reviews, EPA is exploring different ways to use the SACC's expertise for providing independent advice and expert consultation after the peer reviews of the first 10 chemical risk evaluations are completed. The Agency is considering requesting that the SACC review significant, cross-cutting science issues on exposure, risk, and modeling, similar to how the Agency uses the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Scientific Advisory Panel (SAP) for health and safety issues related to pesticides.

As such, EPA needs also to consider potential or actual conflicts of interest or appearances of a loss of impartiality with respect to both ongoing or future risk evaluations and other science issues that the SACC may be called on to review.

In these comments, we provide information on specific nominees that identifies actual or potential conflicts of interest or appearances of a loss of impartiality (or both), including with respect to specific chemicals that have been, are, or could be subject to risk evaluations or broader scientific issues (e.g., application of systematic review methodology or dose-response modeling). Among the approaches we used to focus our research in identifying concerns was to examine linkages between candidates and companies that reported making or using (or trade

³ See: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2020-0135-0002>.

associations that represent companies that reported making or using) any of the chemicals that have undergone or are or could in the near future be undergoing risk evaluation. Our examination was constrained by the fact that we had to rely on EPA's public 2016 and 2012 Chemical Data Reporting (hereinafter CDR).⁴ A considerable amount of information reported to EPA under the CDR is not publicly disclosed. As a result, more companies may manufacture the relevant TSCA chemicals than we have been able to identify from the public CDR. EPA, which of course has access to the full CDR dataset, is able to and should undertake a full examination.

Given that many more chemicals and companies than those we have examined may or will be subject to various EPA actions in both the short- and longer-term, our research is clearly limited in scope. A broader look involving more chemicals and companies may well uncover additional concerns beyond those we identify here. Hence EPA should examine potential concerns raised by nominees' associations with additional chemicals and companies relevant to TSCA implementation.

⁴ Chemical Data Reporting results, US EPA, available at: <https://www.epa.gov/chemical-data-reporting/2016-chemical-data-reporting-results>.

Specific comments on nominees

The table below lists 19 nominees we believe have actual or potential financial conflicts of interest and an appearance of a loss of impartiality. See the remainder of these comments for details.

Nominee	Title and Affiliation
<u>MICHAEL L. DOURSON</u>	Director of Science, Toxicology Excellence for Risk Assessment (TERA)
<u>CARR J. SMITH</u>	Toxicology Advisor, Albemarle Corporation
<u>BRYAN D. HARDIN</u>	Vice President - Principal Toxicologist J.S. Held LLC
<u>LAURA M. PLUNKETT</u>	Partner at BioPolicy Solutions LLC; Adjunct professor Baylor University; Registered Patent Agent, Licata & Tyrrell, P.C.
<u>JULIE E. GOODMAN</u>	Principal at Gradient
<u>RICHARD B. BELZER</u>	Independent consultant
<u>ROBERT BUDINSKY</u>	Science Leader, The Dow Chemical Company
<u>MARK A. MADDALONI</u>	Senior Managing Health Scientist, Cardno/ChemRisk
<u>JON A. HOTCHKISS</u>	Inhalation Toxicology Consultant, JAHotchkiss Inhalation Toxicology Consulting LLC
<u>ELLIOT B. GORDON</u>	Principal Toxicologist, Elliot Gordon Consulting, LLC
<u>MARYANN HOFF</u>	Director, Global Product Stewardship & Corporate Advocacy, PPG Specialty Coatings & Materials
<u>VIJAYAVEL (“VIGAY”) KANNAPPAN</u>	Manager, Regulatory Toxicology, Georgia Pacific LLC
<u>LISA M. NESPOLI</u>	Manager, Product Safety and Stewardship at Covestro
<u>ANDREW W. PAWLISZ</u>	Senior Toxicologist, Trihydro Corporation
<u>SOL BOBST</u>	President, ToxSci Advisors LLC; Adjunct Assistant Professor, Boonshoft School of Medicine and University of Texas Medical Branch
<u>DAVID V. GAUVIN</u>	Director, Neurobehavioral Sciences, Charles River Laboratories, Inc.
<u>FRANKLIN MINK</u>	President, MAI
<u>HONG ZHUANG</u>	Senior Regulatory Scientist, Symrise Inc.
<u>AGNES KARMAUS</u>	Senior Toxicologist, Integrated Laboratory Systems (ILS)

Dr. Michael L. Dourson

Dr. Michael L. Dourson is among the most conflicted of all the current nominees. He has a long history of being paid by industry groups to undermine existing chemical standards or press federal, state or local governments to adopt weak ones. This mercenary work has extended to dozens of chemicals relevant to TSCA implementation. His conflicts of interest were so extensive and so obvious that his 2017 nomination to serve as EPA Assistant Administrator for toxic substances drew strong bipartisan opposition, forcing him to withdraw from consideration. See Attachments A and B for details on his work as of 2017, listing some of the chemicals involved and the industry groups who paid him. Many of these chemicals are those EPA has been reviewing or is currently conducting or expected to conduct reviews of in the near term under TSCA. Based on that track record alone, appointing Dr. Dourson to the SACC would be a travesty and make a mockery of the SACC's role to serve as independent scientific experts free of conflicts of interests and of an appearance of a loss of impartiality.

Since withdrawing his nomination, Dr. Dourson has continued unabated to undertake paid work on behalf of chemical industry clients. Here are recent relevant examples published since or not cited in Attachments A and B:

- Tetrabromobisphenol, or TBBPA: This chemical⁵ is one of the 23 chemicals⁶ for which EPA has recently initiated risk evaluations under TSCA. In 2018, Dr. Dourson published a paper on TBBPA including the following from the paper's acknowledgments/conflicts of interest section (emphases added):⁷

Funding for this work was provided by *the American Chemical Council* [sic]. ... This manuscript was developed from a report on the cancer and non-cancer toxicology of TBBPA submitted to the American Chemistry Council (ACC) under a previous contract. Additional funding was supplied from ACC. ... [B]efore journal submission, the manuscript was reviewed by ... ACC.

⁵ See: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-44-1-methylethylidenebis2-6>.

⁶ See: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/chemicals-undergoing-risk-evaluation-under-tsca>.

⁷ Pecquet, A. M, Martinez, J. M., Vincent, M., Erraguntla, N., and **Dourson, M.** (2018). Derivation of a no-significant-risk-level for tetrabromobisphenol A based on a threshold non-mutagenic cancer mode of action, *Journal of Applied Toxicology*, Volume 38, Issue 6, Pages 862-878, available at: <https://onlinelibrary.wiley.com/doi/full/10.1002/jat.3594>.

The American Chemistry Council (ACC) is the main chemical trade association for the chemical industry, whose members are companies that manufacture new and existing chemicals that have been, are being, or could be assessed by the agency.

- Cobalt compounds: These chemicals are listed on the 2014 TSCA Work Plan⁸ from which EPA is to draw chemicals to be subject to risk evaluation under TSCA in the near term. In 2020, Dr. Dourson published a study on cobalt compound funded by the cobalt industry.⁹ The paper's funding section states: "This work was funded by the organizations *Cobalt Institute and Cobalt REACH Consortium (CI/CoRC)*." According to the Cobalt Institute's website: "The Cobalt Institute (CI) is a non-profit trade association composed of producers, users, recyclers, and traders of cobalt."¹⁰ According to the Cobalt REACH Consortium's website, it is a wholly-owned subsidiary of the Cobalt Institute.¹¹
- 1,4-dioxane: This chemical¹² is one of the first 10 chemicals¹³ for which EPA is conducting or has conducted risk evaluations under TSCA. Dr. Dourson was the first author on a 2017 paper on 1,4-dioxane funded by PPG.¹⁴ The paper's acknowledgments section states (emphasis added): "Sources of funding for this activity at the TERA Center at the University of Cincinnati include *Hamp, Mathews & Associates, Inc., PPG Corporation, Waste Management*, and the University of Cincinnati, College of Medicine."
- 3-Monochloropropane-1,2-diol (3-MCPD), 5-Hydroxymethylfurfural (HMF), Nickel, and Perchlorate: Nickel and nickel compounds are listed on the 2014 TSCA Work Plan. In 2018, Dr. Dourson published a paper on benchmark dose modeling including nickel and

⁸ See: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-chemical-assessments-2014-update>.

⁹ Danzeisen, R., Williams, D. L., Viegas, V., *Dourson, M.*, Verberckmoes, S., and Burzloff, A. (2020). Bioelution, Bioavailability, and Toxicity of Cobalt Compounds Correlate, *Toxicological Sciences*, 174(2): 311–325, available at: <https://academic.oup.com/toxsci/article/174/2/311/5736147>.

¹⁰ "About Us," Cobalt Institute. Available at: <https://www.cobaltinstitute.org/about.html>.

¹¹ "About CoRC," Cobalt REACH Consortium. Available at: <https://www.cobaltreachconsortium.org/about-us.html>.

¹² See: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-14-dioxane>.

¹³ See: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/chemicals-undergoing-risk-evaluation-under-tsca>.

¹⁴ *Dourson, Michael L*; Higginbotham, Jeri; Crum, Jeff; Burleigh-Flayer, Heather; Nance, Patricia; Forsberg, Norman D; Lafranconi, Mark; Reichard, John (2017). Update: Mode of action (MOA) for liver tumors induced by oral exposure to 1,4-dioxane, *Regulatory Toxicology and Pharmacology*, Vol: 88, Page: 45-55, available at: <https://www.sciencedirect.com/science/article/pii/S0273230017300429?via%3Dihub>.

perchlorate as case studies.¹⁵ The paper's declaration of interest section states (emphases added):

Financial support was received from the *Grocery Manufacturers Association, the Institute of Shortening and Edible Oils, the EU Vegetable Oil & Proteinmeal Industry, the Infant Nutrition Council of America, FoodDrink Europe, and the International Technical Caramel Association*. ... The initial case study on 3-MCPD was conducted by MLD [Michael L. Dourson] and AP with funding from *Abbott Nutrition and the Grocery Manufacturers Association (GMA)*. The initial case study on 5-hydroxymethylfurfural (HMF) was conducted by MLD and AP with funding from the *Coca-Cola Company*, and was presented as a poster at the Society of Toxicology annual meeting in 2016. ... MLD has worked on perchlorate since 1995. Prior work on perchlorate informed the text in the manuscript, and was funded by the *Perchlorate Study Group (PSG), supplemented by additional tasks for Kerr-McGee Chemical Corporation and Aerojet*.

According to SourceWatch,¹⁶ the Perchlorate Study Group is (emphasis added) “comprised of manufacturers and users of the chemical perchlorate, including *Aerojet, American Pacific Corporation, Kerr-McGee Chemical, and Lockheed Martin*.”

Though not specifically mentioned in the paper, Dr. Dourson has conducted work on nickel compounds paid for by the Nickel Producers Environmental Research Association (NiPERA, Inc.).¹⁷

Given his history, we believe that Dr. Dourson has financial conflicts of interest and an appearance of a loss of impartiality with respect to TSCA chemical risk evaluations and related scientific issues.

¹⁵ Lynne T. Haber, *Michael L. Dourson*, Bruce C. Allen, Richard C. Hertzberg, Ann Parker, Melissa J. Vincent, Andrew Maier & Alan R. Boobis (2018). Benchmark dose (BMD) modeling: current practice, issues, and challenges, *Critical Reviews in Toxicology*, 48:5, 387-415, available at <https://www.tandfonline.com/doi/full/10.1080/10408444.2018.1430121>.

¹⁶ “Perchlorate Study Group,” Source Watch. Available at: https://www.sourcewatch.org/index.php/Perchlorate_Study_Group.

¹⁷ “Nickel Ion Bioavailability Workshop,” TERA. Available at: <https://www.tera.org/Peer/NiBioavailability/>.

Dr. Carr J. Smith

Dr. Carr J. Smith is a Toxicology Advisor at Albemarle Corporation. Dr. Smith worked for RJ Reynolds Tobacco Company for several decades earlier in his career.

Albemarle is a major chemical manufacturer, producing or importing many chemicals subject to TSCA review and regulation.

According to the 2016 CDR data, Albemarle currently manufactures at least one of the 20 chemicals currently undergoing TSCA risk evaluation: 2,2',6,6'-Tetrabromobisphenol A (TBBPA), which it domestically manufactures including for use in children's products. In 2012, Albemarle also reported importing triphenylphosphate (TPP), which is also currently undergoing TSCA risk evaluation. According to the 2016 CDR data, Albemarle also manufactures or imports decabromodiphenyl ether (DecaBDE), 1-bromopropane, and hexabromocyclododecane (HBCD) – each of which is now undergoing risk management under TSCA.

