IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

STYRENE INFORMATION AND RESEARCH CENTER, INC., *et al.*,	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 1:11-cv-01079-RBW**
KATHLEEN SEBELIUS, *et al.*,	)	
Defendants.	)	

PLAINTIFFS' REPLY TO DEFENDANTS' OPPOSITION TO
PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

The government admits that NTP engaged in data manipulation in reaching its conclusion to list styrene in the 12th Report on Carcinogens ("RoC"). It also does not dispute that NTP ignored the conclusions drawn by the authors of two studies that form the evidentiary basis of that listing. Even so, the government argues that Plaintiffs are not entitled to the preliminary injunction they seek.

The government first attacks Plaintiffs' standing and their claim of irreparable harm. Although there was no defect in either claim, Plaintiffs have submitted supplemental declarations to the Court that clearly demonstrate that the Styrene Information and Research Center ("SIRC") and Dart Container Corporation ("Dart") each has a "personal stake" in this litigation and that the listing of styrene on the RoC has already caused Dart to experience the beginning of deselection of its styrenic products. In the face of its admissions, the government further claims that the NTP process was appropriate and supports the listing of styrene on the RoC. To the contrary, the NTP process was flawed from the start and the many subsequent layers of scientific review did not rectify those flaws. Once the foundation was rotten no number of subsequent

blessings of that foundation can change that fact. NTP and it Expert Panel unjustifiably rejected the conclusions of the authors of the two key studies upon which NTP relies in order to justify the listing of styrene. Without those studies, the listing cannot stand. And because the listing of styrene on the RoC is the second of two conflicting determinations on styrene that HHS has issued within the past eight months, without any explanation for the contradictions, it is, on its face, arbitrary and capricious.

I. PLAINTIFFS HAVE PROVEN THAT STYRENE'S LISTING ON THE REPORT ON CARCINOGENS IS LIKELY TO CAUSE IRREPARABLE HARM AND THEY HAVE STANDING TO MAINTAIN THEIR LAWSUIT

A. Plaintiffs Have Adequately Shown Irreparable Harm

In its Opposition, the government argues that Plaintiffs "fail to demonstrate irreparable harm warranting preliminary relief." Defendant's Memorandum in Opposition to Plaintiffs' Motion for a Preliminary Hearing [Docket No. 12] ("Opp.") at 22. According to the government, Plaintiffs have offered no evidence that they have lost customers or sales or that any orders have been canceled. *Id.* at 23. The government's contentions must be rejected based on the supplemental declaration from Dart that customers are already expressing concern about the safety and health risks of styrene and that Dart is already experiencing the beginnings of deselection. *See* Declaration of Thomas A. Jewell ("Jewell Declaration") at ¶ 12, attached hereto as Exhibit A.

Furthermore, SIRC's company members likely will experience similar deselection as has been demonstrated by declarants familiar with the market for styrene and styrenic products. *See* Declaration of Michael Levy at Ex. 1, and Declaration of John Schweitzer at Ex. 2 [Docket No. 3-2] to Plaintiffs' Memorandum of Points and Authorities in Support of Plaintiffs' Motion for a Preliminary Injunction [Docket No. 3-1].

