IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ENVIRONMENTAL WORKING GROUP, *et al.*, Plaintiffs, – against – UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al*., Defendants.	Case No. 1:16-cv-02435-CKK

MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' AMENDED COMPLAINT

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Plaintiffs Environmental Working Group ("EWG") and Women's Voices for the Earth ("WVE") respectfully submit this Memorandum of Law, together with the declarations of Melanie Benesh ("Benesh Dec.") and Jamie McConnell ("McConnell Dec."), in opposition to the motion by defendants United States Food and Drug Administration ("FDA") and FDA Commissioner Dr. Scott Gottlieb for dismissal of plaintiffs' Amended Complaint ("AC").

PRELIMINARY STATEMENT

Plaintiffs' Amended Complaint alleges that FDA has violated the Administrative Procedure Act, 5 U.S.C. §§ 701-706 ("APA") by unreasonably delaying, and unlawfully withholding, action on a citizen petition (the "Petition") filed by plaintiff EWG more than *six years* ago. The Petition asked FDA, *inter alia*, to review whether to ban the use of formaldehyde and formaldehyde-releasing chemicals in keratin hair straighteners, given the significant health hazard that formaldehyde poses to salon workers and consumers when used in such products, and to require warning labels warning of the hazards of these products.

For years—despite FDA's awareness of overwhelming evidence of the dangers of formaldehyde exposure (including information on FDA's own website)—FDA all but ignored the Petition, providing only cursory, non-substantive responses to plaintiffs' inquiries as to the status of the Petition. Finally, after plaintiffs filed this action in December 2016, FDA issued a letter in March 2017 in the hope of mooting the lawsuit without actually taking any substantive action on the Petition.

FDA's March 2017 letter purported to "grant" the Petition's request for a review of whether to ban formaldehyde and formaldehyde-releasing chemicals from keratin hair straighteners—conceding that such a review has, at all times, been necessary and appropriate—but made clear that after six years, FDA has taken only the most rudimentary steps toward such a review. FDA then tried to use its own investigative foot-dragging as a reason to "deny" the

Petition's request for warning labels, asserting that, since FDA still had not completed its review relating to a possible ban, proceeding with the less restrictive remedy of requiring warning labels would be premature.

In their motion to dismiss, defendants argue that plaintiffs lack standing to bring this action. But both EWG and WVE satisfy the requirements for organizational standing. FDA's refusal to act has adversely impacted the activities of both of the plaintiffs, forcing them to divert funds from other advocacy programs to continue to educate the public and advocate on behalf of salon workers and consumers who are harmed by exposure to formaldehyde in keratin hair straighteners. WVE also has members of its organization who have suffered, and continue to suffer, concrete, particularized injury as a result of FDA's inaction, and thus satisfies the elements of associational standing as well.

Defendants' argument that FDA's March 2017 letter somehow moots plaintiffs' claim of unreasonable delay also is incorrect. In the Amended Complaint, plaintiffs allege that the March 2017 letter does not constitute action on the Petition, as the APA requires, and that FDA continues to unreasonably delay and unlawfully withhold such action. Plaintiffs have not received all of the relief requested, including that the Court retain jurisdiction of this matter and impose deadlines on defendants with respect to the Petition. Thus, plaintiffs' unreasonable delay claim is not moot.

Defendants' motion to dismiss for failure to state a claim also fails. The APA requires FDA to "conclude" a matter presented to it "within a reasonable time." 5 U.S.C. § 555(b). Plaintiffs have sufficiently alleged that FDA's failure to complete its review and reach a substantive decision is unreasonable in light of the substantial time that has passed since the Petition was filed and the overwhelming evidence that FDA's inaction threatens serious

consequences to human health. While defendants argue that FDA is not required to undertake a review of any kind, its decision to do so —and thereby avoid a challengeable decision to the contrary—subjects the pace of its progress to review under the APA.

To the extent that anything in the March 2017 letter constitutes "agency action" for purposes of the APA—as defendants apparently contend that FDA's "denial" of the Petition's request for a warning label requirement does—plaintiffs have sufficiently alleged that such action is arbitrary and capricious. Defendants' characterization of plaintiffs' allegations as "conclusory" ignores plaintiffs' voluminous factual allegations demonstrating the need for FDA action and the danger to the public of FDA's continued inaction, all of which contradict any reasonable determination that further information-gathering is required after six years.