Albemarle advocated directly to the SACC on its peer review of 1-bromopropane, a chemical in which the company has a vested financial interest. Robert Miller, Jr., Senior Director, Global Product Stewardship at Albemarle, provided both oral¹⁸ and written¹⁹ comments to the SACC, citing the research conducted by Dr. Smith and colleagues described below.

Dr. Smith has played a key role in defending the chemical 1-bromopropane on behalf of Albemarle, downplaying its cancer risk and questioning the NTP 2-year cancer bioassay.

- In 2019, Dr. Smith and Dr. Thomas Perfetti – a frequent co-author of Dr. Smith's since their days together at RJ Reynolds Tobacco – published an article seeking to question use of the NTP 2-year rodent bioassay; the authors indicate that their focus on the NTP bioassay originated from an interest in 1-bromopropane.²⁰ Dr. Smith and Dr. Perfetti

¹⁸ See: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0235-0062>.

¹⁹ See: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0235-0029>.

²⁰ **Smith, C. J.** and Perfetti, T. A. (2019). Reconsidering the utility of the National Toxicology Program 2-year rodent cancer bioassay, *Toxicology Research and Application*, 3, 1-3, available at: <https://journals.sagepub.com/doi/full/10.1177/2397847319867476>. The first sentence of the paper states, “Our interest in understanding the 2-year rodent cancer bioassay data in the National Toxicology Program (NTP) database began as a limited inquiry as to why lung tumors were induced by 1-bromopropane via inhalation in only female mice and not in male mice, nor male and female rats.”

published a similar paper in 2018.²¹ Neither article discloses any conflicts of interest, despite Dr. Smith's employment by Albemarle.

- In 2015, Dr. Smith submitted a letter to California's Office of Environmental Health Hazard Assessment (OEHHA), asserting that 1-bromopropane may not be a genotoxic carcinogen.²²
- In 2011, Dr. Smith coauthored a Letter for the Editor of the *Journal of Occupational and Environmental Medicine*, questioning the findings of another study on workplace exposures to 1-bromopropane. The journal disclosed:

C.J.S. and T.S. are employed by Albemarle Corporation, a manufacturer of 1-bromopropane. M.B. has received honoraria totaling \$2000.00 in the past from Albemarle Corporation for his contribution on studies with brominated flame retardants. No form of remuneration was provided for his contribution herein. G.T.J., R.D.H., Y.Z., and R.V.L. have no financial interest in the content of this letter.

The biosketch provided by EPA conspicuously fails to mention Dr. Smith's long-term employment by the tobacco industry prior to his employment for Albemarle. Dr. Smith worked at RJ Reynolds Tobacco Company for several decades – and until at least 2004²³ – publishing widely to downplay the risks of smoking.²⁴ A 1994 RJ Reynolds Tobacco Company staff memo lauded Dr. Smith on his promotion, stating (emphases added):²⁵

One of the major things that Carr has been able to accomplish in the brief time he has worked with us is to initiate a program in the area of human cardiovascular disease. Carr has accepted the challenge to build this program and has made significant progress to reach his goal. *He has carefully reviewed the literature*

²¹ **Smith, C. J.** and Perfetti, T. A. (2018). The “false-positive” conundrum in the NTP 2-year rodent cancer study database, *Toxicology Research and Application*, 2, 1-13, available at:

<https://journals.sagepub.com/doi/full/10.1177/2397847319867476>.

²² See: <https://oehha.ca.gov/media/downloads/proposition-65/crn/comments/0904151bromopropanecomments.pdf>.

²³ See Dr. Smith's listed affiliation in Smith et al., 2004:

<https://www.sciencedirect.com/science/article/pii/S0278691503002333?via%3Dihub>.

²⁴ “Carr J. Smith – Major Accomplishments During 1999 (Revised 1/20/00).” UCSF Truth Tobacco Industry Documents. Retrieved October 28, 2020. Available at:

<https://www.industrydocuments.ucsf.edu/tobacco/docs/#id=kxbh0024>.

²⁵ “Promotion of Carr J. Smith, Ph.D.” UCSF Truth Tobacco Industry Documents. Retrieved October 28, 2020. Available at: <https://www.industrydocuments.ucsf.edu/tobacco/docs/#id=hnkf0077>.

and written several review articles on the relationship between smoking and cardiovascular disease. One major conclusion is that the cardiovascular risks of smoking and nicotine use have been grossly exaggerated by individuals outside the Company. These articles are being submitted for publication in peer reviewed journals. Additionally, *Carr has been actively involved in studies with smokers to support product development efforts.* Carr's depth of knowledge in human clinical studies is invaluable to all of us. He has been a *critical participant in our continuing efforts to bring scientific rigor to the question of the health effects of environmental tobacco smoke.* Carr was actively involved in responding to the EPA and he has a key role in *our current attempts to educate OSHA on the scientific facts.*

Just three years ago, in 2017, Dr. Smith presented the Tobacco Science Research Conference Lifetime Achievement Award to his longtime colleague and co-author Dr. Perfetti, demonstrating his continued close affiliation with the tobacco industry.²⁶

Given his current employment at Albemarle and longstanding affiliation with the tobacco industry, we believe that Dr. Smith has financial conflicts of interest and an appearance of a loss of impartiality with respect to TSCA chemical risk evaluations and related scientific issues.

Dr. Bryan D. Hardin

Dr. Bryan D. Hardin is a Vice President – Principal Toxicologist at J.S. Held LLC.

In this role, Dr. Hardin advocated to the SACC during its peer review of asbestos, submitting written comments.²⁷ While his comments failed to provide any financial disclosure, J.S. Held LLC has clients in both the construction and manufacturing industries,²⁸ and Dr. Hardin himself

²⁶ **Smith, C. J.** Dr Thomas A. Perfetti, Recipient of the 2017 Tobacco Science Research Conference Lifetime Achievement Award, *International/Contributions to Tobacco Research*, 27(8): 184-185, available at:

[https://content.sciendo.com/configurable/contentpage/journals\\$002fcttr\\$002f27\\$002f8\\$002farticle-p184.xml](https://content.sciendo.com/configurable/contentpage/journals$002fcttr$002f27$002f8$002farticle-p184.xml).

²⁷ See: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0501-0064>.

²⁸ For example, see: <https://jsheld.com/solutions/construction> and <https://jsheld.com/solutions/manufacturing>.

has served as an expert witness on behalf of various automakers and manufacturers involved in asbestos litigation (e.g., wrongful death suits).^{29, 30}

In fact, Dr. Hardin has a long history of failing to disclose financial conflicts of interest. For example, Dr. Hardin’s failure to disclose financial ties to companies involved in asbestos litigation was highlighted in a 2017 article titled, “What should journals do when peer reviewers do not disclose potential conflicts?” The article states (emphases added):³¹

Take this case: In a court transcript from Feb. 23, 2017, [Bryan Hardin](#) testified that he was a peer reviewer on a 2016 paper in *Critical Reviews in Toxicology*, which found that asbestos does not increase the risk of cancer. In the deposition, Hardin—who works at the consulting firm [Veritox](#)—also said that he has testified in asbestos litigation on behalf of automakers, such as Ford, General Motors, and Chrysler, but said he had not disclosed these relationships to the journal. ...

We obtained a copy of the transcript from Christian Hartley, who was representing a man suing a mining company because the man developed cancer after being exposed to asbestos at work. When Hartley asked Hardin whether he had told the journal about testifying for companies involved in asbestos litigation, Hardin responded:

No. If — if that’s a new expectation, I’m not aware that as a peer reviewer you’re supposed to disclose that sort of thing, but I — I don’t recall that I did.

When we asked Hardin to confirm whether he had reviewed the 2016 paper and had disclosed his industry relationships to the journal, Hardin responded “*I have been a peer reviewer on more than one asbestos-related paper*” and “*I have been retained by ‘several’ companies involved in asbestos litigation.*”

This was not the first time that Dr. Hardin has been publicly accused of failing to disclose critical conflicts of interest. A 2007 *Wall Street Journal* article, “Amid Suits Over Mold, Experts Wear Two Hats,” detailed Dr. Hardin’s participation in developing a position paper of the American College of Occupational and Environmental Medicine (ACOEM) that became a “key defense

²⁹ “Years of exposure to asbestos caused painful death: estate,” Verdict Search. Available at: <https://verdictsearch.com/verdict/years-of-exposure-to-asbestos-caused-painful-death-estate/>.

³⁰ *Gayoso v. Am. Honda Motor Co. (In re N.Y.C. Asbestos Litig.)*, 2019 N.Y. Slip Op. 31184 (N.Y. Sup. Ct. 2019). Available at: <https://casetext.com/case/gayoso-v-am-honda-motor-co-in-re-nyc-asbestos-litig>.

³¹ “What should journals do when peer reviewers do not disclose potential conflicts?” Retraction Watch. Available at: <https://retractionwatch.com/2017/08/15/journals-peer-reviewers-not-disclose-potential-conflicts/>.

tool wielded by builders, landlords and insurers in litigation,” while failing to disclose his conflicts. With respect to Dr. Hardin, the WSJ article states (emphases added):³²

Bryan Hardin, says he hadn't worked on any mold lawsuit at that point, though he was a consultant on other matters for GlobalTox Inc., a firm that regularly worked for the defense in mold cases. *And Dr. Hardin says he consulted for the defense in a mold case while he was helping write the ACOEM paper.*

In a Feb. 27, 2002, email, Dr. [Jonathan] Borak [another paid consultant] told Dr. Hardin: "That position paper would be prepared by you and your GlobalTox colleagues." Dr. Borak says he believes he didn't know at the time that GlobalTox did mold defense work.

A GlobalTox colleague who aided Dr. Hardin was Bruce Kelman, now president of the firm, which recently changed its name to Veritox Inc. *Drs. Kelman and Hardin, now principals at the firm and entitled to a share of its profits, were two of the ACOEM paper's three authors. They are paid \$375 to \$500 an hour for work on mold cases, court records say.*

A 2007 Special Contribution in the *International Journal of Occupation and Environmental Health* further details the controversial ACOEM statement and Dr. Hardin's conflicted role.³³

In the early 2000s, Dr. Hardin published several papers on trichloroethylene (TCE), arguing that the chemical does not have teratogenic effects. While Dr. Hardin asserts he had not received funding from the chemical industry for this work, his track record of lack of disclosure calls this into question. His co-authors on two of the papers (“Trichloroethylene and dichloroethylene: A critical review of teratogenicity”³⁴ and “Trichloroethylene and Cardiac Malformations”³⁵) indicated they had conflicts; both articles include the following conflict of interest statement:

B.D.H. has had no consulting relationships involving trichloroethylene (TCE) or dichloroethylene. B.J.K. provided testimony as a defense expert in TCE litigation

³² Armstrong, David. “Amid Suits Over Mold, Experts Wear Two Hats.” The Wall Street Journal. January 9, 2007. Available at: <https://www.wsj.com/articles/SB116831654647871083>.

³³ Ladou, J., et al. (2007). American College of Occupational and Environmental Medicine (ACOEM): A Professional Association in Service to Industry, *Int J Occup Environ Health*, 13:404-426, available at: https://www.survivingmold.com/docs/Resources/ACOEM/IJOEH_Oct07_LaDou.pdf.

¹¹¹ **Hardin, B. D.**, Kelman, B. J., and Brent, R. L. (2005). Trichloroethylene and dichloroethylene: A critical review of teratogenicity, *Birth Defects Research*, 73(12): 931-955, available at: <https://onlinelibrary.wiley.com/doi/abs/10.1002/bdra.20192>.

³⁵ **Hardin, B. D.**, Kelman, B. J., and Brent, R. L. (2004). Trichloroethylene and Cardiac Malformations, *Environ Health Perspect*, 112(11): A607-A608, available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1247505/>.

pertaining to congenital malformations. R.L.B. provided testimony in 1995 and 1997 as a defense expert in TCE litigation pertaining to congenital malformations of the heart.

These papers have subsequently been cited by the Halogenated Solvents Industry Alliance (HSIA) and others representing companies making or using TCE. For example, HSIA referenced these papers in its comments to EPA on the TSCA section 6 proposed rule to ban high-risk uses of TCE³⁶ as well as in its most recent comments to the SACC on the draft TCE risk evaluation.³⁷

Given Dr. Hardin's direct advocacy before the SACC, his industry employment, and his long track record of failing to disclose relevant financial conflicts, we believe he has financial conflicts of interest and an appearance of a loss of impartiality with respect to TSCA chemical risk evaluations and related scientific issues.

Dr. Laura M. Plunkett

Dr. Plunkett is a Partner at BioPolicy Solutions, LLC. Prior to this role, she was the President of Integrative Biostrategies, LLC (2001 – June 2020).