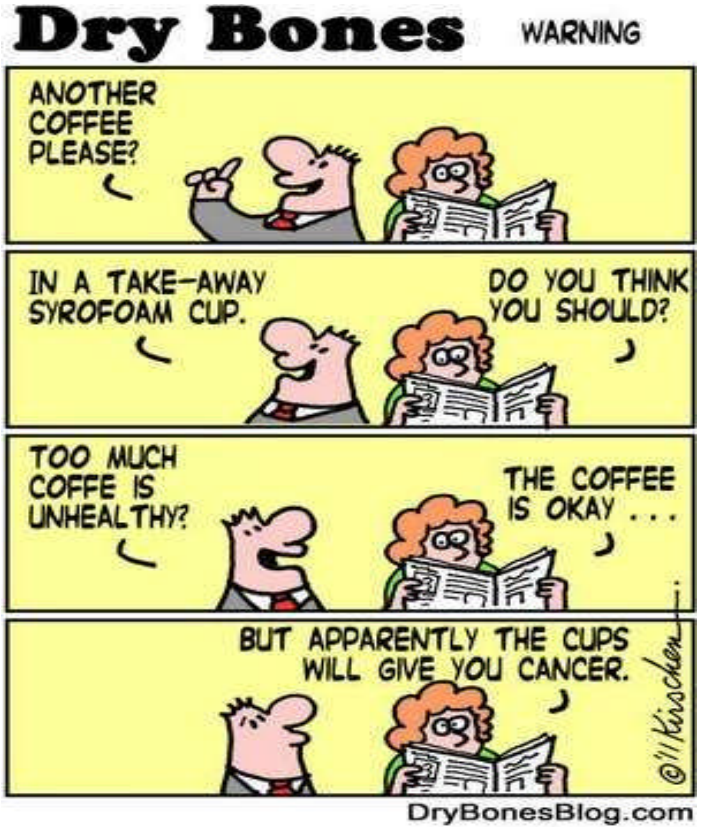
Contrary to the government's argument, the styrene listing has already triggered OSHA requirements for employers whose workers are exposed to styrene – such as Dart and many members of SIRC. On July 1, 2011, OSHA published a newsletter stating that all Material Product Data Sheets ("MSDS") for styrene must now indicate that the NTP lists the chemical as a carcinogen. OSHA Quick Takes, July 1, 2011, attached hereto as Exhibit B. Moreover, the government does not deny that OSHA now requires containers of styrene to be marked as a carcinogen; it merely claims that there is a 90-day enforcement stay on changes. Opp. at 20. But the discretionary enforcement stay does not suspend all label change obligations. Labels must be updated along with the MSDS or risk violation of the "appropriate hazard warning" requirement in the Hazard Communications Standard. *See* 29 C.F.R. § 1910.1200(f)(1)(ii). Furthermore, the likelihood of a Proposition 65 listing for styrene is not as remote as the government implies. Opp. at 20-21. An NTP listing, in and of itself, provides the basis for a Proposition 65 listing. In 2009 California tried to include styrene on the Proposition 65 list based on the IARC listing, but a court found the IARC listing insufficient. California Office of Environmental Health Hazard Assessment ("OEHHA"), "Request For Comments On Chemicals Proposed For Listing By The Labor Code Mechanism (CARCINOGENS)" (June 12, 2009), available at http://www.oehha.ca.gov/prop65/docs_admin/LCCIC061209.html. No such insufficiency exists based on the NTP listing. Additionally, a member of the California office that administers Proposition 65 was on the NTP Expert Panel and voted in favor of the listing. *See* Opp. Ex. 3 at 1 (identifying a member of the Expert Panel as working for OEHHA). Therefore, it is likely that such a listing will be forthcoming.

In total, then, there is sufficient evidence of actual harm and even more evidence of a likelihood of irreparable injury to Plaintiffs, which satisfies Plaintiffs' legal requirement on this element.

Second, the government's cramped analysis of the standard for irreparable harm is not the law in this Court. This case is on all fours with this Court's decision in *Feinerman v. Bernardi*, 558 F. Supp. 2d 36 (D.D.C. 2008) (Walton, J.). In *Feinerman* this Court preliminarily enjoined HUD's ban of plaintiff Feinerman "from future participation in transactions with the executive branch of the federal government for three years." *Id.* at 41. In finding that Mr. Feinerman had demonstrated irreparable harm sufficient to justify a preliminary injunction, the Court found that Feinerman's claims that the ban would ruin his personal and professional reputation, would interfere with his private career outside of his service on the housing authority from which the ban arose, and would foreclose public service as a career option were sufficient. *Id.* In making that finding, the Court relied on Feinerman's declaration that unless his ban was enjoined his "insurance business may be severely damaged because long-standing clients may be unwilling or unable to do business with a debarred individual and it will be difficult for him to attract new customers." *Id.* at 50.

Plaintiffs in this case are identically situated to Mr. Feinerman, and the same finding on irreparable harm should obtain. As demonstrated in Plaintiffs' supporting declarations, unless the RoC for styrene is withdrawn, Dart, as well as members of SIRC, will lose current and prospective business through the process of deselection of styrenics by customers unable or unwilling to use styrenic products. In fact, Dart reports that the deselection process has already begun. Jewell Declaration, Ex. A, at ¶ 12. Once deselection begins, it is difficult or impossible

to undo because the process involves redesigning large systems of packaging, printing, loading and marketing. *Id.* at ¶ 11. Additionally, customer and public opinions harden and the change usually remains permanent. *Id.* The listing of styrene on the RoC also will cause a loss of goodwill for styrene and will permanently alter public opinion on the safety of styrene. *Id.* In fact, that process has already begun as demonstrated in the following cartoon that was published on June 13, 2011—three days after publication of the RoC.



Dart is the world's largest manufacturer of Styrofoam cups. *Id.* at ¶ 2.

