MESSAGE FROM THE EDITORS

Nepolina K. Chhetri and Anthony G. Hopp

In the season six episode of Seinfeld titled “The Beard,” George Costanza, played by actor Jason Alexander, immortalized the saying “It’s not a lie, if you believe it.”

Mark Twain is famous for identifying three types of lies: “lies, damned lies, and statistics.”

These statements are funny because they strike a chord. We all know people who fervently believe something that is not true, and we have all been bewildered by arguments based on data or statistics we do not understand or do not have access to. While it may be true that “numbers don’t lie,” people sometimes do. And while lies, and overblown allegedly data-driven arguments may be innocuous or even amusing on television, they can have serious consequences when they form the basis of health-care or health policy decisions.

The well-known case of Andrew Wakefield, M.D., is an example. In 1998, he announced his concerns about the safety of the measles, mumps, rubella (MMR) vaccine and its alleged connection to autism. Susan Dominus, The Crash and Burn of an Autism Guru, N.Y. TIMES, Apr. 20, 2011, http://www.nytimes.com/2011/04/24/magazine/may-24/autism-t.html. While Wakefield never claimed that the MMR vaccine caused autism, his widely publicized “concerns” were enough to convince many parents to refuse to vaccinate their children. Since then, however, his theories have been thoroughly refuted, and the British General Medical Counsel has revoked his medical license citing numerous ethical violations that tainted his work, such as failing to disclose that he had been financed by lawyers who were mounting a case against the vaccine’s manufacturers. Id. The LANCET, which had published Wakefield’s MMR paper, retracted it. Id. The BRITISH MEDICAL JOURNAL has called Dr. Wakefield’s research “fraudulent.” Id. Some have attributed the recent upsurge in whooping cough and measles directly to Dr. Wakefield’s now-discredited work. Id.

And Dr. Wakefield is not alone, the online blog RETRACTION WATCH (http://retractionwatch.wordpress.com) regularly reports on scientific papers that have been retracted by authors or journals. Often, the retractions are based on plagiarism and the authors’ failure to disclose funding sources, which create conflicts of interest (e.g., drug companies or attorneys). Other times, the issue is much more serious and involves fabricated or manipulated data. Authors sometimes make up data entirely, or claim that their data support a particular conclusion, when in fact they do not.

Arguably, the public tends to lump all “scientists” together and to perceive science as an objective endeavor in which bias has no place. The data “are what they are,” right? The “numbers don’t lie,” do they? In reality, the world of science has always been factious, and more than one scientific debate has ended in a fistfight. Academic researchers cannot escape the
pressure to obtain tenure, and the competition for research grants can be intense. Lucrative patents drive universities to pressure researchers, and university researchers may be driven to build their resumes. Industry scientists face similar pressures. Sometimes the future of the company may rest on the next “blockbuster” discovery. More often, an industry scientist’s continued employment, promotion, or bonus will hinge on the success of his or her work. All of these pressures can lead to data manipulation, fabrication, or, at the very least, unexplained gaps between the authors’ data and his or her conclusions.

To be clear, the vast majority of academic and corporate researchers are undoubtedly scrupulously honest and would never attempt to publish or publicize a conclusion that was not well grounded in the underlying data. The articles that follow address the exceptions to the general rule: scientists who have misread their data or studies being used to promote unjustified regulatory or legal agendas. These fringe scientists and the advocates they attract are the ones who can do the most damage to the scientific community as a whole.

So how do the public, the regulatory community, and the legal community distinguish valid scientific research from faulty studies? Unfortunately, there is no single easy solution. The authors of the articles in this issue suggest a step in the right direction: transparency. A scientist who seeks to publish a novel claim should be willing to make his or her underlying data available for review by others in the scientific or regulatory community. While allowing access to underlying data will not eliminate outright fabrication, making researchers “put up or shut up” may make them less likely to stretch their data to justify untenable conclusions.
THE PERILS OF FAILING TO CRITICALLY EVALUATE THE QUALITY AND RELIABILITY OF PEER-REVIEWED SCIENTIFIC DATA: A CASE STUDY WITH DECBROMODIPHENYL ETHER