Dr. Plunkett has close ties to ACC, for which she has directly consulted.³⁸ She also regularly publishes studies funded by ACC along with co-authors from ACC and ACC chemical company members (e.g., DuPont), and has received direct funding from ACC for this work. For example:

- In 2016, Dr. Plunkett co-authored a study arguing that a number of rodent cancer endpoints are not likely relevant to humans. The linked “Transparency Document” makes clear that she received 1) personal fees from ACC for her work on the study, and 2) personal fees from AMVAC Chemical Corporation, Balchem Corporation, ADAMA, and other organizations in the 36 months prior to publication.³⁹
- In 2015, Dr. Plunkett co-authored a study with Dr. Richard Becker, who is employed by ACC. The Disclosure states (emphasis added): “L. Plunkett and A.M. Kaplan received

³⁶ See HSIA comments: <https://hsia.org/wp-content/uploads/2018/07/HSIA-TCE-Aerosol-Spot-Cleaning-Comments.pdf>.

³⁷ See: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0500-0094>.

³⁸ “Laura Plunkett,” Science 2.0. Available at: https://www.science20.com/profile/laura_plunkett.

³⁹ Cox, L. A., Popken, D. A., Kaplan, A. M., **Plunkett, L. M.**, and Becker, R. A. (2016). How well can *in vitro* data predict *in vivo* effects of chemicals? Rodent carcinogenicity as a case study, *Regulatory Toxicology and Pharmacology*, 77: 54-64, available at: <https://www.sciencedirect.com/science/article/pii/S0273230016300289>.

funding to support this research from the *American Chemistry Council (ACC)*. R Becker is employed by ACC, a trade association of U. S. chemical manufacturers.”⁴⁰

- In 2007, Dr. Plunkett co-authored a study with employees of ACC and DuPont. The Acknowledgements states (emphasis added): “Funding for portions of this study was provided by the *American Chemistry Council*.”⁴¹

Dr. Plunkett has also blogged on the heavily industry-leaning science20.com on issues of chemical safety, articulating industry talking points. For example, in 2014, she published a blog post titled, “There Is No Pandemic Of Chemicals Causing Brain Disorders In Children,”⁴² seeking to refute conclusions in a landmark Lancet study conducted by Dr. Philippe Grandjean and Dr. Philip J. Landrigan. Dr. Plunkett also submitted a Correspondence to the Lancet criticizing the study; while it is not clear whether or by whom Dr. Plunkett was paid for this work, she does disclose (emphasis added): “I am an independent scientific consultant, and have served as a consultant on toxicology and risk assessment issues to the *American Chemistry Council*, a trade organisation that represents chemical manufacturers.”⁴³ Other frequent science20.com contributors include a number of ACC employees.⁴⁴

Dr. Plunkett has also provided testimony in numerous product liability litigations,⁴⁵ and, remarkably, her testimony has been rejected by at least two federal courts. Specifically, two federal court judges have excluded her testimony or opinions based on lack of scientific rigor.

⁴⁰ **Plunkett, L. M.**, Kaplan, A. M., and Becker, R. A. (2015). Challenges in using the ToxRefDB as a resource for toxicity prediction modeling, *Regulatory Toxicology and Pharmacology*, 72(3): 610-614, available at: <https://www.sciencedirect.com/science/article/pii/S0273230015001129?via%3Dihub>

⁴¹ Becker, R. A., **Plunkett, L. M.**, Borzelleca, J. F., and Kaplan, A. M. (2007). Tiered toxicity testing: Evaluation of toxicity-based decision triggers for human health hazard characterization, *Food and Chemical Toxicology*, 45(12): 2454-2468, available at: <https://www.sciencedirect.com/science/article/pii/S0278691507002128?via%3Dihub>.

⁴² **Plunkett, Laura**. “There Is No Pandemic of Chemicals Causing Brain Disorders In Children,” Science 2.0. February 18, 2014. Available at: https://www.science20.com/laura_plunkett/there_no_pandemic_chemicals_causing_brain_disorders_children-129838.

⁴³ **Plunkett, L. M.** (2007). Developmental neurotoxicity of industrial chemicals, The Lancet: Correspondence, 369(9564): P821, available at: [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(07\)60396-1/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(07)60396-1/fulltext).

⁴⁴ See: <https://www.science20.com/contributors>.

⁴⁵ See, for example: https://www.govinfo.gov/content/pkg/USCOURTS-almd-2_15-cv-00553/pdf/USCOURTS-almd-2_15-cv-00553-2.pdf; <https://www.docketbird.com/court-documents/Johnson-Johnson-Talcum-Powder-Products-Marketing-Sales-Practices-and-Products-Liability-Litigation/Exhibit-1/njd-3:2016-md-02738-09885-003>; and <https://aboutlawsuits-wpengine.netdna-ssl.com/wp-content/uploads/2018-10-24-Order.pdf>.

One judge concluded her opinion was unreliable because it “exceeds the boundaries of the sources she relies on by going beyond what the sources concluded” and another judge held that her opinions were “beset by methodological deficiencies” and thus inadmissible in court.⁴⁶

Given Dr. Plunkett’s close affiliation with and financial ties to ACC and chemical companies as well as her history of having her testimony rejected in courts of law, we believe she has financial conflicts of interest and an appearance of a loss of impartiality with respect to TSCA chemical risk evaluations and related scientific issues.

Dr. Julie Goodman

Dr. Julie Goodman is a Principal at Gradient, an environmental and risk sciences firm with extensive contracts with industry clients all along the chemical supply chain.

For her work, Dr. Goodman has received funding from companies that have a financial interest in chemicals that are or could be under review by EPA. For example, Dr. Goodman has received extensive industry funding for her work on health impacts from asbestos, which has led to

⁴⁶ For the relevant cases, see: “Federal court: Expert’s testimony doomed by misuse of data,” Daily Journal, June 8, 2020, available at: <https://www.dailyjournal.com/articles/357985>.

numerous publications,^{47,48,49,50} presentations,⁵¹ and litigation support.^{52,53} Further, Dr. Goodman submitted written comments to the SACC on its peer review of asbestos;⁵⁴ remarkably, in light of this history, Dr. Goodman's comments assert they were developed "with no financial support."

Beyond specific chemical reviews, Dr. Goodman has published manuscripts addressing critical aspects of risk assessment and systematic review that were funded by companies with a vested interest in how TSCA risk evaluations are conducted. For example, Goodman was first author of a manuscript criticizing chemical hazard assessment practices of the internationally renowned International Agency for Research on Cancer (IARC) – critiques broadly relevant to chemical hazard and risk evaluations.⁵⁵ The publication was co-authored and funded by ACC.

⁴⁷ Comment on "Exposure-response modeling of non-cancer effects in humans exposed to Libby Amphibole Asbestos; update" by Benson et al. (2015) <https://www.sciencedirect.com/science/article/pii/S0273230016301283?via%3Dihub> (Funding provided by W.R. Grace & Co, a company that made asbestos-containing products and owned vermiculite mine in Libby, MO that was contaminated with asbestos).

⁴⁸ Pleural plaques and lung function in the Marysville worker cohort: a re-analysis <https://www.tandfonline.com/doi/full/10.1080/08958378.2016.1210704?scroll=top&needAccess=true> (Funding provided by W.R. Grace & Co.)

⁴⁹ Systematic review of pleural plaques and lung function <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4364260/> (Funding provided by W.R. Grace & Co.)

⁵⁰ Comment on "A systematic review of the association between pleural plaques and changes in lung function" by Kopylev et al (2014) <https://oem.bmj.com/content/72/9/684.1.long> (Funding provided by W.R. Grace & Co.)

⁵¹ Comment on "HRCT/CT and Associated Spirometric Effects of Low Libby Amphibole Asbestos Exposure" by Lockey et al (2015) https://journals.lww.com/joem/Fulltext/2015/07000/Comment_on_HRCT_CT_and_Associated_Spirometric.25.aspx (Funding provided by W.R. Grace & Co.)

⁵² Chronic inflammation, Adverse Outcome Pathways, and risk assessment: A diagrammatic exposition <https://pubmed.ncbi.nlm.nih.gov/32330641/> Conflict of Interest Statement notes "Dr. Goodman has served as an expert in multiple litigation matters involving asbestos-containing products."

⁵³ Pleural plaques and lung function in the Marysville worker cohort: a re-analysis. The Declaration of Interest notes "Dr. Goodman has served as an expert witness on cases involving chrysotile asbestos and cancer risk and has received funding from Tucker Ellis & West LLP for the preparation of scientific manuscripts regarding radiation, mesothelioma and lung cancer." <https://www.tandfonline.com/doi/full/10.1080/08958378.2016.1210704?scroll=top&needAccess=true>

⁵⁴ See: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0501-0032>.

⁵⁵ Recommendations for further revisions to improve the International Agency for Research on Cancer (IARC) Monograph program <https://www.sciencedirect.com/science/article/pii/S0273230020300659> (Funding provided by ACC).

Another example is a publication⁵⁶ Goodman co-authored arguing against using linear low-dose extrapolation for noncancerous effects – in contrast to recommendations of the National Academies.⁵⁷ This publication included a co-author from Dow Chemical Company and was funded by ACC. These are but two of a number of Goodman’s publications funded by the chemical industry that review and make recommendations related to risk assessment.^{58,59,60,61,62}

Dr. Goodman has also published work on environmental pollutants outside the purview of TSCA for private entities that have a vested interest in chemical assessment activities occurring under

⁵⁶ Linear low-dose extrapolation for noncancer health effects is the exception, not the rule, 2011, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3038594/> (Funding provided by ACC).

⁵⁷ <https://www.nap.edu/catalog/12209/science-and-decisions-advancing-risk-assessment>

⁵⁸ Letter to the editor re: Guyton et al. (2018), “Application of the key characteristics of carcinogens in cancer hazard identification”: <https://academic.oup.com/carcin/article/39/8/1089/5048109> (Funding provided by ACC).

⁵⁹ Improving the International Agency for Research on Cancer’s consideration of mechanistic evidence <https://www.sciencedirect.com/science/article/pii/S0041008X17300479#ac0005> (Funding provided by ACC)

⁶⁰ More clarity needed in the Navigation Guide systematic review framework <https://europepmc.org/article/med/28222917> (Funding provided by ACC, ACC co-authored)

⁶¹ Systematic Comparison of Study Quality Criteria <https://www.sciencedirect.com/science/article/pii/S0273230015301525?via%3Dihub#ack0010> (Funding provided by ACC)

⁶² Critical Comments on the WHO-UNEP State of the Science of Endocrine Disrupting Chemicals <https://www.sciencedirect.com/science/article/pii/S0273230014000269> (Funding provided by American Chemistry Council (ACC), CropLife America (CLA), CropLife Canada (CLS), CropLife International (CLI), European Chemical Industry Council (Cefic), and European Crop Protection Association (ECPA)).

TSCA. For example, she has received extensive funding from the American Petroleum Institute and Exxon Mobil for research on air pollutants and various health outcomes.^{63,64,65,66,67,68,69}

Dr. Goodman's notoriety as a scientist hired by companies and trade associations to advocate on behalf of their financial interests was featured in an investigative article by the Center for Public Integrity (CPI).⁷⁰ In this article, CPI describe many of Gradient's chemical industry-funded projects, including those led or co-led by Dr. Goodman, noting the poor scientific merits of Gradient's work. Below are some relevant excerpts taken directly from the article:

- “A group of academic researchers were so outraged by an article on BPA [bisphenol A] written by Gradient's Julie Goodman and Lorenz Rhomberg that they wrote a lengthy response with a table listing all the ‘false statements’ in it.”
- “Gradient's Goodman wrote a lengthy public comment in 2014 paid for by a maker of n-propyl bromide. In it, Goodman argued that a government study showing high rates of cancer among rats exposed to the chemical had no relevance for humans.” [Note this study was conducted by the authoritative U.S. interagency National Toxicology

⁶³ Impact of respiratory infections, outdoor pollen, and socioeconomic status on associations between air pollutants and pediatric asthma hospital admissions. <https://pubmed.ncbi.nlm.nih.gov/28719626/> (Funding provided by Exxon Mobil)

⁶⁴ Do individuals with asthma experience airway hyper-responsiveness after exposure to nitrogen dioxide? <https://www.sciencedirect.com/science/article/pii/S0273230017302179?via%3Dihub#ack0010> (Funding provided by the American Petroleum Institute)

⁶⁵ Applying Nonparametric Methods to Analyses of Short-Term Fine Particulate Matter Exposure and Hospital Admissions for Cardiovascular Diseases among Older Adults <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5615588/> (Funding provided by American Petroleum Institute)

⁶⁶ Evaluation of neural reflex activation as a mode of action for the acute respiratory effects of ozone. <https://www.tandfonline.com/doi/full/10.1080/08958378.2016.1213332> (Funding provided by Exxon Mobil)

⁶⁷ Weight-of-evidence evaluation of associations between particulate matter exposure and biomarkers of lung cancer <https://www.sciencedirect.com/science/article/pii/S0273230016302951> (funding provided by Exxon Mobil)

⁶⁸ Do group responses mask the effects of air pollutants on potentially sensitive individuals in controlled human exposure studies? <https://www.sciencedirect.com/science/article/pii/S0273230015000203> (funding provided by the American Petroleum Institute)

⁶⁹ Providing perspective for interpreting cardiovascular mortality risks associated with ozone exposures. <https://pubmed.ncbi.nlm.nih.gov/25817736/> (funding provided by the American Petroleum Institute)

⁷⁰ Meet the Rented White Coats who Defend Toxic Chemicals <https://publicintegrity.org/environment/meet-the-rented-white-coats-who-defend-toxic-chemicals/>.