Like Feinerman, Plaintiffs have alleged sufficient likelihood of harm to support a finding on this prong of the preliminary injunction test. *See also Nalco Co. v. United States Environmental Protection Agency*, No. 11-760, 2011 WL 1882397, *10 (D.D.C. May 18, 2011)

(holding that potential loss of long-standing clients, difficulty in attracting new ones, loss of sales and loss of goodwill are sufficient to show irreparable harm).

Indeed, the damage that the listing will cause to the business reputations of Plaintiffs is itself a basis for finding irreparable harm. *See Patriot, Inc. v. U.S. Dep't of Hous. & Urban Dev.*, 963 F. Supp. 1, 5 (D.D.C. 1997) (holding that damage to business reputation satisfies irreparable harm standard).

The government also argues that economic harm cannot be irreparable unless the economic harm "is so severe as to cause extreme hardship to the business or threaten its very existence." Opp. at 22. The government tells only half the story. Government counsel in *Feinerman* made a similar argument about the economic impact of plaintiff's ban from government contracting. 558 F.Supp.2d at 51. This Court agreed "as a general matter," but went on to hold that "where, as here, the plaintiff in question cannot recover damages due to the defendants' sovereign immunity, any loss of income suffered by a plaintiff is irreparable, *per se*." *Id.* In May of this year, the court in *Nalco* agreed with the Court's ruling in *Feinerman*, holding that "EPA's actions threaten a loss of sales and goodwill for which Nalco will have no right of recourse against the federal government. Where a plaintiff cannot recover damages from the defendant due to the defendant's sovereign immunity any loss of income suffered by plaintiff is irreparable *per se*." 2011 WL 1882397, *10 (internal quotations and citations omitted).

The government cites the Court's opinion in *Nat'l Mining Ass'n v. Jackson*, No. 10-1220, 2011 WL 124194, *13 (D.D.C. Jan. 14, 2011), for the point that sovereign immunity does not compel a finding of irreparable harm. Opp. at 22 n.3. However, *Nat'l Mining Ass'n* was clear that "recoverability of monetary losses can, and should, have some influence of the irreparable

harm calculus." 2011 WL 124194, *13. In the instant case, Plaintiffs cannot maintain a claim for damages against the government. Under *Feinerman*, *Nalco*, and *Nat'l Mining Ass'n*, that fact is dispositive in the irreparable harm analysis.

B. Plaintiffs Have Standing

The government also attacks the standing of both SIRC and Dart. The government argues that SIRC lacks associational standing because it fails to identify any member who has standing in its own right. That situation has been remedied. First, Dart and other manufacturers and processers of styrene are members of SIRC. Second Declaration of John O. Snyder ("2nd Snyder Declaration") at ¶ 3, attached hereto as Exhibit C; Jewell Declaration, Ex. A at ¶ 5. SIRC has adequately pled the additional requirements for associational standing, *see* Complaint at ¶ 2; 2nd Snyder Declaration, Ex. C at ¶¶ 3-4, 6, and the government does not dispute that in its Opposition.

The government next argues that Dart failed to plead any actual, concrete injury that would entitle it to maintain this action. Although Dart has demonstrated standing under the court's *Feinerman* and *Nalco* decision, in which the court apparently found that plaintiffs had standing based on their likelihood of economic and reputational injury flowing from the complained-of government action, Dart has now supplemented the record with evidence that it manufacturers styrene, it sells products in California and the process of deselection of its styrenic products has already begun. Jewell Declaration, Ex. A at ¶¶ 5, 12. Standing has been established.

The government also relies on *Tozzi v. Dep't of Health and Human Servs.*, 271 F.3d 301 (D.C. Cir. 2002), but *Tozzi* supports Plaintiffs. *Tozzi* involved a challenge to HHS' decision to

upgrade dioxin in the 8th RoC from reasonably anticipated to be a human carcinogen to a known human carcinogen. *Id.* at 306. The government challenged the standing of a number of plaintiffs, including Brevet Industries, which manufactured disposable plastic connectors used in surgical applications. *Id.* at 307. The court held that Brevet had standing based on the fact that (1) a large percentage of Brevet's sales depending on the use of PVC plastic by the medical establishment; (2) healthcare companies have expressed concern over the dioxin hazards associated with incinerating PVC; (3) some municipalities have adopted resolutions calling for the phasing out of PVC-containing products; and (4) Brevet's profits, reputation and goodwill would be adversely affected by dioxin being listed on the RoC as a substance known to cause cancer. *Id.* at 307-08. Dart's situation is similar, and *Tozzi* support a finding that Dart has standing.