Marek Banasik, Nepolina K. Chhetri, and Julie E. Goodman

The U.S. Environmental Protection Agency’s (EPA) Integrated Risk Information System (IRIS) develops quantitative human health assessments on chemicals present in the environment. IRIS values are used globally and represent an international benchmark of high-quality reference values and cancer risk estimates that have undergone extensive rounds of peer review. Therefore, in theory, it is seemingly impossible that data quality and reliability issues should not survive such scrutiny and remain in final IRIS documents; however, the IRIS documents on decabromodiphenyl ether (BDE-209) provide a textbook example of how easily this may occur. The events that led up to IRIS’s 2010 acknowledgment of this issue demonstrate that the use of the best available science can be ignored. Part I of this article begins with the events that led up to EPA’s request for data on BDE-209 from an academic research laboratory, followed by EPA’s cosponsored expert panel that identified the experimental design used in the academic research on BDE-209 as flawed. Viberg et al. (2003) employed a controversial experimental design for DNT studies (for discussion, see Julie E. Goodman, Neurodevelopmental Effects of Decabromodiphenyl Ether (BDE-209) and Implications for the Reference Dose, 54 REGUL. TOXICOL. PHARMACOL. 91–104 (2009)). The chemical manager requested the raw data because it was necessary to reconstruct the study and to reevaluate the researchers’ data (FOIA, supra); however, the researchers did not provide the data.

I. Background


During the drafting stage of the IRIS health assessment on BDE-209, the chemical manager requested the raw data for the Viberg et al. (2003) study (Freedom of Information Act (FOIA)), response letter dated Aug. 15, 2007, from Peter W. Preuss, Ph.D., Director, National Center for Environmental Assessment (NCEA), Office of Research and Development, EPA, to Marcia L. Hardy, D.V.M., Ph.D., Senior Toxicology Advisor, Albemarle Corporation; subject: FOIA Request: HQ-RIN-01639-07; a copy of an e-mail dated Feb. 4, 2005, that was sent from Joyce M. Donohue, Ph.D., Chemical Manager, Health and Ecological Criteria Division, Office of Science and Technology, Office of Water, EPA to Drs. Henrik Viberg and Per Eriksson was enclosed). Viberg et al. (2003) employed a controversial experimental design for DNT studies (for discussion, see Julie E. Goodman, Neurodevelopmental Effects of Decabromodiphenyl Ether (BDE-209) and Implications for the Reference Dose, 54 REGUL. TOXICOL. PHARMACOL. 91–104 (2009)). The chemical manager requested the raw data because it was necessary to reconstruct the study and to reevaluate the researchers’ data (FOIA, supra); however, the researchers did not provide the data.
Though the chemical manager was unable to obtain the raw data, EPA cosponsored an expert panel on DNT testing, which issued a peer-reviewed report of its findings in June 2007. In the report, the panel concluded that the same experimental design employed in the Viberg et al. studies was unacceptable and statistically invalid. Specifically, the panel stated: “[Per Eriksson et al.’s (2005)] conclusion is inaccurate,” “there are litter effects on spontaneous motor activity,” and “ignoring litter effects in the statistical analysis of DNT studies is simply not an acceptable practice” (R. Robert Holson et al., Statistical Issues and Techniques Appropriate for Developmental Neurotoxicity Testing—A Report from the ILSI Research Foundation/Risk Science Institute Expert Working Group on Neurodevelopmental Endpoints, 30 Neurotoxicol. Teratol. 326, 335 (2008), available online June 15, 2007 at doi: 10.1016/j.ntt.2007.06.001).

However, the panel’s conclusions were published after the IRIS program had issued the external review drafts for the BDE-209 documents (EPA, Draft Toxicological Reviews of Polybrominated Diphenyl Ethers (PBDEs): In Support of the Summary Information in the Integrated Risk Information System (IRIS), 71 Fed. Reg. 77,015–17 (2006), available at http://www.gpo.gov/fdsys/pkg/FR-2006-12-22/pdf/E6-21969.pdf). Therefore, revising the documents to reflect the findings of the panel’s conclusions would have, presumably, caused significant delays with issuing the final documents.