Program⁷¹ and n-propyl bromide is one of the first 10 chemicals to undergo risk evaluation under TSCA.]

- “In congressional testimony in 2012, Goodman accused the EPA of being biased by giving too much weight to the Harvard and American Cancer Society studies while ignoring ‘dozens of other epidemiology studies,’ including many that found no health problems caused by current levels of air pollution. In her testimony, Goodman cited only six studies that she said show no harmful effects from soot. But two of those studies were funded by industry. And authors of the other four say their findings supports those of the Six Cities Study. ‘It would be wrong for her to say that we didn’t find an effect,’ said Dr. Bill McDonnell, a former EPA scientist whose work was cited by Goodman. ‘We did find a relationship. It just seems like you can just make up your own facts now.’”
- “Goodman has criticized a U.S.-government-funded study led by a group of public-health scientists at the University of California, Berkeley. The study explored whether smog was linked to deaths.... In a 2011 letter published in *Environmental Health Perspectives*, Goodman described the work as ‘an uncorroborated study that likely misinterpreted the findings regarding ozone effects.’ Jerrett was not given the opportunity to respond. ‘I felt that that letter was not following the normal conventions that we would use for scientific debate in the literature,’ he said. The ozone study was published in 2009 in the venerable *New England Journal of Medicine*. Jerrett said it went through two rounds of peer review with more than 50 pages of questions and another 40 pages of responses. ‘I don’t think we’ve misinterpreted the findings at all,’ he said.”
- “Goodman continues to testify in mesothelioma lawsuits and write articles exonerating asbestos. Citing other industry-funded research, she wrote in 2013 that the most common form of asbestos — chrysotile — wasn’t responsible for higher rates of mesothelioma and lung cancer in electricians.....In 2012, the International Agency for Research on Cancer, part of the World Health Organization, concluded that all forms of asbestos cause mesothelioma. That same year, a coalition of nine epidemiological organizations issued a joint statement calling for a worldwide ban of asbestos.”

Given Dr. Goodman’s close affiliation with and financial ties to chemical companies and ACC and other trade associations, we believe she has financial conflicts of interest and an appearance of a loss of impartiality with respect to TSCA chemical risk evaluations and related scientific issues.

⁷¹ NTP TECHNICAL REPORT ON THE TOXICOLOGY AND CARCINOGENESIS STUDIES OF 1-BROMOPROPANE (CAS NO. 106-94-5) IN F344/N RATS AND B6C3F1 MICE (INHALATION STUDIES) https://ntp.niehs.nih.gov/ntp/htdocs/lt_rpts/tr564.pdf.

Dr. Richard B. Belzer

Dr. Belzer is a consultant specializing in regulation, risk, economics, and information quality. His educational background and training were focused on economics and public policy, and he has published widely on regulatory impact and cost-effectiveness. While these topics may be relevant to some aspects of chemical regulation, they do not meet the needs of the SACC, as specified both in TSCA and by EPA on its SACC website; the Agency specifically identifies its need for experts in:

- *toxicology;*
- *environmental risk assessment;*
- *exposure assessment; and*
- *related sciences, e.g., synthetic biology, pharmacology, biotechnology, nanotechnology, biochemistry, biostatistics, PBPK modeling, computational toxicology, epidemiology, environmental fate, and environmental engineering and sustainability.*⁷²

Dr. Belzer does not have the appropriate expertise to serve as a SACC member, given the important role of this committee in the scientific review of TSCA risk evaluations and related matters.

Beyond this mismatch in expertise, Dr. Belzer has an extensive history of paid work for industries and organizations with financial interests in the outcome of state and federal regulations. For example, in 2017, he was commissioned to develop comments on California's Proposed Maximum Contaminant Level (MCL) for 1,2,3-Trichloropropane (TCP) on behalf of the California Manufacturers & Technology Association (CMTA) and the ACC.⁷³ In 2013, he authored a report, "Costs and Benefits of a Hexavalent Chromium Drinking Water Standard in Willows and Dixon, California," on behalf of the California Water Service Company, which argued against the economic feasibility of drinking water treatment to reduce hexavalent chromium cancer risk.⁷⁴ He published work on naphthalene that was funded by the Electric Power Research Institute, the American Petroleum Institute, the Naphthalene Council, Inc., the Association of Railroads, the American Coke and Coal Chemicals Institute, the Asphalt Institute,

⁷² See: <https://www.epa.gov/tsca-peer-review/science-advisory-committee-chemicals-basic-information>.

⁷³ Public Comments on Proposed Maximum Contaminant Level (MCL) for 1,2,3 Trichloropropane (TCP) - "SBDDW-17-001". Available at:

https://www.cmta.net/multimedia/cmta_and_acc_comments_tcp_mcl.pdf.

⁷⁴ **Belzer, Richard B.** "Costs and Benefits of a Hexavalent Chromium Drinking Water Standard in Willows and Dixon, California." (2013). Available at:

http://www.rbbelzer.com/uploads/7/1/7/4/7174353/131206x_belzer_cr6_cba_for_willows_dixon.pdf.

and the National Petrochemical Refiners Association.⁷⁵ He also published work on decabromodiphenyl ether (decaBDE) – which is subject to a risk management rule EPA is developing under TSCA– funded by the industry group the Bromine Science and Environmental Forum.⁷⁶ Most recently, in 2019, he co-authored work on pulmonary function testing with Exxon Mobil Biomedical Sciences;⁷⁷ the funding source for this work was not disclosed.

Additionally, Dr. Belzer has recently submitted public comments on behalf of the George Washington University Regulatory Studies Center,^{78,79} whose invitation-only Regulation & Innovation Roundtable includes and is supported by the major industry groups ACC, American Petroleum Institute, National Association of Manufacturers, Chevron, Dow Chemical Company, ExxonMobil, and more.⁸⁰ In these and other public comments,^{81,82} he has repeatedly asserted that the potential costs of environmental health regulations exceed potential benefits.

Also of note, Dr. Belzer was involved in the Trump EPA’s failed efforts to rescind the glider truck provisions of the “Greenhouse Gas Emissions and Fuel Efficiency Standards for Medium- and Heavy-Duty Engines and Vehicles” rule. In a 2018 House Oversight Hearing, Dr. Belzer testified concerning work he conducted for Fitzgerald Glider Kits, LLC, as “a strawman Regulatory Impact Analysis” for EPA.⁸³ In an associated blog post, Dr. Belzer stated: “This strawman RIA should be sufficient to justify repealing the glider provisions.”⁸⁴ In December

⁷⁵ **Belzer, Richard B.**, et al. "The naphthalene state of the science symposium: Objectives, organization, structure, and charge." *Regulatory Toxicology and Pharmacology* 51.2 (2008): 1-5.

⁷⁶ Hays, Sean, **Richard Belzer**, and Richard Pleus. "New Information on Decabromodiphenyl Ether and How it Changes Our Interpretations of Risk." *Organohalogen Compounds* 66 (2004): 3800-3806.

⁷⁷ **Belzer, Richard B.**, and R. Jeffrey Lewis. "The Practical Significance of Measurement Error in Pulmonary Function Testing Conducted in Research Settings." *Risk Analysis* 39.10 (2019): 2316-2328.

⁷⁸ **Belzer RB**, 2018. "Public Interest Comment on The Food Safety and Inspection Service’s Proposed Rule: Egg Products Inspection Regulations," [George Washington University Regulatory Studies Center](#), June 12.

⁷⁹ Comments on [National Primary Drinking Water Regulations: Proposed Lead and Copper Rule Revisions; Notice of Proposed Rulemaking](#) (NPRM, Docket ID No.EPA-HQ-OW-2017-0300), George Washington University Regulatory Studies Center, January 12.

⁸⁰ “Support: GW Regulatory Studies Center.” <https://regulatorystudies.columbian.gwu.edu/support>

⁸¹ Comments on [Increasing Consistency and Transparency in Considering Costs and Benefits in the Rulemaking Process](#) (ANPRM; Docket ID No. EPA–HQ–OA–2018–0107), August 13, 2018

⁸² Comments on [National Primary Drinking Water Regulations: Proposed Lead and Copper Rule Revisions; Notice of Proposed Rulemaking](#) (NPRM, Docket ID No.EPA-HQ-OW-2017-0300), George Washington University Regulatory Studies Center, January 12.

⁸³ See: <https://science.house.gov/imo/media/doc/Belzer%20Testimony%2C%20Bio.pdf>.

⁸⁴ **Belzer, R.** “Regulatory Impact Analysis for Repeal of Emission Requirements for Glider Vehicles, Glider Engines, and Glider Kits.” May 15, 2018. Available at: <http://www.rbbelzer.com/blog/regulatory-impact-analysis-for-repeal-of-emission-requirements-for-glider-vehicles-glider-engines-and-glider-kits>.

2019, the EPA Inspector General ultimately determined that former Administrator Scott Pruitt failed to follow legal and public health safeguards in the proposed Glider Repeal rule.⁸⁵

Given his extensive financial relationships with industry as well as clear bias against health-protective regulations, we believe that Dr. Belzer has financial conflicts of interest and an appearance of a loss of impartiality with respect to TSCA chemical risk evaluations and related scientific issues.

Dr. Robert Budinsky

Dr. Robert Budinsky is a Science Leader at The Dow Chemical Company's ("Dow") Toxicology, Environmental Research and Consulting group.

According to the 2016 CDR data, Dow currently manufactures at least one of the 20 chemicals currently undergoing TSCA risk evaluation: 1,2-dichloropropane. In 2012, Dow also reported under the CDR manufacturing 1,3-butadiene; 1,1-dichloroethane; 1,2-dichloroethane; 1,1,2-trichloroethane; and methylene chloride – in addition to 1,2-dichloropropane. Based on EPA's 2016 CDR data, Dow also manufactured at least two of the first ten chemicals to undergo TSCA risk evaluations (carbon tetrachloride and hexabromocyclododecane); based on 2012 CDR data, Dow recently manufactured four more of the first ten chemicals (1-bromopropane, methylene chloride, tetrachloroethylene, and trichloroethylene). In late 2015, Dow sold some of its chlorinated solvents business to Olin Corporation.⁸⁶

In his role as a Science Leader at Dow, Dr. Budinsky advocated to the SACC by providing oral comment during its peer reviews of 1,4-dioxane, arguing that 1,4-dioxane should be regulated as a threshold carcinogen.⁸⁷ Dow produces bulk chemicals contaminated with 1,4-dioxane that are sold to processors in the cleaning market.⁸⁸ Further, Dow was sued by over two dozen New

⁸⁵ See: <https://www.epa.gov/office-inspector-general/report-epa-failed-develop-required-cost-and-benefit-analyses-and-assess-air>.

⁸⁶ "Olin Announces The Completion Of The Merger With Dow's Chlorine Products Businesses And Election Of New Directors," Cision PR Newswire. October 5, 2015. Available at: <https://www.prnewswire.com/news-releases/olin-announces-the-completion-of-the-merger-with-dows-chlorine-products-businesses-and-election-of-new-directors-300154156.html>.

⁸⁷ See: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0064>.

⁸⁸ "Low 1,4-Dioxane Levels of Dow Products," Dow. Retrieved on October 28, 2020. Available at: <https://www.dow.com/en-us/product-technology/pt-solvents-glycols/1-4-dioxane.html>.

York water authorities over 1,4-dioxane contamination of their water; in June, 2020, a New York federal judge ruled in favor of the water authorities.^{89,90,91}

Dr. Budinsky also signed up to provide oral comment on methylene chloride.⁹² While Dow was not identified as reporting manufacture of the chemical under the non-confidential version of the 2016 CDR, it appears that the company is still making, using or releasing the chemical based on a Cognitive Market Research report, “Global Dichloromethane (DCM) Market Report 2020”⁹³ and based on 2019 TRI reporting indicating that Dow sites in Midland, Michigan⁹⁴ and Plaquemine, Louisiana released methylene chloride (163,456 pounds and 4,491 pounds, respectively).⁹⁵

Thus, Dow has a clear vested interest in the outcome of both of these EPA TSCA risk evaluations and related scientific issues.