Importantly, the D.C. Circuit in *Tozzi* noted that "Congress intended the Report on Carcinogens to serve as the federal government's authoritative statement on the current state of knowledge regarding the carcinogenicity of various chemicals. . . . Congress also intended the list to serve as a resource for state, federal and local regulatory authorities." 271 F.3d at 309. The RoC, therefore, is "widely disseminated and highly influential." *Id.* As regarded dioxin in *Tozzi*, the court held that it was "not at all speculative to expect that the dioxin upgrade will cause some non-trivial number of state and local agencies to regulate dioxin." *Id.* Furthermore, in *Tozzi*, dioxin was already on the RoC as a substance reasonably anticipated to be a human carcinogen; the lawsuit was over its upgrade to known-carcinogen status. In the instant case, the stakes are even higher for styrene and its producers and manufacturers, as this is the first appearance of styrene on the RoC. But in any event, "[w]hen the government attaches an

inherently pejorative and damaging term such as 'carcinogen' to a product, the probability of economic harm increases exponentially." *Tozzi*, 271 F.3d at 309.

Because Plaintiffs have adequately demonstrated the existence of irreparable harm, the Court may conclude as a matter of law that Plaintiffs have standing to pursue their claims. The government's contention that "for Article III standing purposes, 'likely' is not enough: an injury must be 'certainly impending'" would end federal jurisdiction over claims for injunctive relief. *See* Opp. at 20. The case cited by the government for this proposition, *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 345 (2006), did not involve a claim for an injunction, but yet another futile attempt to establish taxpayer standing. Under apposite case law, as shown above, Plaintiffs have adequately pled facts necessary to satisfy the Constitutional requirements for standing.

II. THIS COURT STILL APPLIES A SLIDING SCALE WHEN ANALYZING THE FOUR PRELIMINARY INJUNCTION FACTORS

The government claims that the traditional "sliding scale" analysis of the four preliminary injunction factors "is no longer viable," based on the concurring opinion in *Davis v. PBGC*, 571 F.3d 1288, 1296 (D.C. Cir. 2009) (Kavanaugh & Henderson, JJ., concurring). Opp. at 18. The government is wrong.

In the *Davis* concurrence, Judge Kavanaugh only expressed his "tendency" to agree with a Ninth Circuit opinion finding that the sliding scale approach is "no longer controlling or viable." *Id*. at 1296. In contrast, our court of appeals has twice refused to determine whether to abandon the sliding scale approach: first in *Davis, supra*, and more recently in *Sherley v. Sebelius*, Case No. 10-5287, 2011 WL 1599685 (D.C. Cir. April 29, 2011). As a result, the sliding scale is still being applied in this circuit. *E.g., Sherley, supra* (Henderson, J., dissenting); *Jackson v. District of Columbia*, 692 F. Supp.2d 5 (D.D.C. 2010) (Roberts, J.); *In Defense of*

Animals v. Salazar, 675 F. Supp.2d 89 (D.D.C. 2009) (Friedman, J.); *Advanta Bank v. FDIC*, 684 F. Supp.2d 17, (D.D.C. 2010) (Facciola, MJ).

III. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS BECAUSE DEFENDANTS' UNEXPLAINED CONTRADICTORY POSITIONS ON STYRENE ARE ARBITRARY AND CAPRICIOUS

HHS has spoken out of both sides of its mouth on styrene, and the government has not offered this Court, or the public, any explanation for the contradictory positions. Having failed to offer an explanation for its inconsistency, HHS has acted arbitrarily, capriciously and not according to law. *See e.g., Fox v. FCC*, 129 S.Ct. 1800 (2009). In *Fox*, the Supreme Court noted that "an agency may not depart from a prior policy *sub silentio*." *Id*. at 1819. Instead, an "the agency must show that there are good reasons for the new policy." In doing so, the agency must provide a more detailed justification when "its new policy rests on upon factual findings that contradict those which underlay its prior policy. . . It would be arbitrary or capricious to ignore such matters." *Id. See also, Ramaprakash v. FAA*, 346 F.3d 1121, 1125 (D.C. Cir. 2003) (An agency's "failure to come to grips with conflicting precedent constitutes an inexcusable departure from the essential requirement of reasoned decision making."). Accordingly, agency action will be set aside as arbitrary and capricious if the agency fails to provide a reasoned explanation for its decision. *See, e.g., Massachusetts v. EPA*, 127 S. Ct. 1438, 1463 (2007) ("EPA has offered no reasoned explanation for its refusal to decide whether greenhouse gases cause or contribute to climate change. Its action was therefore arbitrary, capricious, . . . or otherwise not in accordance with law.") (ellipses in original; internal quotation marks omitted).