For all of these reasons, the Court should deny defendants' motion to dismiss.[1]

STATEMENT OF FACTS[2]

A. The Parties

EWG, a not-for-profit corporation organized under District of Columbia law, is a research and advocacy organization dedicated to empowering people to live healthier lives in a healthier environment through its educational reports, online guides, mobile apps, and related campaigns. AC (Dkt. 19) ¶ 6. EWG's activities include advocating reform of federal cosmetics

[1] The Petition also requested that FDA investigate the marketing and labeling practices of certain manufacturers. FDA's March 2017 letter stated that FDA is still "seeking information to understand what products are on the market today and the concentration of [methylene glycol/formaldehyde] in those products, as well as what products are associated with adverse event reports, which will enable [FDA] to take additional company-specific compliance or regulatory measures in the future if such action is warranted." AC ¶ 74. While plaintiffs believe this response is grossly insufficient in light of the wealth of information already available to FDA, plaintiffs agree with FDA that judicial review of FDA's non-enforcement is limited.

[2] The Statement of Facts recites material allegations in the Amended Complaint, which must be accepted as true for purposes of this motion, and additional facts set forth in the declarations of Melanie Benesh and Jamie McConnell, which are relevant to defendants' Fed. R. Civ. P. 12(b)(1) motion.

laws to give the public greater assurance that such products are safe for use. *Id.* WVE, a not-for-profit Montana corporation, is a women-led environmental organization with the mission of amplifying women's voices to eliminate toxic chemicals that harm health and communities. *Id.* ¶ 7.

FDA is responsible for implementing the Food, Drug & Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"), including the FDCA's provisions regarding the regulation of chemical ingredients in cosmetics. AC ¶ 8.

B. The Dangers of Formaldehyde

Formaldehyde is a colorless and strong-smelling gas that occurs naturally, at least in small amounts, and has been manufactured commercially for over a century. AC ¶ 12. Among other uses, formaldehyde is an ingredient in certain cosmetic products. *Id.*

Keratin hair straighteners temporarily straighten hair by connecting strands of hair or keratin together. *Id.* ¶ 13. This connection is accomplished by using a liquid solution of keratin and a chemical cross-linking agent that are applied to hair and then set with heat from a hot hair dryer or flat iron. *Id.* Federal and state government agencies have identified numerous keratin hair straighteners that contain formaldehyde or formaldehyde-releasing compounds. *Id.*

Salon workers and consumers are at risk for formaldehyde exposure throughout the process of using such products. *Id.* For example, workers handling these products may absorb formaldehyde directly through the skin, eyes and mucous membranes to the extent they come into direct contact with the product. *Id.* Likewise, salon workers and salon patrons are at risk of inhaling the formaldehyde gas that the keratin hair straighteners release when they are exposed to heat through blow-drying or flat ironing after application to a salon customer's hair. *Id.*

Scientists have documented extensively the health risks associated with formaldehyde exposure. *Id.* ¶ 15. Formaldehyde is a sensitizing allergen, and the chance of an allergic reaction

increases with additional exposure. *Id.* Short-term effects of such exposure include eye, nose and throat irritation, anosmia, increased upper respiratory disease, dry and sore throats, respiratory tract irritation, cough, chest pain, shortness of breath and wheezing. *Id.* In addition, contact with formaldehyde-containing solutions can cause symptoms such as skin irritation and dermatitis. *Id.* The United States Agency for Toxic Substances and Disease Registry, the National Institute of Environmental Health Sciences and the International Agency for Research on Cancer classify formaldehyde as a known human carcinogen. *Id.* ¶ 16.

In light of the hazards that formaldehyde poses to human health, U.S. Occupational Safety and Health Administration ("OSHA") regulations strictly limit workplace exposure of employees to formaldehyde, and OSHA has issued a "hazard alert" warning salon workers against the use of keratin hair straighteners containing formaldehyde. *Id.* ¶¶ 18, 51. Other government and industry organizations urge even tighter restrictions on formaldehyde exposure than those mandated by OSHA regulations. *Id.* ¶¶ 19-20.