Dr. Budinsky has also played an integral role in downplaying the risks of TCE in order to directly impact EPA’s science and decision-making under TSCA.

- Dr. Budinsky is a co-author of the DeSesso, et al. 2019 study on TCE conducted by Charles River Laboratories sponsored by the ACC and HSIA.⁹⁶ The study was cited by

⁸⁹ Chawage, Peter. “1,4-Dioxane Contamination Lawsuits Are Piling Up In Long Island,” Water Online. October 29, 2019. Available at: <https://www.wateronline.com/doc/dioxane-contamination-lawsuits-are-piling-up-in-long-island-0001>.

⁹⁰ Adams, Mike. “Water District Receives \$4.48 Million Grant To Filter 1,4-Dioxane,” The Roslyn News. January 15, 2020. Available at: <https://roslyn-news.com/water-district-receives-4-48-million-grant-to-filter-14-dioxane/>.

⁹¹ “Dow Chemical, Others Must Face 24 Contaminated Water Suits,” Law360. June 5, 2020. Available at: <https://www.law360.com/articles/1280456/dow-chemical-others-must-face-24-contaminated-water-suits>.

⁹² See: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0437-0080>. It appears that Dr. Budinsky may not have showed up for comment based on the meeting’s transcript: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0437-0078>.

⁹³ “Global Dichloromethane (DCM) Market Report 2020,” Cognitive Market Research. January 15, 2020. Available at: https://www.cognitivemarketresearch.com/chemical-%26-materials/dichloromethane-%28dcm%29-market-report#download_report.

⁹⁴ See: <https://echo.epa.gov/detailed-facility-report?fid=110043787408>.

⁹⁵ See: <https://echo.epa.gov/trends/loading-tool/water-pollution-search/tri-results/?s=aa054a90132972a1606bbb47b8a35041612e3886>.

⁹⁶ Coder, P. S. (2019) Final Report. An Oral (Drinking Water) Study of the Effects of Trichloroethylene (TCE) on Fetal Heart Development in Sprague Dawley Rats. Charles River Laboratories, Laboratory Project ID 00459506. <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0737-0120>.

HSIA,⁹⁷ ACC,⁹⁸ and Exponent (in work done on behalf of ACC and HSIA)⁹⁹ in their comments to the SACC during its peer review of the TCE draft risk evaluation, in seeking to refute the evidence for TCE-induced congenital heart defects and EPA's use of the Johnson et al. 2003 study as a basis for the reference dose. The study's Conflict of Interest statement reads:

Dr. Pottenger is retired from the Olin Corporation, a member company of HSIA and a producer of TCE. Dr. Bevan is the Director, Scientific Programs at HSIA and was formerly a consultant to Westlake Chemical Company, a member of HSIA. Dr. Budinsky is an employee of The Dow Chemical Company, a member company of HSIA. The employer of Drs. Bus and DeSesso, Exponent, Inc., has contracts with HSIA. Dr. York is a consultant to HSIA. Drs. Coder and Sen and Ms. Lucarell are employees of Charles River Laboratories Ashland, the contract research organization that performed the research.

In response to DeSesso et al. 2019, Runyan et al. – experts in developmental toxicology and cardiac malformations – published a letter to the editor detailing the flaws in DeSesso et al. 2019.¹⁰⁰ With the study's co-authors, Dr. Budinsky subsequently published a response to Runyan et al. 2019, further asserting the absence of sufficient evidence for TCE-induced cardiac malformations.¹⁰¹

- Prior to this, Dr. Budinsky directly participated in an industry-funded study which appears to have been designed to rebut EPA's 2014 TCE Work Plan Risk Assessment.

In October 2018, Dr. Budinsky coauthored a study on TCE, Zhang et al., funded by HSIA.¹⁰² The intent of this study appears to be to downplay the potential carcinogenicity of TCE, in which Dow and employers of the other authors have a vested financial interest. The conflict of interest statement in the study states:

⁹⁷ See: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0500-0094>.

⁹⁸ See: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0500-0103> and <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0500-0051>.

⁹⁹ See: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0500-0048>.

¹⁰⁰ Runyan, R.B., Selmin, O.I., Smith, S.M. and Freeman, J.L. (2019), Letter to the Editor. *Birth Defects Research*, 111: 1234-1236. doi:10.1002/bdr2.1573.

¹⁰¹ DeSesso, J. M., Coder, P. S., York, R. G., **Budinsky, R. A.**, et al. (2019). Response to the comments of Runyan et al. on "Trichloroethylene in drinking water throughout gestation did not produce congenital heart defects in Sprague Dawley rats," *Birth Defects Research: Correspondence*, 111(16): 1237-1239, available at: <https://onlinelibrary.wiley.com/doi/full/10.1002/bdr2.1577>.

¹⁰² Zhang, F., Marty, S., **Budinsky, R.**, Bartels, M., Pottenger, L. H., Bus, J., Bevan, C. Erskine, T., Clark, A., Holzheuer, B., and Markham, D. (2018). Analytical methods impact estimates of trichloroethylene's glutathione conjugation and risk assessment, *Toxicology Letters*, 296, 82-94. Available: <https://www.sciencedirect.com/science/article/pii/S0378427418314905?via%3Dihub>.

Drs. Zhang, Budinsky, Bartels, Marty and Mr. Erskine, Ms. Clark, Mr. Holzheuer, and Mr. Markham are all employees of The Dow Chemical Company, a member company of HSIA. Dr. Pottenger is retired from the Olin Corporation, a member company of HSIA and a producer of TCE. Dr. Bevan was a paid consultant to Westlake Chemical Company, a member company of HSIA and a producer of TCE and is currently the Science Director of HSIA. The employer of Dr. Bus, Exponent, Inc., has contracts with HSIA and The Dow Chemical Company.

In May 2017, HSIA submitted a letter to EPA requesting that it revise its TCE Work Plan Risk Assessment (a second request the association sent to EPA after receiving a denial in 2016).¹⁰³ In support, HSIA cites the abstract of another paper that appears to have arisen from the same underlying HSIA-funded study, based on the similarity in content and authorship (which again includes Dr. Budinsky).¹⁰⁴

- Dr. Budinsky has also received industry funding to work on bisphenol A (BPA). In 2015, Dr. Budinsky co-authored a study on BPA funded by the Polycarbonate/BPA Global Group of ACC.¹⁰⁵ While BPA is not currently undergoing TSCA risk evaluation, it is on the 2014 TSCA Work Plan and so is likely to be assessed under TSCA in the coming years.

Finally, Dr. Budinsky's biosketch provided by EPA further illustrates that a key aspect of his role at Dow is precisely to influence TSCA risk evaluations and regulations:

- "He currently leads Dow's Global Chemicals and Health issues teams responsible for regulatory initiatives in the United States, Europe, Asia Pacific and Latin America,

¹⁰³ May 26, 2017 letter from HSIA to EPA. Available here:

https://www.epa.gov/sites/production/files/2017-06/documents/request_for_reconsideration.pdf.

¹⁰⁴ *Id.* at Appendix 3. Abstract and authors listed: Comparison of Liquid Chromatography-Ultraviolet and Liquid Chromatography-Positive Electrospray Tandem Mass Spectrometry Quantitative Analysis of the Major Glutathione Conjugate Biomarkers of Trichloroethylene: Dichlorovinyl Cysteine and Dichlorovinyl Glutathione. Fagen Zhang, Sue Marty, **Robert Budinsky**, Michael Bartels, Lynn H. Pottenger, James Bus, Chris Bevan, Tim Erskine, Amy Clark, Brian Holzheuer, Dan Markham

¹⁰⁵ Buscher, B., van de Lagemaat, D., Gries, W., Beyer, D., Markham, D.A., **Budinsky, R.A.**, Dinmond, S. S., Nath, R.V., Snyder, S.A., and Hentges. (2015). Quantitative analysis of unconjugated and total bisphenol A in human urine using solid-phase extraction and UPLC-MS/MS: Method implementation, method qualification and troubleshooting, *Journal of Chromatography B*, 1005(15): 30-38. Available: <https://www.sciencedirect.com/science/article/pii/S1570023215301951?via%3Dihub>.

including working with U.S. Environmental Protection Agency's (EPA) Toxic Substances Control Act (TSCA) program..."

- "Dr. Budinsky has served as a toxicology consultant to numerous Dow businesses engaged in the production of biocides, glycol ethers, vinyl acetate, *1,3-butadiene*, *bisphenol A* and *epoxy materials*, for example." (Emphases identify chemicals on the 2014 TSCA Work Plan.)
- "He has been directly involved with two of the first 10 TSCA risk evaluations and is familiar with the TSCA prioritization and risk evaluation steps..."

Given Dr. Budinsky's employment at Dow and his direct advocacy to the SACC, we believe that Dr. Budinsky has financial conflicts of interest and an appearance of a loss of impartiality with respect TSCA chemical risk evaluations and related scientific issues.

Mark A. Maddaloni

Dr. Maddaloni is Senior Managing Health Scientist at Cardno ChemRisk.

Cardno ChemRisk is a consulting firm that was formed through the merger of Cardno and ChemRisk in 2012. These companies have an extensive history of providing consulting services to major users and producers of chemicals, including Johnson & Johnson, John Crane Group, Ford Motor Company, and Union Carbide. The firm also frequently represents companies in lawsuits related to chemical use and contamination, including Pacific Gas and Electric Company in a lawsuit for Hexavalent chromium groundwater contamination; BP for the 2010 Deepwater Horizon oil spill; and DuPont in relation to chemicals released from one of its plants during Hurricane Katrina.^{106,107,108,109}

Scientists at Cardno ChemRisk regularly publish papers financially supported by industrial users and producers of chemicals, including those that could be under review by the SACC. A few of

¹⁰⁶ "ChemRisk." <https://en.wikipedia.org/wiki/ChemRisk>.

¹⁰⁷ Meier, Barry (11 October 2015). "Science Consultant Pushes Back Against Unlikely Opponents". *The New York Times*. Retrieved August 12, 2020. Available at: <https://www.nytimes.com/2015/10/12/business/energy-environment/years-after-criticism-of-its-practices-science-consultant-pushes-back.html?smid=pl-share>.

¹⁰⁸ Foytlin, Cherri (14 October 2013). "ChemRisk, BP and Purple Strategies: A Tangled Web of Not-So-Independent Science". Huffington Post. Retrieved August 12, 2020. Available at: https://www.huffpost.com/entry/chemrisk-bp-and-purple-st_b_4095131.

¹⁰⁹ "How industry scientists stalled action on carcinogen – Center for Public Integrity". Retrieved August 12, 2020. Available at: <https://publicintegrity.org/environment/how-industry-scientists-stalled-action-on-carcinogen/>.

the many examples include publications supported by ANGUS chemical,¹¹⁰ Chaz Dean,^{111,112} the Foundation for Chemistry Research and Initiatives (established by ACC and affiliated with the Chlorine Chemistry Foundation, the mission of which is to advocate for “the benefits of the element chlorine”¹¹³), and the Electric Power Research Institute.¹¹⁴

Further, Cardno ChemRisk advocated to the SACC on its peer reviews of three chemicals, including directly on behalf of the chemical industry for at least two:

- 1) Four Cardno ChemRisk employees submitted written comments on the asbestos risk evaluation and one provided oral comment.¹¹⁵
- 2) A Cardno ChemRisk Senior Principal Health Scientist submitted written comments on the draft methylene chloride risk evaluation “on behalf of, and in part financially supported by, the Halogenated Solvents Industry Alliance (HSIA).”¹¹⁶ He also provided oral comments directly to the SACC, stating that “My time and travel are financially supported by the Halogenated Solvents Industry Alliance.”¹¹⁷ A Senior Managing Health Scientist with Cardno ChemRisk submitted another set of written comments, “[w]ith support and on behalf of the Halogenated Solvents Industry Alliance (HSIA).”¹¹⁸ HSIA, a trade organization that represents manufacturers of methylene chloride, in turn referenced Cardno ChemRisk’s comments in its own comments to the agency.¹¹⁹
- 3) A Senior Managing Health Scientist with Cardno ChemRisk provided oral comments to the SACC and submitted written comments on the draft perchloroethylene risk evaluation that were provided “[w]ith support and on behalf of the Halogenated Solvents Industry Alliance (HSIA).”¹²⁰ HSIA, which also represents manufacturers of

¹¹⁰ Gadagbui, Bernard, et al. "Derivation of cancer no significant risk levels and screening safety assessment for 2-nitropropane in spray products." *Journal of Applied Toxicology* 40.5 (2020): 691-705.