Concurrent with the BDE-209 assessment, IRIS and other divisions within EPA’s Office of Research and Development were being evaluated under the White House’s Program Assessment Rating Tool (PART). Annual performance measures (APMs) factor heavily into the PART evaluations, and since IRIS based two additional assessments on studies by Drs. Viberg and Eriksson, adhering to the recommendations in Holson et al. might have required the removal of three separate assessments from IRIS’s targeted APMs (i.e., IRIS (2008b); IRIS (2008c), Toxicological Review of 2,2’,4,4’,5-Pentabromodiphenyl Ether (BDE-99) (CAS No. 60348-60-9)—In Support of Summary Information on the Integrated Risk Information System (IRIS), EPA/635/R-07/006F, 128 pp., at 63, available at http://www.epa.gov/iris/toxreviews/1008tr.pdf; IRIS (2008d), Toxicological Review of 2,2’,4,4’,5-Tetrambromodiphenyl Ether (BDE-47) (CAS No. 5436-43-1)—In Support of Summary Information on the Integrated Risk Information System (IRIS), EPA/635/R-07/005F, 85 pp., at 45, available at http://www.epa.gov/iris/toxreviews/1010tr.pdf). While it cannot be known for certain, it is possible that IRIS’ desire to credit the BDE-209 health assessment toward its APM influenced this decision.

II. The Chemical Industry’s Formal Raw Data Request

In December 2007, a manufacturer of BDE-209 submitted a formal raw data request and research integrity concern to the vice chancellor at the university where the Viberg et al. (2003) study was performed. Raw data for an additional study published by the same authors in 2007 were also requested (Henrik Viberg et al., Changes in Spontaneous Behaviour and Altered Response to Nicotine in the Adult Rat, After Neonatal Exposure to the Brominated Flame Retardant, Decabrominated Diphenyl Ether (PBDE 209), 28 Neurotoxicology 136–42 (2007)). It should be noted that the standard practice for these types of requests is to maintain confidentiality in order to safeguard the rights of both the complainant and the respondent (European Science Foundation, Good Scientific Practice in Research and Scholarship, 10 EUR. SCI. FOUND. POLICY BRIEFING 1, 14 (2000); see also Bengt Gustafsson et al., Good Research Practice—What Is It? Views, Guidelines and Examples, Swedish Research Council, Stockholm, Sweden, 89 pp., at 78 (2006), available at http://vt.se/download/18.6b2f98a910b3e260ae28000469/Good+Research+Practice+20+april.pdf). However, a local newspaper in Sweden somehow obtained a copy of the letter. A story followed which chastised the manufacturer for its request (Niklas Skeri, Amerikanskt Företag Kritiserar Uppsalaforskning, UPPSALA Nya TIDNING, Jan. 17, 2008, http://www.unt.se; see also Kemföretag Förökte Misskreditera Viktig Forskning, NATURSKYDDSFÖRENINGEN, Jan. 17, 2008, http://www.naturskyddsforeningen.se; Emil Schön, Kemijätte Angriper Forskare, FLAMMAN, Jan. 24,
Thereafter, the researchers provided partial hard copies of the raw data—that is, the exact information that the IRIS chemical manager had initially requested. The original hard copies of these raw data were submitted to EPA on February 21, 2008 (letter with attachments dated Feb. 21, 2008, from Niomi Krzystowczyk, Ph.D., Vice President, Health, Safety & Environment, Albemarle Corporation, to George M. Gray, Ph.D., Assistant Administrator for Research and Development, EPA; subject: individual animal data for Viberg et al. (2003, 2007)). On April 14, 2008, EPA acknowledged receipt of these raw data and stated: “In response to your letter, I am pleased to inform you that the Agency is currently examining the raw data to determine the utility and applicability of the provided data to perform further scientific analysis” (response letter dated Apr. 14, 2008, from Gray to Krzystowczyk, supra).

Despite the foregoing statement, IRIS issued the final documents on BDE-209 in June 2008 with an RfD based on the Viberg et al. (2003) study, along with a footnote that stated: “Attempts to obtain numerical values and other information on the data from the authors [i.e., Viberg et al. (2003)] were not successful” (IRIS (2008b), supra, at 32, note 1).