HHS has recently issued two evaluations of styrene: one in November 2010 from the HHS's Public Health Service, Agency for Toxic Substances and Disease Registry ("ATSDR") titled "Toxicological Profile for Styrene" ("ATSDR Report"), attached hereto as Exhibit D, and

the other on June 10, 2011, from HHS' National Toxicology Program ("NTP") titled the Report on Carcinogens, Twelfth Edition ("12th RoC"). Both reports are mandated by Congress. *See* 42 U.S.C. § 9604(i) (ATSDR) and 42 U.S.C. § 241(b)(4)(A) (NTP). Both reports were the results of years of work and were reviewed by scientists in and out of the government. Both reports purport to be based on essentially the same publicly-available, *peer-reviewed* scientific literature. Each reached a different conclusion.

In the discussion portion of its paper, ATSDR said that "[o]verall, human and animal studies suggest that styrene may be a weak human carcinogen." ATSDR Report, Ex. D at 12. In the "Public Health Statement" issued with the ATSDR report, the only information HHS included on "cancer" was that "[t]he International Agency for Research on Cancer has determined that styrene is a *possible* carcinogen." ATSDR Report at 5. Elsewhere, ATSDR has explained that this IARC ranking is not sufficient to support a list under the NTP. *See* Memorandum of Points and Authorities in Support of Plaintiffs' Motion for a Preliminary Injunction [Docket No. 3-1] at 9. And yet, NTP has now identified styrene as "[r]easonably anticipated to be a human carcinogen." 12th RoC at 383.

The government has tried to offer reasons why these reports are not contradictory. Opp. at 28-29. For instance, the government asserts that the definitions of IARC classifications demonstrate that the IARC classification for styrene supports an NTP listing (a correlation that, if correct, would result in cellular phones being listed as "reasonably anticipate to cause cancer" in a future RoC). *See* "Carcinogenicity of radiofrequency electromagnetic fields" The Lancet Oncology, Vol. 12, Issue 7, at 624-26 (July 2011) (IARC Cancer Monograph Working Group; including mobile telephones). *See* Opp. at 27. But there can be no doubt that ATSDR was

familiar with the relevant definitions when it prepared the chart showing that no such relationship exists, and HHS should be estopped now from repudiating the finding (which remained on ATSDR's website at the time this suit was filed). Also, the government cannot substitute the argument of its counsel for the agency's rationale or lack thereof. *See, e.g., SEC v. Chenery Corp*., 318 U.S. 801 (1943); *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962).

Similarly, the incomplete letter from the current Director of the National Center for Environmental Health and ATSDR to his superiors claiming that there is no contradiction between the "may be" and "reasonably anticipated to be" designations is neither acceptable nor convincing. *See* Opp. At Ex. 9. First, the letter is incomplete as it is missing the referenced attachments. Further, as it notes, it was written only to bolster HHS' litigation posture in response to positions taken by industry in correspondence with the General Counsel of HHS. An agency's position developed for litigation purposes cannot be relied upon in defending the agency's action. *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 212 (1988) (holding that "deference to what appears to be nothing more than an agency's convenient litigating position would be entirely inappropriate"). Furthermore, the letter is not part of the administrative record because there is no evidence that it was ever presented to NTP during the process of creating the NTP report. Finally, the Director's claim that to scientists and to the public "may be" and "may possibly be" mean the same thing as "reasonably anticipated" belies common usage and is not credible.[1]

[1] "Anticipate" is defined as "to expect" while "possibly" mean "perhaps; maybe." Webster's Encyclopedic Unabridged Dictionary (Gramercy Books, 1996).

Therefore, the Court need go no further. HHS's concurrent, unexplained contradictory positions on styrene are arbitrary and capricious and the 12th RoC must be withdrawn until that contradiction has been adequately explained through the appropriate process.

IV. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS BECAUSE THE NTP PROCESS WAS FATALLY FLAWED

The NTP process was fatally flawed from the beginning and no amount of subsequent review and comment could cure it.

As the 12th RoC makes clear, NTP is supposed to perform a review of the published peer-reviewed literature to determine whether the consensus of the science supports a listing the RoC. NTP was not charged by Congress with conducting original research or reanalysis of published work in support of the NTP. Rather, NTP is charged with looking for a consensus in the scientific community, based on the accumulated peer-reviewed published literature, about the carcinogenicity of a particular substance.