¹¹¹ Towle, Kevin M., et al. "Risk assessment of the skin sensitization induction potential of Kathon CG in rinse-off and leave-on personal care and cosmetic products." *Dermatitis* 29.3 (2018): 132-138.

¹¹² Drechsel, Derek A., et al. "Skin sensitization induction potential from daily exposure to fragrances in personal care products." *Dermatitis* 29.6 (2018): 324-331.

¹¹³ See: <https://foundationforchemistry.org/about/>.

¹¹⁴ Checkoway, Harvey, et al. "Peak Exposures in Epidemiologic Studies and Cancer Risks: Considerations for Regulatory Risk Assessment." *Risk Analysis* 39.7 (2019): 1441-1464.

¹¹⁵ See: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0501-0090>.

¹¹⁶ See: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0437-0046>.

¹¹⁷ See: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0437-0078>.

¹¹⁸ See: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0437-0045>.

¹¹⁹ See: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0437-0067>.

¹²⁰ See: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0502-0027>.

perchloroethylene, in turn referenced these comments in its own comments to the agency.¹²¹

Given his senior management role at Cardno Chemrisk and the company's longstanding financial relationships with major companies that use and produce chemicals that have been or could be subject to TSCA risk evaluations as well as its direct advocacy before the SACC on behalf of the industry groups with direct financial interests in the chemicals under review, we believe that Dr. Maddaloni has financial conflicts of interest and an appearance of a loss of impartiality that precludes membership on the SACC.

Dr. Jon A. Hotchkiss

Dr. Hotchkiss is the principal at JAHotchkiss Inhalation Toxicology Consulting LLC. Prior to opening his consultancy in April 2020,¹²² Dr. Hotchkiss worked at Dow Chemical Company ("Dow") for 19 years.

According to the 2016 CDR data, Dow currently manufactures at least one of the 20 chemicals currently undergoing TSCA risk evaluation, 1,2-dichloropropane. In 2012, Dow also reported under the CDR manufacturing several additional chemicals among the 20 chemicals: 1,3-butadiene; 1,1-dichloroethane; 1,2-dichloroethane; and 1,1,2-trichloroethane – in addition to 1,2-dichloropropane. Based on EPA's 2016 CDR data, Dow also manufactured at least two of the first ten chemicals to undergo TSCA risk evaluations (carbon tetrachloride and hexabromocyclododecane); based on 2012 CDR data, Dow recently manufactured four more of the first ten chemicals (1-bromopropane, methylene chloride, tetrachloroethylene, and trichloroethylene). In late 2015, Dow sold some of its chlorinated solvents business to Olin Corporation.¹²³

Throughout his career, Dr. Hotchkiss has published studies both on these and other chemicals produced by Dow and on scientific issues that were funded by chemical company trade associations in which the associations' member companies have a vested financial interest. For example:

¹²¹ See: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0502-0053>.

¹²² "JAHOTCHKISS INHALATION TOXICOLOGY CONSULTING L.L.C.," Michigan Company Directory. Retrieved on October 28, 2020. Available at: <https://michigan-company.com/co/jahotchkiss-inhalation-toxicology-consulting-l-l-c>.

¹²³ "Olin Announces The Completion Of The Merger With Dow's Chlorine Products Businesses And Election Of New Directors," Cision PR Newswire. October 5, 2015. Available at: <https://www.prnewswire.com/news-releases/olin-announces-the-completion-of-the-merger-with-dows-chlorine-products-businesses-and-election-of-new-directors-300154156.html>.

- In 2016, Dr. Hotchkiss published an article on respiratory sensitization along with co-authors from ExxonMobil, GlaxoSmithKline, Syngenta, Bayer, ILSI, and others.¹²⁴ ILSI's Health and Environmental Sciences Institute's (HESI) corporate sponsors funded the study; HESI's members include Dow.¹²⁵ Further, in the paper's "Transparency Document," Dr. Hotchkiss specifically declared a financial interest in respiratory sensitization: "I am a full-time employee of The Dow Chemical Company. The issue of respiratory sensitization is relevant to the company's commitment to safe and responsible use of its products."¹²⁶
- In 2012, Dr. Hotchkiss co-authored a study with five other Dow employees funded by HSIA, of which Dow Chemical Company is or was a member. The study downplayed the immunotoxicity potential of trichloroethylene and perchloroethylene – two chemicals that HSIA members produce¹²⁷ and are currently undergoing TSCA risk evaluations.¹²⁸ As noted above, while Dow did not report producing trichloroethylene and perchloroethylene in the most recent CDR reporting year (2016), it did report manufacturing both chemicals in 2012.
- In 2010, Dr. Hotchkiss co-authored a study with five other Dow employees on 1,2-dichloroethane.¹²⁹ The study was funded by an industry coalition, the HAP Task Force, of which Dow was a member.

¹²⁴ North, C. M., Ezendam, J., *Hotchkiss, J. A.*, et al. (2016). Developing a framework for assessing chemical respiratory sensitization: A workshop report, *Regulatory Toxicology and Pharmacology*, 80, 295-309, available at:

<https://www.sciencedirect.com/science/article/pii/S0273230016301647?via%3Dihub>.

¹²⁵ "Current Partners," HESI. Retrieved on October 28, 2020. Available at:

<https://hesiglobal.org/partner/our-partners/>.

¹²⁶ "ICMJE Form for Disclosure of Potential Conflicts of Interest," International Committee of Medical Journal Editors. Available at: <https://ars.els-cdn.com/content/image/1-s2.0-S0273230016301647-mmc1.pdf>.

¹²⁷ See: <https://hsia.org/>.

¹²⁸ Boverhof, D. R., Krieger, S. M., *Hotchkiss, J. A.*, et al. (2012). Assessment of the immunotoxic potential of trichloroethylene and perchloroethylene in rats following inhalation exposure, *Journal of Immunotoxicology*, 10(3): 311-320, available at:

<https://www.tandfonline.com/doi/full/10.3109/1547691X.2012.735275>.

¹²⁹ *Hotchkiss, J. A.*, Andrus, A. K., Johnson, K. A. (2010). Acute toxicologic and neurotoxic effects of inhaled 1,2-dichloroethane in adult Fisher 322 rats, *Food and Chemical Toxicology*, 48(2): 470-481, available: <https://www.sciencedirect.com/science/article/pii/S0278691509005006>.

Given his recent employment and long tenure at Dow, we believe that Dr. Hotchkiss has financial conflicts of interest as well as an appearance of a loss of impartiality with respect to TSCA chemical risk evaluations and related scientific issues.

Dr. Elliot B. Gordon

Dr. Elliot B. Gordon is a Principal Toxicologist at Elliot Gordon Consulting, LLC. Directly preceding this role, he worked at Makhteshim Agan of North America, Inc. (rebranded as ADAMA in 2014¹³⁰), which is a major agrochemical producer.

According to his website, Dr. Gordon's current clients include the pharmaceutical industry, food and nutritional supplement industry, pesticide industry, art materials industry, and fragrance industry.¹³¹ At least the latter two (art materials and fragrances) include chemicals that fall within the jurisdiction of TSCA.

Dr. Gordon has a long history of downplaying the risks of chemicals on behalf of the industry in which he has been employed. While working at Makhteshim Agan and subsequently while consulting for the same company, Dr. Gordon published extensively on pesticides produced by the company, including folpet and captan, often downplaying their carcinogenic risks.^{132,133,134,135} While funding sources for these studies often are not disclosed, at least some of these studies

¹³⁰ "26/01/2014 - Makhteshim Agan to re-brand global business as 'ADAMA.'" Available at: <https://www.adama.com/en/media/press-releases/makhteshim-rebrand.html>.

¹³¹ "Clients," Elliot Gordon Consulting, LLC. Retrieved October 28, 2020. Available here: <https://ebgfox.wixsite.com/elliott-gordon/clients>.

¹³² **Gordon, E.** (2007). Captan: Transition from 'B2' to 'not likely'. How pesticide registrants affected the EPA Cancer Classification Update, *Journal of Applied Toxicology*, 27, 5: 519-529, available at: <https://onlinelibrary.wiley.com/doi/abs/10.1002/jat.1265>.

¹³³ Bernard, B. K. and **Gordon, E. B.** (2000). An Evaluation of the Common Mechanism Approach to the Food Quality Protection Act: Captan and Four Related Fungicides, a Practical Example, *International Journal of Toxicology*, 19:43-61, available at: <https://journals.sagepub.com/doi/pdf/10.1080/109158100225033>.

¹³⁴ Cohen, S. M., **Gordon, E. B.**, Singh, P., Arce, G., T., and Nyska, A. (2010) Carcinogenic mode of action of folpet in mice and evaluation of its relevance to humans, *Critical Reviews in Toxicology*, 40(6): 531-545, DOI: 10.3109/10408441003742903.

¹³⁵ **Elliot Gordon**, Samuel M. Cohen & Pramila Singh (2012). Folpet-induced short term cytotoxic and proliferative changes in the mouse duodenum, *Toxicology Mechanisms and Methods*, 22:1, 54-59, DOI: 10.3109/15376516.2011.593054.

were directly funded by Makhteshim Agan¹³⁶ and several include disclosures noting the authors' financial ties to Makhteshim Agan. For example (emphases added):

- “The authors’ employment affiliations are shown on the front page. Dr. Singh is employed by Makhteshim Agan of North America, Inc., a producer of folpet and captan. Drs. Cohen, Gordon, and Arce have *served as consultants for Makhteshim Agan of North America, Inc.*, and Dr. Nyska was the study pathologist on some of the folpet chronic bioassays. The contents of this review reflect solely the view of the authors.” [footnote 134]
- “Elliot Gordon and Samuel M. Cohen are *consultants that have worked for Makhteshim Agan of North America, Inc.* Pramila Singh was formerly employed by Makhteshim Agan of North America, Inc., a producer of folpet.” [footnote 135]

EPA’s posted biosketch states that: “Dr. Gordon spearheaded the successful reclassification of Captan from ‘B2’ to ‘not likely’,” lauding as one of his achievements the downgrading of the cancer classification of one of his employer’s chemicals. In 2007, Dr. Gordon published a paper titled “Captan: Transition from ‘B2’ to ‘not likely’. How pesticide registrants affected the EPA Cancer Classification Update,” which was written with “support provided by Captan Task Force.”¹³⁷ At the time, Makhteshim-Agan was a member of the Captan Task Force, along with Arvesta Corporation.¹³⁸ Likewise, Dr. Gordon’s consulting firm’s website prominently includes “Cancer reclassification” as a service it provides to the pesticide industry.¹³⁹

Dr. Gordon has also advocated directly to EPA, including at public meetings on chlorpyrifos¹⁴⁰ and inorganic arsenic and hexavalent chromium.¹⁴¹ The latter of these meetings was boycotted

¹³⁶ Christian Strupp, Deborah A. Banas, Samuel M. Cohen, **Elliot B. Gordon**, Martina Jaeger, Klaus Weber (2012). Relationship of Metabolism and Cell Proliferation to the Mode of Action of Fluensulfone-Induced Mouse Lung Tumors: Analysis of Their Human Relevance Using the IPCS Framework, *Toxicological Sciences*, 128(1): 284-294, available at: <https://doi.org/10.1093/toxsci/kfs127>.

¹³⁷ **Gordon, E.** (2007), Captan: Transition from ‘B2’ to ‘not likely’. How pesticide registrants affected the EPA Cancer Classification Update. *J. Appl. Toxicol.*, 27: 519-526, available at: <https://onlinelibrary.wiley.com/doi/abs/10.1002/jat.1265>

¹³⁸ See, for example, Captan Task Force sponsors of this study: [https://www.tera.org/Peer/CAPTAN/Final%20Captan%20Overview%20Document%20\(01-13-04\).pdf](https://www.tera.org/Peer/CAPTAN/Final%20Captan%20Overview%20Document%20(01-13-04).pdf).

¹³⁹ “Clients,” Elliot Gordon Consulting, LLC. Retrieved October 28, 2020. Available here: <https://ebgfox.wixsite.com/elliott-gordon/clients>.

¹⁴⁰ See: https://archive.epa.gov/scipoly/sap/meetings/web/pdf/chlorpyrifos_sap_agenda_final.pdf.

¹⁴¹ See: https://www.epa.gov/iris/iris-bimonthly-public-meeting-jun-2014#mtg_docs.

by some stakeholders for its heavy industry influence.¹⁴² The failure of Gordon and other industry-affiliated consultants to disclose who was paying them for their appearances, presentations and comments led to calls for the IRIS program to compel such disclosures,¹⁴³ which the program subsequently began requiring.¹⁴⁴

Given his long history of advocating on behalf of the chemical industry by which he is employed or consults for, we believe that Dr. Gordon has financial conflicts of interest and an appearance of a loss of impartiality with respect to TSCA chemical risk evaluations and related scientific issues.