The above statement is factually correct—that is, Drs. Viberg and Eriksson did not provide their data to the EPA; however, the statement is also misleading. The IRIS did not disclose that prior to issuing the final BDE-209 documents, it had the Viberg et al. (2003, 2007) raw data in its possession and even evaluated them. It wasn’t until March 2010 that EPA informed a manufacturer of BDE-209 that the NCEA and the IRIS program concluded the following about the raw data for Viberg et al. (2003, 2007): “The National Center for Environmental Assessment (NCEA) evaluated the data for use in conjunction with its Integrated Risk Information System (IRIS) and concluded that the raw data could not be utilized for IRIS. No written analyses were generated as a result of the data evaluation.” This admission only came to light after the manufacturer submitted a FOIA request for EPA’s analyses of the Viberg et al. (2003, 2007) raw data (response letter dated Mar. 22, 2010, from Amy E. Battaglia, Acting Director, Office of Resources Management and Administration, EPA, to Dr. Hardy, supra; subject: FOIA Request: HQ-FOIA-00149-10).

It is unclear why EPA considered the summarized data in the Viberg et al. (2003) publication to be suitable for use in its documents on BDE-209, but the underlying raw data were not. After all, EPA requested the raw data because of its concerns over the summarized data in the publication. It stands to reason that if the raw data were not suitable for human health assessment, then a summary of those data was also not suitable for this purpose.

III. The Chemical Industry’s Research and Hazard Evaluation on BDE-209

Since IRIS issued the BDE-209 documents, an industry-sponsored DNT study was completed and published in the peer-reviewed literature (see John A. Biesemeier et al., infra) using the most recent internationally validated test guideline for evaluating DNT (i.e., Organisation of Economic Co-operation and Development (OECD) test guideline 426). EPA described the test guideline as follows: “The OECD DNT guideline represents the best available science for assessing the potential for DNT in human health risk assessment, and data generated with this protocol are relevant and reliable for the assessment of these end points” (Susan L. Makris et al., A Retrospective Performance Assessment of the Developmental Neurotoxicity Study in Support of OECD Test Guideline 426, 117 ENVIRON. HEALTH PERSPECT. 17, 17 (2009)).

Biesemeier et al. evaluated the potential for BDE-209 to cause DNT at dose levels ranging from one milligram per kilogram body weight per day (mg/kg-bw/day) up to 1000 mg/kg-bw/day (John A. Biesemeier et al., An Oral Developmental Neurotoxicity Study of Decabromodiphenyl Ether (DecaBDE) in Rats, 92 BIRTH DEFECTS RES. B DEV. REPROD. TOXICOL. 17–35 (2011)). Unlike the Viberg et al. (2003, 2007) studies that only evaluated motor activity, Biesemeier et al. performed a complete assessment of the following end points on the offspring:
detailed clinical observations (PND 4, 11, 21, 35, 45, and 60); auditory startle response (PND 20 and 60); motor activity (PND 13, 17, 21, 61, 120, and 180); early learning and memory (PND 22); late learning and memory (PND 62); and brain weight, neuropathology, and morphometry (PND 21 and 72) (id.). Biesemeier et al. did not find evidence of BDE-209-induced DNT at any of the dose levels evaluated.

As the above example with the IRIS documents illustrates, the absence of transparency when scientific data are being used for regulatory decision-making activities can lead to erroneous conclusions of hazard, as well as the unnecessary allocation of research funds and experimental animals. A number of regulatory agencies have recognized this problem and have formally issued specific screening and/or in-depth criteria for assessing the quality, reliability, and relevancy of data used in support of regulatory decisions. For example, the European Chemicals Agency (ECHA), EPA, and the European Food Safety Authority (EFSA) have issued the following guidance documents:


Utilizing the above-mentioned screening criteria by the ECHA (2008) and the more in-depth criteria from EPA (2003), Hardy et al. applied a two-tiered evaluation of the toxicology data on BDE-209 (Marcia L. Hardy et al., Toxicology and Human Health Assessment of Decabromodiphenyl Ether, 39 CRIT. REV. TOXICOL. 1, 32–33 (2009)). The Viberg et al. (2003, 2007) studies were coded as “not reliable” during the first tier evaluation because the studies “were carried out or generated according to a method which is not acceptable [see, e.g., Holson et al., supra, at 335], the documentation of which is not sufficient for an assessment and which is not convincing for an expert judgment [see, e.g., FOIA, supra]” (Hans-Joachim Klimisch et al., A Systematic Approach for Evaluating the Quality of Experimental Toxicological and Ecotoxicological Data, 25 REGUL. TOXICOL. PHARMACOL. 1, 2–3 (1997)).