In the case of styrene, NTP abandoned that role. It rejected the findings of two studies and admittedly performed new analyses designed to support conclusions not drawn by the authors. Such conduct is improper. *See, e.g., General Electric Co. v. Joiner*, 522 U.S. 136, 143-44 (1997) (holding that, under *Daubert*, the trial court had not abused its discretion when it excluded proposed expert testimony that drew different conclusions than the research on which it was based); *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 270 (2d Cir. 2002) (holding that the trial court properly excluded proposed expert testimony because there was "too great an analytical gap between the conclusions reached by the authors of Dr. Moline's cited articles and the conclusions that she draws from their work."). S*ee also LeBlanc v. Chevron USA, Inc.*, 396 Fed Appx. 94 (5th Cir. 2010) (upholding exclusion of medical expert's opinion

on causation of plaintiff's injuries because the studies on which the expert purported to base his opinions did not support the conclusions the expert intended to draw).

A. The Basis of the Styrene Listing

The RoC articulated the following bases for its listing of styrene: that there is limited evidence of carcinogenicity from studies in humans, sufficient evidence of carcinogenicity from studies in experimental animals, and supporting data on mechanisms of carcinogenesis. 12th RoC at 383. Although listed collectively, only the first and second reasons would support the NTP listing.[2] But each such "finding" is based on the improper reanalysis of a study to support a conclusion different from that reached by the authors and thus is arbitrary, capricious and not in accordance with the law.

B. The Animal "Finding" is Flawed

To support the finding of "sufficient evidence of carcinogenicity from studies in experimental animals," NTP was required to find that

> There is sufficient evidence of carcinogenicity from studies in experimental animals, which indicates there is an increased incidence of malignant and/or a combination of malignant and benign tumors (1) in multiple species or at multiple tissue sites, or (b) by multiple routes of exposure, or (3) to an unusual degree with regard to incidence, site, or type of tumor, or age at onset.

According to the RoC, the "most robust" studies finding tumors in animals are a 2001 study by Cruzan and the 1979 NCI study discussed in our moving papers. Neither study supports a conclusion that styrene is "reasonably anticipated" to induce cancer in humans.

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[2] NTP provides for listing based on mechanism of action if "there is *convincing* relevant information that the agent acts through mechanisms indicating it would likely cause cancer in humans." (Emphasis added.) NTP made no such finding for styrene; at best, it found "supporting data."

The Cruzan paper found lung tumors in mice. It was considered and discussed by ATSDR. In fact, ATSDR observed that "[t]he relevance of these tumors to humans has been questioned due to species differences in the metabolism of styrene in the lungs. . . . Mice appear to be very sensitive to the induction of lung tumors, and the mechanism of inducing lung tumors is not likely to be relevant to humans." ATSDR Report at 77. Thus, HHS has concluded that the Cruzan study hardly can be evidence or an indicator of the likelihood of styrene causing cancer in humans. Even if the Cruzan study supported such a conclusion, it involves only one species and one tissue site; not enough, alone, to support an NTP listing for styrene. Thus, NTP must rely on the NCI study if it is to support a listing.

But, the NCI study cannot serve that role. The study's authors concluded that "under the conditions of this bioassay, no convincing evidence for the carcinogenicity of . . .[styrene] was obtained in Fischer 344 rats or B6C3F1 mice of either sex." Bioassay of Styrene for Possible Carcinogenicity ("NCI Study") at vii, attached hereto as Exhibit F. The authors explained that

> There was a significant positive association between styrene dosage and the incidences of a combination of adenomas and carcinomas of the lung. . . . However, the variation of the incidence of these neoplasms in historical control male mice at this laboratory *does not permit a firm conclusion of carcinogenicity*.

Id. (emphasis added). To rely on the NCI study, NTP admittedly rejected the authors' conclusions, instead developing a new conclusion based on substituted data. NTP admits that it substituted new and different control animals for those used by the study authors in order to allegedly find a causal association between styrene and cancer. Opp. at 40. NTP is not permitted to do this under its own study process, and therefore it constitutes arbitrary and

capricious conduct. Since reliance on the NTP study is also invalid, there are now no robust animal studies of styrene satisfying that prong of the NTP's listing criteria.