Ms. Maryann Hoff

Ms. Hoff is Director of Global Product Stewardship & Corporate Advocacy at PPG Specialty Coatings & Materials. By revenue, PPG is the largest global supplier of paints, coatings, and related materials.^{145,146}

Many of the next 20 chemicals designated for TSCA risk evaluations are used in paints, coatings, and associated products, and/or their manufacturing processes. These chemicals include: o-dichlorobenzene, phthalic anhydride, formaldehyde, 1,3-butadiene, triphenyl ester, tris(2-chloroethyl) phosphate, dicyclohexyl phthalate, di-isobutyl phthalate, di-ethylhexyl phthalate, butyl benzyl phthalate, and dibutyl phthalate. Additionally, according to EPA's 2016 CDR data, PPG manufactures at least two of the 20 chemicals for which EPA is currently conducting risk evaluations: trans-1,2-dichloroethylene and 1,2-dichloroethane.

Given her employment at PPG, we believe that Ms. Hoff has financial conflicts of interest and an appearance of a loss of impartiality with respect to TSCA chemical risk evaluations and related scientific issues.

¹⁴² "Boycott of EPA's June 2014 IRIS inorganic arsenic and hexavalent chromium meeting." June 24, 2014. Available at: http://www.sciencecorps.org/Boycott_Statement_to_EPA_re_IAs_&_CrIV_mtg_6-24pm.pdf.

¹⁴³ See EDF Health blog: <http://blogs.edf.org/health/2014/11/07/time-to-come-clean-iris-needs-to-require-stakeholders-attending-its-meetings-to-disclose-their-conflicts-of-interest/>.

¹⁴⁴ See EDF Health blog: <http://blogs.edf.org/health/2014/11/25/epa-iris-program-requests-conflict-of-interest-disclosures-by-commenters/>.

¹⁴⁵ "PPG Industries." Available at: https://en.wikipedia.org/wiki/PPG_Industries.

¹⁴⁶ "About PPG." Available at: https://s23.q4cdn.com/399447945/files/doc_downloads/facts_about_ppg/PPG_Fact_Sheets_About_PPG_Final.pdf.

Dr. Vijayavel Kannappan

Dr. Kannappan is a Regulatory Toxicology Manager at Georgia-Pacific, LLC.

Georgia-Pacific, a Koch Industries company, is self-described as “one of the world’s leading makers of tissue, pulp, packaging, building products and related chemicals.”¹⁴⁷ Many products listed on Georgia-Pacific’s website include or entail use of chemicals that would fall under TSCA’s jurisdiction, including adhesives, chemical intermediates, insulation, electronics, wood products, and more. Therefore, Georgia-Pacific has a clear vested interest in the outcome of TSCA risk evaluations.

According to the 2012 CDR data, Georgia-Pacific manufactured 73,500,000 pounds of formaldehyde – one of the next 20 chemicals currently undergoing TSCA risk evaluation – in 2011. While Georgia-Pacific is not identified as having reported formaldehyde in the 2016 CDR,¹⁴⁸ based on its website Georgia-Pacific continues to produce formaldehyde: “Georgia-Pacific Chemicals produces formaldehyde (HCHO) or formalin solutions at concentrations up to 52%, in both uninhibited and methanol-inhibited grades.”¹⁴⁹

According to his LinkedIn profile, in his role at Georgia-Pacific, Dr. Kannappan is responsible for a number of consumer product categories falling under TSCA’s jurisdiction, including paper products (e.g., kitchen towels) and air care (e.g., room fresheners). Among other responsibilities listed, he “write[s] dossiers and position papers for new product registration” and “manage[s] post market safety complaints in consultation with business partners & legal counsel.”¹⁵⁰

Given Dr. Kannappan’s employment at Georgia-Pacific, we believe he has financial conflicts of interest and an appearance of a loss of impartiality with respect to TSCA chemical risk evaluations and related scientific issues.

¹⁴⁷ “About Georgia-Pacific,” Georgia Pacific. Available at: <https://www.gp.com/about-us>.

¹⁴⁸ Because companies can claim their own identity as confidential business information in their CDR submissions, it is not possible to know whether or not the company reported its manufacture of formaldehyde in 2016.

¹⁴⁹ “Formaldehyde Solutions and Concentrate,” Georgia Pacific. Retrieved October 28, 2020. Available at: <https://gp-chemicals.com/formaldehyde/>.

¹⁵⁰ See Vinjay Kannappan’s LinkedIn profile: <https://www.linkedin.com/in/vijay-kannappan-ph-d-ert-1149b325>.

Ms. Lisa M. Nespoli

Ms. Nespoli is the Product Safety and Stewardship Manager in the Product Safety and Regulatory Affairs group at Covestro. Covestro produces polymers used in a variety of sectors, including automotive, construction, healthcare, and electronics.

According to the 2016 CDR data, Covestro manufactures at least one of the 20 chemicals currently undergoing TSCA risk evaluation: triphenylphosphate (TPP). However, Covestro likely has a vested interest in many others. For example, Covestro's "Impranil® VP LS 2346" product, is a polyacrylate resin that is advertised as "crosslinkable with melamine/formaldehyde."¹⁵¹

As noted in EPA's biosketch, Ms. Nespoli represents Covestro on a variety of industry trade association groups such as ACC, the American Coatings Association (ACA), and the Adhesive and Sealant Council (ASC). As of at least 2018, Ms. Nespoli served as the chair of ACC's Aliphatic Diisocyanates Panel.¹⁵² Aliphatic diisocyanates are primarily used in paints and coatings, and could well be evaluated under TSCA in the future. In her role as a Covestro representative for ACA, Ms. Nespoli recently participated in an ACA meeting covering a variety of relevant TSCA issues, including ACA's recent controversial petition requesting that EPA develop a risk management procedural rule under TSCA.¹⁵³

Given Ms. Nespoli's employment at Covestro and close affiliation with chemical industry associations, we believe she has financial conflicts of interest and an appearance of a loss of impartiality with respect to TSCA chemical risk evaluations and related scientific issues.

¹⁵¹ Covestro Solution Center, "Impranil® VP LS 2346". Retrieved October, 29 2020. Available at: https://solutions.covestro.com/en/products/impranil/impranil-vp-ls-2346_05438535-12982036?SelectedCountry=US.

¹⁵² "DRI Faculty List," Toxic Torts and Environmental Law Seminar. March 1-2, 2018. Available at: <http://www.dri.org/docs/default-source/event-brochures/2018/toxic-torts/20180210-speaker-list037a3a570102663cbcd7ff00009eb89a.html?sfvrsn=2>.

¹⁵³ American Coatings Association, Product Stewardship Committee Meeting, Meeting Minutes, March 31, 2020. Available at: https://www.paint.org/wp-content/uploads/dlm_uploads/2020/05/PSC-minutes-March-2020-Meeting.pdf.

Dr. Andrew W. Pawlisz

Dr. Andrew W. Pawlisz is a Senior Toxicologist at Trihydro Corporation. Prior to assuming this role in 2018, Dr. Pawlisz was a Toxicologist at Phillips 66 (Oil & Energy).¹⁵⁴

Trihydro Corporation is a consulting firm that is self-described¹⁵⁵ as “the largest HUBZone contractor in the continental U.S. under NAICS 562910,” which covers remediation services.¹⁵⁶ Its remediation projects have included TSCA chemicals, such as perchloroethylene contamination at a former dry cleaning site.¹⁵⁷

As described by his employer, “Andrew comes to Trihydro after working on Toxic Substances Control Act (TSCA), per- and Polyfluoroalkyl Substances (PFAS), and Total Petroleum Hydrocarbons (TPH) projects as a consultant and directly for major petroleum and transportation companies.”¹⁵⁸

One of Dr. Pawlisz’s main areas of focus is TSCA compliance for industry clients. The biosketch provided by EPA describes his TSCA responsibilities as follows:

He has served as the TSCA subject matter expert in consulting and industry for over a decade and has completed multiple projects in compliance with the legacy, as well as the Reformed TSCA. Mr. Pawlisz assisted with TSCA regulatory compliance, new substance Pre-manufacture Notices (PMNs), Significant New Use Rules (SNURs), Significant New Use Notices (SNUNs), Chemical Data Reporting (CDR), Active/Inactive TSCA Inventories, product classification under Globally Harmonized System (GHS),

¹⁵⁴ NAICS code 562910: “This industry comprises establishments primarily engaged in one or more of the following: 1) Remediation and cleanup of contaminated buildings, mine sites, soil, or ground water; 2) Integrated mine reclamation activities, including demolition, soil remediation, waste water treatment, hazardous material removal, contouring land, and revegetation; and 3) Asbestos, lead paint, and other toxic material abatement.

¹⁵⁵ See LinkedIn profile for Trihydro Corporation: https://mt.linkedin.com/company/trihydro-corporation?trk=jobs_jserp_job_listing_company_name.

¹⁵⁶ See LinkedIn profile for Andrew Pawlisz: https://www.linkedin.com/in/andrewpawlisz?challengeId=AQFxEEXELJKRrSwAAAXVGwXKRMjurtAB0U_RPagMb8InHxFmN0YpNIXIauTaOwXch0GNycJeMhnr32b_wowpkm4OE_4qLY1szw&submissionId=64aa9f2a-e5be-3f16-65b2-f266d1b92d51.

¹⁵⁷ “Third Party Oversight: Former Drycleaner Facility Denver, Colorado,” Trihydro. Retrieved October 28, 2020. Available at: <https://www.trihydro.com/projects/project-details/third-party-oversight>.

¹⁵⁸ “Say Hello to Andrew, New Toxicologist at Trihydro,” Trihydro. Retrieved on October 28, 2020. Available at: <https://trihydro.com/news/news-details/2018/11/06/say-hello-to-andrew-new-toxicologist-at-trihydro>.

participation in industry associations and commenting on reformed TSCA rulemaking activities.

Also according to his biosketch, Dr. Pawlisz was an affiliate of the TSCA industry member committees established by the American Petroleum Institute (API; 2016-2018) and the American Fuel and Petrochemical Manufacturers (AFPM; 2016-2020). The member companies of both AFPM and API – which include many petrochemical producers^{159,160} – have a strong vested interest in the outcome of TSCA risk evaluations.

Given his close association with the chemical and petroleum industries, we believe that Dr. Pawlisz has or may have financial conflicts of interest and an appearance of a loss of impartiality with respect to TSCA chemical risk evaluations and related scientific issues.

Dr. Sol Bobst

Dr. Bobst is President and Principal Advisor of ToxSci Advisors LLC.

He has a history of paid work for the chemical industry, including ACC. For example, as noted in the SACC biosketches provided by EPA, he has chaired a study committee with the ACC. While employed by Shell Oil Company, he published scientific research funded by ACC.¹⁶¹

¹⁵⁹ “Members,” API. Retrieved October 28, 2020. Available at:

<https://www.api.org/membership/members>.

¹⁶⁰ “AFPM Membership,” AFPM. Retrieved October 28, 2020. Available at:

<https://www.afpm.org/membership/membership>.

¹⁶¹ Snellings, W. M., Corley, R. A., McMartin, K. E., Kirman, C. R., and **Bobst, S. M.** (2013). Oral Reference Dose for ethylene glycol based on oxalate crystal-induced renal tubule degeneration as the critical effect, *Regulatory Toxicology and Pharmacology* 65(2): 229-241, available at:

<https://pubmed.ncbi.nlm.nih.gov/23266425/>.

In 2017, he published a textbook, “History of Risk Assessment in Toxicology,”¹⁶² in collaboration with the Grocery Manufacturers Association and Ted Simon, a consultant with extensive ties to ACC.^{163,164,165}

Dr. Bobst also currently serves as the chair of the ZNPO standard committee at the International Association of Plumbing and Mechanical Officials, a major industry trade group.

Given these extensive previous and potentially ongoing collaborations and financial relationships, we believe that Dr. Bobst has or is likely to have financial conflicts of interest and an appearance of a loss of impartiality with respect to TSCA chemical risk evaluations and related scientific issues.

Dr. Franklin L. Mink

Dr. Franklin L. Mink is the President of MAI Engineering. Prior to this role, Dr. Mink held several roles at industry consulting companies, including Entrix (which was acquired by Cardno in 2010 and later merged with Chemrisk in 2012) and Environ.¹⁶⁶

MAI Engineering provides consulting services to a variety of industries relevant to TSCA, including chemical, mining, petroleum, plastics, automotive, manufacturing, and pulp/paper.¹⁶⁷ As described on his LinkedIn webpage, Dr. Mink provides “[e]nvironmental health/occupational risk assessment and research consulting internationally with Global corporations (Energy, Pharma, health, food, and chemical).”