IV. Conclusions

IRIS’ handling of the BDE-209 documents is troubling because, at present, EPA has no intention of updating these documents, despite the conclusions of these documents being based on less than credible studies. Despite this situation being in sharp contrast to the EPA’s administrator’s claim that decisions will be based on the best available science, the reality is that no substantive recourse is available to ensure that these documents are revised based on the best available science. IRIS documents are not regulations; therefore, there is only one possible remedy for challenging the data on which the documents are based. The IRIS documents could be challenged under the Information Quality Act by submitting a request for correction (RFC); however, RFCs are evaluated by EPA. If the RFC is denied, the petitioner may submit a request for reconsideration (RFR), which would also be reviewed by EPA. If the agency denies the RFR, no additional recourse is available because final agency decisions on RFRs, at present, are not judicially reviewable (see,
e.g., Salt Institute v. Michael O. Leavitt, 440 F.3d 156, U.S. Court of Appeals, Fourth Circuit (2006), available at http://openjurist.org/440/f3d/156/salt-institute-v-o-leavitt). Though it remains to be seen whether future judicial challenges will invalidate the Fourth Circuit precedent, Banasik et al. proposed the following solution for ensuring that government agency decisions are based on the best available science: “We encourage the [scientific] societies to require the disclosure of all underlying raw data, if requested, for manuscripts published in their journals. This transparency will afford the scientific community, as well as regulators, with the requisite information necessary to evaluate the quality and reliability of data and their relevance to risk assessment” (Marek Banasik et al., Assessing Chemical Risk: Scientists Need to Provide Raw Data, Sci., May 26, 2011, available at http://www.sciencemag.org/content/331/6021/1136.1.citation/reply#sci_el_14544). In the absence of a right to judicial review under the Information Quality Act, this type of approach is possibly the only way to ensure the level of transparency necessary to provide assurance that IRIS evaluations, as well as other scientific determinations, are based on the best available science.

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Triclosan and triclocarban are the active ingredients in antibacterial soaps, mouthwashes, shaving creams, deodorants, and other personal care products (FDA (2011) Triclosan: What Consumers Should Know, Consumer Health Information, U.S. Food and Drug Administration, 1 p., available at: http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM206222.pdf). The consumer uses of triclosan, including antibacterial soaps, are regulated by the U.S. Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (FFDCA). These compounds are under considerable scrutiny because of less than credible research studies, which claim adverse health effects to humans or the environment. As discussed herein, the controversy surrounding the safety of triclosan has stimulated congressional inquiries and lawsuits against the FDA, as well as consumer class action suits. Central to these complaints are studies that utilized novel, unvalidated experimental approaches, which are neither placed into context with the available high quality studies performed on triclosan nor the available government risk assessments (none of which identify significant risks).

On January 5, 2010, Congressman Edward Markey sent a letter to the administrator of the FDA asking for information regarding the FDA’s plans to regulate triclosan. The FDA’s response stated that it was working on a proposed rule to amend its tentative 1994 decision on triclosan and that the proposed rule would require additional data gathering regarding the safety and effectiveness of triclosan and other topical antimicrobial products. The “FDA also said that it ‘shared’ Congressman Markey’s ‘concern over the potential effects of triclosan and triclocarbon as endocrine disruptors . . .’ but that it did not yet have sufficient data to draw conclusions about the potential long-term health effects of the products” (Anthony G. Hopp, Is Triclosan the Next BPA? Probably Not, at Least for Now, 25 Toxics L. Rep. 1–6 (2010), available at http://www.wildmanharrold.com/article/123010Hopp.pdf).