Numerous other government agencies and advocacy groups in the United States and around the world have investigated or taken action in recent years regarding formaldehyde concentrations in keratin hair straighteners. *Id.* ¶¶ 24-40. These have included:

- A 2010 Report and Hazard Alert issued by the Oregon Occupational Safety and Health Division ("Oregon OSHA"), which found that exposures to formaldehyde gas during keratin hair straightener treatments significantly exceeded recommended limits (*id.* ¶¶ 26-31);
- A Canadian public health advisory warning about excessive formaldehyde levels in keratin hair straighteners (*id.* ¶ 34);
- Product recalls in France and Italy (*id.* ¶¶ 35-36);

- A lawsuit brought by the California Attorney General against a manufacturer of keratin hair straighteners (*id.* ¶ 37);
- A recommendation by the National Institute for Occupational Safety and Health that one salon discontinue the use of the keratin straightener product (*id.* ¶ 50); and
- Letters from members of Congress and the Commissioner of the New York State Department of Health pleading for FDA action, including a second letter from members of Congress expressing concern about FDA's lack of progress (*id.* ¶¶ 45-48).

FDA is well aware of the scientific evidence regarding the dangers of formaldehyde in cosmetics. In addition to the actions noted above, in or about March 2011, at an Expert Panel meeting of the Cosmetic Ingredient Review ("CIR")—a group established by an industry trade association with FDA support—that was attended by an FDA representative, scientists expressed concern that the formaldehyde concentrations in some keratin hair straightener products rendered them comparable to "an explosive." *Id.* ¶ 23. And in a 2013 report sent to FDA, a CIR Expert Panel concluded that "formaldehyde and methylene glycol [a formaldehyde-containing solution] are unsafe for use in the present practices of use and concentration in hair-smoothing products." *Id.* ¶¶ 21.

Meanwhile, in or about April 2012, one hair stylist, WVE member Jennifer Arce, delivered 40 letters from fellow salon workers to FDA, requesting an immediate recall of formaldehyde-containing products. *Id.* ¶ 56; McConnell Dec. ¶ 6. These letters provided detailed accounts of the health effects suffered by salon workers in connection with the use of these products. AC ¶¶ 56-57. A number of these workers subsequently traveled to Washington,

D.C., to tell their stories, meeting with members of Congress and several agencies, including FDA. *Id.* ¶ 58.

In addition, FDA has received as many as 188 adverse event reports since 2008 documenting ill effects attributed to the use of hair-straightening products. *Id.* ¶ 59. These adverse event reports describe symptoms including burning throat, nose, scalp and face; extreme hair loss; chest discomfort; change in heart rate; blisters in the nose; migraines; nausea; insomnia; flu symptoms; shaking; and even hearing loss. *Id.* More than a thousand people have contacted FDA requesting that the agency issue a voluntary recall of keratin hair-straightening products that contain or release formaldehyde, and nearly 20,000 people have signed a petition asking FDA to recall these products. *Id.* ¶ 61.

FDA internal emails further demonstrate FDA's longstanding awareness of the public's concern about these products and the need for FDA involvement. *Id.* ¶ 62. A September 2011 FDA email regarding a manufacturer's response to an FDA warning letter stated that "[a]s most of you are aware, the public curiosity relative to this case has been vast and the events reported by way of use of this product has been unfavorable by some measure. Our report and further actions will no doubt set a precedent for future cases (if present) and establish our position with these keratin hair straightening treatments." *Id.*

C. The Petition

On or about April 12, 2011, as concerns over keratin hair-straightening products continued to mount, EWG filed its Petition, requesting that FDA take immediate action to protect the public from formaldehyde-containing keratin hair straighteners. *Id.* ¶ 41. The Petition requested that FDA (i) investigate the marketing and labeling practices of certain manufacturers and respond appropriately; (ii) require manufacturers of keratin hair straighteners to label their products in a manner that discloses the extent to which they contain formaldehyde or

formaldehyde-releasing chemicals; and (iii) review whether to ban the use of formaldehyde and formaldehyde-releasing chemicals in the manufacture of keratin hair straighteners. *Id.* ¶ 43. FDA filed the Petition and assigned it a docket number on or about April 14, 2011. *Id.* ¶ 44.