¹⁶² **Bobst, Sol**, ed. *History of Risk Assessment in Toxicology*. Academic Press, 2017.

¹⁶³ Cox, Louis A. Tony, Ted W. Simon, and Richard A. Becker. "The Predictive Analytics Toolkit (PAT): User-friendly predictive analytics for advancing new approach methodologies (NAMs)." *Computational Toxicology* 12 (2019): 100107.

¹⁶⁴ Patlewicz, G., Simon, T., Goyak, K., et al. "Use and validation of HT/HC assays to support 21st century toxicity evaluations." *Regulatory Toxicology and Pharmacology* 65(2) (2013): 259-268, available: <https://www.sciencedirect.com/science/article/pii/S0273230012002589>.

¹⁶⁵ Patlewicz, G. Wambaugh, J. F., Felter, S. P., Simon, T. W., Becker, R. A. (2018). Utilizing Threshold of Toxicological Concern (TTC) with high throughput exposure predictions (HTE) as a risk-based prioritization approach for thousands of chemicals, *Computational Toxicology* 7: 58-67, available at: <https://www.sciencedirect.com/science/article/pii/S2468111318300689>.

¹⁶⁶ “Franklin Fink CV,” DOCURI. Available at: https://docuri.com/download/franklin-fink-cv_59a8d8e8f581719e12ae6c0c_pdf.

¹⁶⁷ “Industries Served,” MAI Engineering the Future. Retrieved on October 28, 2020. Available at: <http://www.maitech.com/industries-served/>.

Though not mentioned in his biosketch provided by EPA, Dr. Mink also serves as a Senior Health Science Advisor for Leaders in Strategic Communication and Crisis Management (C4CS).¹⁶⁸ C4CS is self-described as specializing in “strategic communication and crisis management precisely tuned to protect and enhance reputation, stakeholder trust and the bottom line” for its business partners. Dr. Mink presented during “Pittsburg Chemical Day,” under his C4CS affiliation.¹⁶⁹

According to one online bio, Dr. Mink has been “a consultant to over 100 Fortune 500 companies in product liability, disease causation, hazard exposure, regulatory practices, warnings, and risk assessment.”¹⁷⁰

Given Dr. Mink’s extensive experience consulting for the chemical industry, we believe he has or is likely to have financial conflicts of interest and an appearance of a loss of impartiality with respect to TSCA chemical risk evaluations and related scientific issues.

Dr. David V. Gauvin

Dr. David V. Gauvin is the Director of Neurobehavioral Sciences at Charles River Laboratories, Inc.

Charles River Laboratories provides laboratory services to a variety of industry clients including the chemical, pharmaceutical, medical device, and biotechnology industries. Charles River Laboratories is self-described as having “over 40 years of experience in serving the needs of the chemical industry.”¹⁷¹ Its clients have included Dow, DuPont, HSIA, ACC, and others.

Charles River Laboratories is one of the go-to laboratories for chemical industry to conduct studies intended and designed to impact regulatory decisions, including those under TSCA. The latest example is a 2019 Charles River Laboratories study of TCE sponsored by ACC and

¹⁶⁸ “C4CS® Principals & Advisers,” C4CS. Retrieved on October 28, 2020. Available at: <https://www.c4cs.com/principals-advisers>.

¹⁶⁹ “Pittsburgh Chemical Day 2020 Schedule,” Pittsburgh Chemical Day. Available at: <https://pittchemday.com/program/>.

¹⁷⁰ *Id.*

¹⁷¹ “Chemical,” Charles River. Retrieved October 28, 2020. Available at.: <https://www.criver.com/industry/chemical>.

HSIA.¹⁷² The study was cited by HSIA,¹⁷³ ACC,¹⁷⁴ and Exponent (in work done on behalf of ACC and HSIA)¹⁷⁵ in their comments to the SACC during its peer review of EPA’s TCE draft risk evaluation; the study was conceived and executed in order to seek to refute independent scientific evidence that links TCE exposure to congenital heart defects.

Dr. Gauvin’s experience is in nonclinical research for the pharmaceutical industry. He has published several studies with pharmaceutical industry funding and/or manuscript review. For example:

- In 2018, Dr. Gauvin and two Charles River Laboratories colleagues published a study that was reviewed prior to publication by employees at Merck & Co, Sanofi, and Amgen.¹⁷⁶ The Acknowledgements state (emphases added):

The authors extend great appreciation to our colleagues: Drs. Richard Briscoe (*Merck*), David Compton (*Sanofi*), Christina Zuch de Zafra (*Amgen*) for reviewing the first draft of the manuscript and providing their valuable insight.

- In 2018, Dr. Gauvin and two Charles River Laboratories colleagues published another study that was reviewed prior to publication by employees at Merck & Co and Janssen Pharmaceuticals, Inc.¹⁷⁷ The Acknowledgements state (emphases added): “The authors greatly appreciate the efforts and courtesy extended by Dr. Richard Briscoe (*Merck*), Dr. Greet Teuns (*JNJ*) and Dr. Mary-Jeanne Kallman (Kallman Consulting) for their pre-submission review of our manuscript.”

¹⁷² Coder, P. S. (2019) Final Report. An Oral (Drinking Water) Study of the Effects of Trichloroethylene (TCE) on Fetal Heart Development in Sprague Dawley Rats. Charles River Laboratories, Laboratory Project ID 00459506. Available at: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0737-0120>.

¹⁷³ See: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0500-0094>.

¹⁷⁴ See: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0500-0103> and <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0500-0051>.

¹⁷⁵ See: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0500-0048>.

¹⁷⁶ **David V. Gauvin**, Zachary J. Zimmermann, Theodore J. Baird (2019). In further defense of nonclinical abuse liability testing of biologics, *Regulatory Toxicology and Pharmacology*, Volume 101, Pages 103-120, available at: <https://www.sciencedirect.com/science/article/pii/S0273230018303015?via%3Dihub>.

¹⁷⁷ **David V. Gauvin**, Zachary J. Zimmermann, Joshua Yoder, Marci Harter, David Holdsworth, Quinn Kilgus, Jonelle May, Jill Dalton, Theodore J. Baird (2018). A predictive index of biomarkers for ictogenesis from tier I safety pharmacology testing that may warrant tier II EEG studies, *Journal of Pharmacological and Toxicological Methods*, 94(1):50-63, available at: <https://www.sciencedirect.com/science/article/abs/pii/S1056871918305884?via%3Dihub>.

- In 2017, Dr. Gauvin published a study funded by Merck & Co along with co-authors employed by Merck & Co.¹⁷⁸

Given Dr. Gauvin's employment at Charles River Laboratories and paid work for industry clients, we believe he has or is likely to have financial conflicts of interest and has an appearance of a loss of impartiality with respect to TSCA chemical risk evaluations and related scientific issues.

Dr. Hong Zhuang

Dr. Hong Zhuang is a Senior Regulatory Scientist at Symrise, Inc.

Symrise is a major manufacturer of chemical fragrances and flavors, many of which may undergo TSCA risk evaluation. CDR data demonstrate that Symrise has recently manufactured or currently manufactures at least two chemicals currently undergoing or expected soon to undergo TSCA risk evaluation: HHCB (or galaxolide) and ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl).¹⁷⁹ In 2011, Symrise reported importing at least 167,423 pounds of HHCB for consumer use – and was one of just four major producers listed in EPA's 2014 TSCA Work Plan Assessment of the chemical.¹⁸⁰ In 2015, Symrise, Inc. imported at least 139,907 pounds of ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl) for consumer use. Therefore, Dr. Zhuang's employer, Symrise, Inc., has a vested interest in the outcome of TSCA risk evaluations.

As described in the biosketch provided by EPA, Dr. Zhuang is actively working on new chemical registrations as well as risk assessments of chemicals regulated under TSCA for Symrise, Inc.

¹⁷⁸ Born S, *Gauvin DV*, Mukherjee S, Briscoe R. (2017). Preclinical assessment of the abuse potential of the orexin receptor antagonist, suvorexant. *Regul Toxicol Pharmacol.*, 86:181-192, available at: <https://pubmed.ncbi.nlm.nih.gov/28279667/>.

¹⁷⁹ Note that EPA should be undertaking a risk evaluation for ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl), given that the chemical was identified as a persistent bioaccumulative and toxic (PBT) chemical but then removed from expedited risk management under TSCA section 6(h) following a request from one of its manufacturers that the agency conduct a risk evaluation. However, there is no public indication that the agency has begun this risk evaluation, despite the request having been made and acknowledged by EPA four years ago.

¹⁸⁰ See: https://www.epa.gov/sites/production/files/2015-09/documents/hhcb_wp_ra_final_08_27_14.pdf.

Given Dr. Zhuan's employment at Symrise, Inc., we believe she has financial conflicts of interest and an appearance of a loss of impartiality with respect to TSCA chemical risk evaluations and related scientific issues.

Dr. Agnes Karmaus

Dr. Karmaus is a Senior Toxicologist at Integrated Laboratory Systems (ILS), Inc.

Dr. Karmaus is closely affiliated with ILSI North America, a collaborative that is primarily funded by its industry members.¹⁸¹ ILSI North America has and is funded by 33 industry members, including producers of “food, beverages, pharmaceuticals, cosmetics, agricultural and other chemicals, personal care and household products or the ingredients, safety testing or production used in such products.”¹⁸² Many of these companies likely manufacture, process, use, or distribute chemicals subject to review under TSCA. For example, according to the 2016 CDR, Henkel Corporation reported manufacturing 138 chemicals subject to TSCA.

Dr. Karmaus served as an ILSI North America 2012 Summer Fellow,¹⁸³ and has since co-authored several studies that were funded, at least in part, by the organization:

- In 2019, Dr. Karmaus published a paper on alternatives to animal testing in collaboration with co-authors from Pespico Inc., ILSI North America, and FDA. Dr. Karmaus received personal fees for her work on this manuscript directly from ILSI North America. The Declaration of competing interests states (emphasis added): “Co-author, Agnes Karmaus, received funds from the *ILSI North America Food and Chemical Safety Committee* for her work on this article.”¹⁸⁴

¹⁸¹ “Who we are,” ILSI North America. Retrieved on October 28, 2020. Available at: <https://ilsina.org/about-us/our-story/>.

¹⁸² “Membership,” ILSI North America. Retrieved on October 28, 2020. Available at: <https://ilsina.org/about-us/membership/>.

¹⁸³ “Food-Use Chemicals in ToxCast: Identification, Curation, and Evaluation.” ILSI North America. EPA Webinar, September 22, 2016. Available at: <https://ilsina.org/event/food-use-chemicals-in-toxcast-identification-curation-and-evaluation/>.

¹⁸⁴ *Agnes L. Karmaus*, Heidi Bialk, Suzanne Fitzpatrick, Mansi Krishan, (2020). State of the science on alternatives to animal testing and integration of testing strategies for food safety assessments: Workshop proceedings, *Regulatory Toxicology and Pharmacology*, 110: 104515, available at: <https://www.sciencedirect.com/science/article/pii/S027323001930279X>.

- In 2017, Dr. Karmaus co-authored a study with employees of General Mills, ILSI North America, and others, with funding from ILSI North America.¹⁸⁵

Given her close affiliation with ILSI North America, we believe that Dr. Karmaus has or is likely to have financial conflicts of interest and an appearance of a loss of impartiality with respect to TSCA chemical risk evaluations and related scientific issues.

* * * * *

As detailed in these comments, the undersigned organizations believe that these nominees have actual or potential financial conflicts of interest or an appearance of a loss of impartiality, the avoidance of which is required for inclusion on this advisory committee or its panels. Moreover, the selection of additional industry-affiliated SACC members, at a time when the SACC currently has no representatives from the labor community and a sole representative from a public interest organization, would upset the statutorily required balance of the SACC. *See* 15 U.S.C. 2625(o)(3) (requiring the SACC to “be composed of representatives of such science, government, labor, public health, public interest, animal protection, industry, and other groups ... including representatives that have specific scientific expertise in the relationship of chemical exposures to women, children, and other potentially exposed or susceptible subpopulations.”) We therefore urge EPA not to select the foregoing nominees.

If you have any questions about this information or wish to discuss it further, please contact Lindsay McCormick at lmccormick@edf.org. We appreciate the opportunity to comment.

Submitted by:

Environmental Defense Fund
Earthjustice
Natural Resources Defense Council
Physicians for Social Responsibility
Union of Concerned Scientists

¹⁸⁵ *Agnes L. Karmaus*, Thomas D. Trautman, Mansi Krishan, Dayne L. Filer, Laurel A. Fix (2017). Curation of food-relevant chemicals in ToxCast, *Food and Chemical Toxicology*, 103: 174182, available at: <https://www.sciencedirect.com/science/article/pii/S0278691517300996?via%3Dihub>.