In April 2010, the FDA issued a fact sheet on triclosan stating that “[t]riclosan is not currently known to be hazardous to humans,” although the FDA acknowledged that recent studies “merit further review” and announced that it would undertake a safety review of triclosan, which the FDA originally promised would be completed in the spring of 2011 (FDA, supra, at 1), but now claims will be released in the “winter of 2012” (http://www.fda.gov/forconsumers/consumerupdates/ucm205999.htm). Thus, some level of uncertainty surrounds the human health effects of triclosan exposure at environmentally relevant doses.

Not surprisingly, Congressman Markey’s inquiry and the FDA’s admissions generated considerable controversy. As discussed below, lawsuits were filed against the FDA and a manufacturer of triclosan over the safety and effectiveness of this substance. Further, several U.S. representatives formally requested that the FDA ban triclosan.

On July 27, 2010, the National Resource Defense Council (NRDC) sued the FDA to force them to issue a final rule on triclosan and triclocarban (Sarah Janssen, NRDC Sues FDA for 30 Year Delay in Regulating Antimicrobials, SARAH JANSSEN’S BLOG (2010), http://switchboard.nrdc.org/blogs/sjanssen/nrde_sues_fda_for_30_year_dela.html.). The NRDC stated that the FDA first proposed a rule that would remove these ingredients from soaps in 1978, but have been “dragging their feet” ever since, which has allowed this product to be sold without regulatory oversight for over thirty years (Sarah Janssen, FDA Still Dragging Their Feet, SARAH JANSSEN’S BLOG (Apr. 8, 2010), http://switchboard.nrdc.org/blogs/sjanssen/fda_stillDragging_their_feet.html).

The NRDC claimed that studies show that antibacterial soaps are no more effective at protecting against illness than regular soap and water (Gergana Koleva, Chemicals in “Antibacterial” Soap Said to Have More Risk than Reward, WalletPop (2010), http://www.walletpop.com/2010/07/28/chemicals-in-
Admittedly, the FDA came to the same conclusion by stating: “At this time, FDA does not have evidence that triclosan added to antibacterial soaps and body washes provides extra health benefits over soap and water” (FDA, supra). The NRDC also contended that triclosan and triclocarban are endocrine disruptors. According to the NRDC:

Laboratory studies have shown that these chemicals are endocrine-disruptors capable of interfering with hormones critical for normal development and reproduction. Such hormonal interference has the potential to cause long-term health problems including poor sperm quality and infertility, and damage to the developing brain leading to poor learning and memory. Several studies suggest that triclosan and triclocarban also may contribute to the development of antibiotic resistant bacteria [NRDC, Lawsuit Seeks Final Rule on “Antibacterial” Chemicals After 32-Year Delay, available at http://www.nrdc.org/media/2010/100727.asp].

However, on January 20, 2011, the U.S. District Court for the Southern District of New York dismissed the NRDC’s claims, holding that the NRDC lacked standing to pursue the lawsuit. The NRDC vowed to appeal (Case No. 1:10-cv-05690-AKH, Doc. No. 22 (1/20/11), but it is not clear that any appeal was ever filed.

On September 23, 2010, David Walls v. Dial Corp. was filed in the U.S. District Court for the Southern District of Illinois (David Walls v. Dial Corp. Civ. Action No. 3:10-CV-00734-WDS-DGW) (S.D. Ill.), available at www.courthousenews.com/2010/09/27/Dial.pdf). Walls was the first consumer class action filed against a manufacturer of a product containing triclosan. Nine additional lawsuits were filed over the following few months. All of the cases are currently pending in an MDL proceeding in the U.S. District Court for the District of New Hampshire, _____ F. Supp. 2d _____, 2011 WL 3654413 (J.P.M.L.).

Relying in large part on recent statements by the FDA and Congressman Edward Markey (D-Mass.), plaintiffs contend that Dial’s claims regarding the health benefits of triclosan in its antibacterial soap were false. The plaintiffs allege that soaps containing triclosan are no more effective in fighting infection than regular soap and water. Plaintiff also cites the FDA’s and Congressman Markey’s recent statements regarding the alleged health risks of triclosan, including endocrine disruption, and assert that Dial committed consumer fraud because it was allegedly aware that triclosan was both ineffective and potentially dangerous, yet sold its triclosan-containing product as a safe, antibacterial hand wash.