C. The Human Studies "Finding" is Flawed.

The finding relating to human studies is similarly flawed. To support a listing as "reasonably anticipated to be a human carcinogen" based on studies of humans, there must be "limited evidence of carcinogenicity from studies in humans, which indicates that causal interpretation is credible, but that alternative explanations, such as chance, bias, or confounding factors, could not adequately be excluded." The primary studies cited by NTP are the Kogevinas 1994 study of European workers in the reinforced-plastics industry and the Delzell 2006 study of styrene-butadiene workers in the synthetic rubber industry. But, the key study here, as HHS admits, is the Delzell study because the Kogevinas study was considered by every other governmental body that has studied styrene and did not lead to a conclusion supporting NTP listing. For example, as ATSDR stated after reviewing Kogevinas and others: "[a]lthough there are several epidemiologic studies which suggest there may be an association between styrene exposure and an increased risk of leukemia and lymphoma, the evidence is generally inconclusive due to multiple chemical exposures and inadequate documentation of the levels and durations of exposures to styrene." ATSDR Report, Ex. D at 72.[3] The Kogevinas study also was considered by IARC in its 2002 monograph on styrene that made a finding in sufficient to support the NTP listing. *See*, IARC Monographs On The Evaluation Of Carcinogenic Risks To Humans, Vol. 82 (2002) at 465-66, 469-71, and 534-535.

[3] This conclusion preceded ATSDR's discussion of both the Kogevinas studies (1993, 1994), and the Kolstad study that NTP identifies, along with Delzell, as "most informative."

That leaves only the Delzell paper, but it does not support the different result that NTP reached. NTP claims that the Delzell study demonstrates "significantly increased risks of non-Hodgkin's lymphoma, NHL-chronic lymphocytic leukemias (NHL_CLL) and leukemia (overall and specific types)" among certain subgroups of workers. However, Dr. Delzell reported that the data for NHL and NHL_CLL "did not indicate clear trends and were not statistically significant." Delzell *et al*., An Updated Study of Mortality Among North American Synthetic Rubber Industry Workers (2006), attached hereto as Exhibit E at 35. She further concluded, as noted in the abstract to the study, that "[a]fter controlling for the effects of BD [1,3-butadiene], we found no consistent exposure-response relation between . . . styrene and all leukemias, chronic myelogenous leukemia, or CLL." Finally, but most importantly, Dr. Delzell informed NTP that she did not agree with its original, tentative conclusion that her study or that of Kogevinas were strong evidence for cancer in humans based on an association between styrene exposure and non-Hodgkin lymphoma (NHL). She wrote that "[r]esults for styrene and NHL from both [Delzell and Kogevinas] studies are unconvincing." Attachment to Letter from Jack Snyder, Executive Director of SIRC, to Samuel Wilson, M.D., Acting Director of NTP's National Institute of Environmental Health Sciences (Oct. 21, 2008), attached hereto as Exhibit G. NTP utterly failed to address this repudiation which further demonstrates that its actions were arbitrary and capricious. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut.*, 463 U.S. 29, 43 (1983) ("entirely fail[ing] to consider an important aspect of the problem."). The government's opposition is also silent on this fundamental point—presumably because there is nothing it can say.

D. Peer Review

The government claims that the peer review process was appropriate. However, the government omits to explain the appropriate standard by which the Expert Panel was to "peer

review" the NTP Background Document. The Background document was a review of the literature. The Expert Panel was charged "to determine whether the information in the draft background document . . . [was] presented in a clear and objective manner, to identify any missing information from the body of knowledge presented in the document, and to determine the utility of the body of knowledge in the background document for drawing conclusions about the carcinogenicity of [styrene] and for applying the RoC criteria to the listing." Opp. at 8-9. Because the NTP Background Document was not original research, there was no basis for suggesting "modifications of data . . . analysis methods," and "recommend[ing] alternative conclusion[s]" as OMB's *Peer Review Bulletin* sanctions in cases where an original research paper is being peer reviewed. 70 Fed. Reg. 2665 (Jan. 14, 2005).[4]

Furthermore, the Panel went beyond its charge. Rather than pointing out the absence of the Delzell paper in the Background Document, it wrote an entry for the Background Document and, based on the entry, found a basis for listing styrene. In the process, as the government admits, Dr. Matanowski proposed a new analysis of Dr. Delzell's data on behalf of the epidemiology group of the Expert Panel and cited that analysis to the Panel as evidence supporting the listing of styrene. *See* Opp. at 37. Dr. Matanowski's reanalysis has never been produced. Although the government claims that that reanalysis was not adopted by the Expert Panel because it is not set out in the Expert Panel report, *id.*, it cannot say that the reanalysis did

[4] Moreover, the *Bulletin* describes those sorts of suggestions as "major changes to the draft." That point highlights Plaintiffs' argument that the NTP's process of finalizing the Background Document before it received comments on the Expert Panel's recommendations is inherently irrational. Such an illogical process can result—and did, in this case—in the final Background Document incorporating recommendations from the Expert Panel that were shown in subsequent comments to be improper.