However, during the six years that have passed since EWG filed the Petition, FDA has done little by way of response. In compliance with regulations requiring that FDA respond to citizen petitions within 180 days of receipt, FDA sent EWG a tentative response to the Petition on or about September 6, 2011. *Id.* ¶ 63. The tentative response stated only that due to "competing priorities," the agency was unable to reach a decision on the Petition and was still evaluating it. *Id.*

After another six months passed without further response, on March 7, 2012, EWG wrote to FDA requesting an update on the status of the Petition and urging FDA to exercise greater leadership in dealing with the important matters of cosmetic safety the Petition raised. *Id.* ¶ 64. More than four months later, on July 27, 2012, FDA responded only that the Petition remained under review and that "as a matter of policy" FDA does not provide detailed status reports concerning its evaluation of citizen petitions under review. *Id.* ¶ 65. EWG did not receive any further communication from FDA about the Petition until, more than four years later, plaintiffs filed this lawsuit. *Id.* ¶ 66.

Meanwhile, in November 2014, WVE, frustrated by FDA's inaction, published a report titled "Beauty and Its Beast—Unmasking the Impacts of Toxic Chemicals on Salon Workers." *Id.* ¶ 67. The report noted that beauty salon workers who were exposed to formaldehyde gas experienced severe irritation to the eyes, nose and throat, and that long-term exposure to formaldehyde in the workplace has been associated with an increased risk of cancer. *Id.* In October 2015, WVE wrote to FDA about its progress with respect to regulating keratin hair-

straightening products. *Id.* FDA replied to WVE that it was reviewing all of the data on formaldehyde and hair straighteners as a category, and would provide more specific responses to WVE's questions in the future. *Id.* ¶ 68. WVE never received those responses. *Id.* ¶ 69.

D. FDA's March 2017 Letter

On December 13, 2016, having received no substantive response to the Petition for more than five and one-half years, plaintiffs filed this action. *Id.* ¶ 70; Dkt. 2. Defendants requested and received an extension of time to respond to the original Complaint until March 30, 2017, representing that FDA intended to respond to the Petition on or before that date. AC ¶ 70.

On March 29, 2017, one day before the due date for defendants' response to the original Complaint, FDA issued a letter purporting to respond to the Petition (the "March 2017 Letter"). *Id.* ¶ 71. With respect to the Petition's request that FDA review whether to ban the use of formaldehyde and formaldehyde-releasing chemicals, the March 2017 Letter admitted that FDA had failed to complete, or even make significant progress toward completing, such a review: "We have not yet made a determination about whether a safe level for the use of [methylene glycol/formaldehyde] in hair smoothers can be established as opposed to a ban. Our next steps in the process would be to complete our scientific evaluation and conduct an analysis of the risks posed to users under the conditions as labeled, or as customary or usual, and then make our ultimate analysis and data available for public comment." *Id.* ¶ 76. Nothing in the March 2017 Letter suggested when these "next steps" would be taken. *Id.*

To the contrary, the March 2017 Letter made clear precisely how little effort FDA had expended on the issue in the six years since the Petition was filed. The primary accomplishment reported in the March 2017 Letter was FDA's request for and receipt of the results of "literature searches for scientific publications concerning the toxicity of formaldehyde-releasing hair smoothers." *Id.* ¶ 71.

The March 2017 Letter denied EWG's request that it require warning labels to warn consumers about the dangerous levels of formaldehyde in keratin hair-straightening products—not because of any determination that warning labels were unnecessary or inappropriate, but because of FDA's own failure to complete its analysis of the chemicals in the products. *Id.* ¶ 76. Again, FDA provided no time frame for completing its review, effectively offering its own investigative delay as an excuse for its lack of progress. *Id.* More than six years after the Petition was filed, FDA has neither analyzed the issue nor determined that no investigation or action is necessary or appropriate.

E. The Impact of FDA's Delay on Plaintiffs

Plaintiffs EWG and WVE have dedicated substantial time and economic resources in their effort to focus FDA's attention on regulating these harmful products, even to the detriment of the other important activities of their organizations. As a result of FDA's delay in responding to its Petition, EWG has expended funds to conduct investigative research and publish articles regarding the cosmetic dangers associated with formaldehyde in hair straighteners; the ban on hair keratin products in countries outside the United States that remain on the market in this country; and the fact that formaldehyde has been classified repeatedly by scientists, government agencies and others as a known human carcinogen. Benesh Dec. ¶ 4. EWG has also spent significant resources promoting legislation to address cosmetics reform, including the issue of formaldehyde in hair straighteners. *Id.* ¶ 6. Over the past six years, EWG has spent over $1.3 million to combat the hazardous cosmetics ingredients and advocate for reforms to the laws that regulate cosmetics in the United States. *Id.* ¶ 8. A substantial portion of these expenses were necessitated by FDA's inaction on the Petition. *Id.*