On November 16, 2010, U.S. Representatives Louise Slaughter (D-N.Y.), Barbara McCollum (D-Minn.), and Raúl Grijalva (D-Ariz.) sent a letter to the commissioner of the FDA calling for a ban on triclosan, based on the representatives’ concerns over this substance’s alleged impact on human health and the public water supply (three-page letter dated Nov. 16, 2010, from Louise M. Slaughter, Betty McCollum, Raúl M. Grijalva, to The Honorable Margaret Hamburg; available at http://www.louise.house.gov/images/stories/FDA_Letter_re_Triclosan_11-16-10.pdf). The foregoing lawsuits and congressional requests represent only part of the activity over the safety of triclosan. Academic researchers are also actively studying the safety of this compound. Many have reported previously unidentified properties that suggest potential health hazards. For example, researchers at the University of Florida’s College of Pharmacy announced on November 4, 2010, the results of an in vitro study in which they reported that triclosan can hinder synthesis of an enzyme linked to the metabolism of estrogen (April Frawley Birdwell, Antibacterial Agent Could Cause Pregnancy Problems, UF | HEALTh SCI. CENTER News & COMM., Nov. 4, 2010, available at http://news.health.ufl.edu/2010/14787). The lead author, Dr. Margaret James, stated that the research could have potential implications for estrogen production in humans during pregnancy; however, she was careful to qualify her findings by stating, “At this point we don’t know if the levels people are exposed to are high enough to cause an adverse effect” (id.). As discussed below, the U.S. Environmental Protection Agency’s (EPA) Office of Pesticides (OPP) performed in-depth
aggregate risk evaluations for humans from exposures to triclosan; no risk concerns were identified (EPA, Reregistration Eligibility Decision for Triclosan, List B, Case No. 2340, EPA 739-RO-8009, 98 pp., at 24–25). Interestingly, James et al. did not cite to or discuss the OPP evaluations, which were on point for Dr. James’s concern about environmental exposures and possible adverse effects (Margaret O. James et al., Triclosan Is a Potent Inhibitor of Estradiol and Estrone Sulfonation in Sheep Placenta, 36 Envtl. Int’l 942–49).

To date, no peer-reviewed papers have been published that actually demonstrate that triclosan has an adverse impact on human health. In fact, the OPP’s aggregate risk assessments on triclosan for children (≥6 years) up to adults and for infants and children (<6 years) concluded that the aggregate risks did not result in risks of concern (id.). The OPP assessment included exposures “that may occur from dietary (i.e., food and drinking water), residential, and other non-occupational sources including triclosan FDA uses such as hand soaps and toothpaste, and from all known plausible exposure routes (oral, dermal, and inhalation)” (id. at 23). It is important to note that when manufacturers register a pesticide with the OPP, they are required to submit the complete research studies including the raw data or face possible study rejection (EPA (1995) Guidelines for Study Rejection Based on GLP Considerations, Memorandum, from Dan Barolo, Director Office of Pesticides Programs, to All Division Directors, Office of Pesticide Programs, 4 pp.). Though one large-scale multi-ethnic longitudinal study of 1151 young women in the United States identified a small inverse association between triclosan and pubic hair stage, the authors noted “some or all of our findings may be due to chance [emphasis added]” (Mary S. Wolff et al., Investigation of Relationship Between Urinary Biomarkers of Phytoestrogens, Phthalates, and Phenols and Pubertal Stages of Girls, 118 Envtl. Health Persp. 1039, 1045 (2010)).

Despite the absence of any verifiable evidence of risk of harm to humans, untold millions of public and private dollars are being spent on studies to evaluate potential hazards from triclosan, a product that has been used safely for over 30 years. The industry is battling 10 consolidated lawsuits, and EPA keeps pushing back the date for release of its “further review.” Still, the NRDC and others continue to characterize triclosan as an endocrine-disrupting chemical that poses real human risk. Depending on one’s point of view, what is happening is either an effort to chase a valuable product off the market using unsubstantiated health claims, or an exercise of the “precautionary principle” where the lawsuits and bad publicity seek to protect the public from an alleged, but completely unproven, potential danger. If data demonstrating that triclosan possesses a real threat to human health and safety exist, those data have yet to be publicly disclosed.

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