not influence it. Instead, the Expert Panel should have returned the Background Report to NTP for consideration of the Delzell study (and any others that had been omitted)

V. THE IQA VIOLATION SUPPORTS A FINDING OF AN APA VIOLATION.

The D.C. Circuit in *Prime Time Int'l Co. v. Vilsack*, 599 F.3d 678, 685 (D.C. Cir. 2010), declared that "Congress delegated to OMB authority to develop binding guidelines implementing the IQA." As a result of this delegation of legislative authority, and because OMB acted via notice and comment (*see* reference to "public . . . involvement," *id*. at 684), the Court of Appeals applied *Chevron* deference to OMB's guidelines, *id*. at 685, which the Supreme Court has held is appropriate only for legislative rules. *See, e.g., U.S. v. Mead*, 533 U.S. 218 (2001). Thus, HHS was required to follow the IQA in issuing the RoC, and its failure to do so is a basis for invalidating its action under the APA as "not in accordance with law." 5 U.S.C. § 706(2)(A).

The government's *only* counter to Plaintiffs' point that APA review includes an evaluation of compliance with the IQA guidelines is that Plaintiffs are challenging "the intermediate steps of the listing process," and those steps are not final agency action. Opp. at 32. Plaintiffs are challenging the listing and the process through which it was issued, not the underlying documents. The *Tozzi* court was clear that publication of the RoC is final agency action, as the government recognizes. *See* Opp. at 32 (citing *Tozzi*, 271 F.3d at 310-11). The Background Report and the Expert Panel report are major components of the "comprehensive scientific review" that "culminat[ed]" in the listing, according to the government. Opp. at 1. The government cannot in the same document affirm and deny that the listing relies on them. The Background Report is not a "simpl[e] compil[ation]" of data, and the NTP *did* accept the Expert Panel's listing recommendations, including its characterization of the Delzell study.

Therefore, when the issuance of those two documents violates the IQA, HHS has acted arbitrarily and capriciously in basing its listing on them.

The government defends Dr. Matanowski's conflict of interest by claiming that she did not review her own work but NTP's discussion of it. Opp. at 38 n.9. This is a distinction without a difference. This much is clear by looking at the National Academies' *Policy on Committee Composition and Balance and Conflicts of Interest* (May 2003), which, according to the government, OMB has "direct[ed]" agencies to follow. Opp. at 38 n.9. The NAS policy states that "[A]n individual should not serve as a member of a committee with respect to an activity in which a critical review and evaluation of the individual's own work . . . is the central purpose of the activity, because that would constitute a conflict of interest. . . ." *Policy on Committee Composition* at 5, available at http://www.nationalacademies.org/coi/bi-coi_form-0.pdf. Given the centrality of the Delzell paper to the NTP's conclusions, and the fact that Dr. Matanoski previously studied that same cohort, had written a paper on it that was cited by the NTP, and was a disappointed bidder for the work that Dr. Delzell performed, she was conflicted and should not have been included on the Expert Panel.

VI. PUBLIC INTEREST

The government asserts that balance of hardship and public interest merge because the government is the opposing party. It then claims that Plaintiffs have not shown harm. However, as demonstrated above, there already has been negative press about styrene, including a cartoon linking polystyrene coffee cups to cancer; there have been customer inquiries about the meaning of the RoC, and the deselection of styrene has begun. Also, the RoC triggers other regulatory responsibilities for Plaintiffs, which NTP has acknowledged. On the other hand, the government suffers no hardship if the injunction is granted.

As to the public interest, the government claims that the public's interest in information about carcinogenic substances tips this factor in favor of the government. However, the true public interest is in reliable, accurate and consistent information about health and safety concerns, which the 12th RoC demonstrably is not. When the process of creating the RoC itself is flawed, the results cannot be relied upon. Since the requested injunction "serves the general public interest in open and accountable agency decision-making," that injunction should be issued. *See Creosote Council v. Johnson*, 555 F. Supp. 2d 36 (D.D.C. 2008).

CONCLUSION

For the reasons stated herein and in Plaintiffs' Motion for Preliminary Injunction, Plaintiffs respectfully request the issuance of a preliminary injunction ordering Defendants to withdraw publication of the RoC as it relates to styrene until the conclusion of the underlying litigation.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on July 1, 2011, a copy of the foregoing Plaintiffs' Reply to Defendants' Opposition to Plaintiffs' Motion for a Preliminary Injunction was filed with the Court's CM/ECF software and served via the same of Defendants' counsel of record.

/s/ Robert A. Sheffield
Robert A. Sheffield