FDA's delayed response to the Petition has also required WVE to expend substantial effort to educate the public and focus FDA's attention on this issue. In addition to the "Beauty

and Its Beast" report published in 2014, WVE published a detailed list of all hair-straightening products containing formaldehyde, including the recalls of such products in other countries. McConnell Dec. ¶ 10. WVE also prepared a list of hair straighteners tested by Oregon OSHA and/or Health Canada that were found to contain varying levels of formaldehyde. *Id.* ¶ 11. WVE further prepared and posted to its website a detailed timeline of FDA's inaction related to keratin hair straighteners through 2015; organized two in-person meetings involving salon workers with FDA concerning the impact of formaldehyde from keratin hair straighteners in 2012 and 2014; sent emails and letters to FDA concerning the toxic chemicals in these hair products; engaged in grass roots efforts to encourage WVE members to contact FDA directly to take action on the hair products, using a link on the WVE website and an online petition; organized congressional briefing sessions; and set up an informational webinar for salon workers regarding how to protect themselves from toxic chemicals such as formaldehyde. *Id.* ¶ 12. WVE also researched and profiled member salon workers' stories in communication materials, including in its annual appeals and annual report, and created a survey to collect specific information from hair workers who had been directly impacted by keratin hair straighteners. *Id.* These efforts required WVE to divert resources away from other issues in which it engages in advocacy, with over $371,000 spent over the past six years on the keratin hair straightener issue. *Id.* ¶ 13.

ARGUMENT

Courts considering motions to dismiss pursuant to Fed. R. Civ. P. 12(b)(1) or Fed. R. Civ. P. 12(b)(6) "treat the complaint's factual allegations as true ... and must grant plaintiff 'the benefit of all inferences that can be derived from the facts alleged.'" *Sparrow v. United Air Lines, Inc.*, 216 F.3d 1111, 1113 (D.C. Cir. 2000) (quoting *Schuler v. United States*, 617 F.2d 605, 608 (D.C. Cir. 1979)) (internal citation omitted); *see also Jerome Stevens Pharms., Inc. v.*

FDA, 402 F.3d 1249, 1253 (D.C. Cir. 2005). On a motion to dismiss, whether for lack of subject matter jurisdiction or for failure to state a cause of action, the allegations of the complaint should be construed favorably to the pleader. *PDK Labs, Inc. v. Reno*, 134 F. Supp. 2d 24, 28 (D.D.C. 2001) (Rule 12(b)(1)) (citing *Walker v. Jones*, 733 F.2d 923, 925–26 (D.C. Cir. 1984)); *see also Center for Biological Diversity v. Tidwell*, No. 15-2176, 2017 WL 943902, at *7 (D.D.C. March 9, 2017) (Rule 12(b)(6)).

When a court considers a motion to dismiss under Rule 12(b)(6), it "tests the legal sufficiency of the factual allegations that appear on the face of the complaint." *See R.J. Reynolds Tobacco Co. v. U.S. Dep't of Agric.*, 130 F. Supp. 3d 356, 369 (D.D.C. 2015). For a plaintiff to survive a motion to dismiss under Rule 12(b)(6), it need only allege "enough facts to state a claim to relief that is plausible on its face" and to "nudge [ ] [his or her] claims across the line from conceivable to plausible." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "[O]nce a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint." *Id.* at 563.

In reviewing a Rule 12(b)(1) motion, a court "may consider materials outside the pleadings in deciding whether to grant a motion to dismiss for lack of jurisdiction." *Jerome Stevens Pharms.*, 402 F.3d at 1253; *see also Center for Biological Diversity v. Environmental Protection Agency*, 861 F.3d 174, 183-185 (D.C. Cir. 2017) (considering declarations submitted by plaintiffs in evaluating standing). The Court considers "the complaint supplemented by undisputed facts evidenced in the record, or the complaint supplemented by undisputed facts plus the court's resolution of disputed facts." *Coalition for Underground Expansion v. Mineta*, 333 F.3d 193, 198 (D.C. Cir. 2003).

A. Plaintiffs have standing to bring their claims.

The Court should deny defendants' motion to dismiss this action, at the pleading stage, for lack of standing so long as plaintiffs demonstrate that they "suffered a concrete and particularized injury that is either actual or imminent, that the injury is fairly traceable to the defendant, and that it is likely that a favorable decision will redress that injury." *Massachusetts v. EPA*, 549 U.S. 497, 517 (2007). EWG and WVE meet that standard here.

1. Injury in fact

An association plaintiff can establish injury in fact through organizational standing or associational standing. *Nat'l Taxpayers Union, Inc. v. United States*, 68 F.3d 1428, 1435 (D.C. Cir. 1995); *People for the Ethical Treatment of Animals v. U.S. Dep't. of Agriculture*, 797 F.3d 1087 (D.C. Cir. 2015). Both plaintiffs meet the requirements for organizational standing, and WVE meets the requirement for associational standing as well.

a. Organizational standing

Both plaintiffs fulfill the requirements for organizational standing. Organizational standing requires only that the plaintiff allege "concrete and demonstrable injury to [its] activities— with a consequent drain on the organization's resources—constituting more than simply a setback to [its] abstract social interests." *Citizens for Resp. and Ethics in Washington v. F.E.C.*, No. 16-259, 2017 WL 1080920, at *8 n. 5 (D.D.C. March 22, 2017) (citations omitted). An organizational plaintiff is considered to have suffered an injury in fact if it "undert[akes] expenditures in response to, and to counteract, the effects of [a] defendant['s] [challenged conduct]." *Equal Rights Center v. Post Properties, Inc.*, 633 F.3d 1136, 1140 (D.C. Cir. 2011).

Both plaintiffs here have undertaken precisely such expenditures as a result of FDA's failure to act on the Petition. EWG has been required to continue to educate and advocate on behalf of the public to address the issue of formaldehyde in hair straightening treatments.

Benesh Dec. ¶ 6. EWG has not only worked on and promoted reports on these products, but has also been actively working to promote legislation introduced in Congress that would change the way personal care products, including formaldehyde hair straighteners, are regulated. *Id.* The legislation would require FDA, within a year of enactment, to initiate precisely the review of formaldehyde in products like hair straighteners that FDA has delayed conducting in response to the Petition. *Id*. EWG also created a website seal to help consumers quickly identify personal care products meeting EWG's high safety standards. *Id.* ¶ 8. Over the past six years, EWG has spent more than $1.3 million to combat hazardous cosmetic ingredients and advocate for reforms to cosmetics regulation in the United States, a substantial portion of which are attributable to EWG's efforts to address the dangers of exposure to formaldehyde in keratin hair straighteners, and were necessitated by FDA's inaction on the Petition. *Id*.

Also as a result of FDA's lengthy and ongoing delay in acting on the Petition, over the past six or seven years WVE—which has an approximate annual budget of only $500,000—has spent approximately $371,000 working on efforts related to the keratin straightener issue. McConnell Dec. ¶ 13. WVE has spent substantial time and resources communicating with members of the government, drafting articles and press releases, conducting research, creating lists and databases with important information regarding these formaldehyde hair straighteners, and engaging in related activities. *Id.* ¶ 12. If FDA had taken timely action on the Petition, WVE would not have been forced to take these actions and divert funds from other important projects of the organization.

Such activities meet the standards for organizational standing. *See People for the Ethical Treatment of Animals*, 797 F.3d at 1093 (PETA adequately pleaded standing at dismissal stage by allegations that USDA's delay injured its interests and, consequently, PETA expended

resources to counteract those injuries to the detriment of its other activities); *Scenic America, Inc. v. U.S. Dep't of Transportation*, 983 F. Supp. 2d 170, 176-177 (D.D.C. 2013) (organization alleged sufficient injury, and thus had standing to challenge agency action regarding certain billboards, where organization was forced to engage in education and advocacy efforts "which had a drain on the organization's resources dedicated to its other conservation programs").

b. Associational standing in a representational capacity

An association has Article III standing to sue if: "(1) at least one of its members would have standing to sue in his own right; (2) the interest it seeks to protect is germane to its purpose; and (3) neither the claim asserted nor the relief requested requires the member to participate in the lawsuit." *Center for Biological Diversity v. EPA*, 861 F.3d at 182. When more than one association brings suit, only one party with standing is necessary to satisfy the requirement. *Id.* Here, WVE has associational standing.

WVE's membership includes at least 20 salon workers, many of whom have been directly impacted by exposure to formaldehyde from keratin hair straighteners currently on the market. McConnell Dec. ¶ 5. These include Jennifer Arce, whose story is published on the WVE website and describes symptoms that escalated into bloody noses, blistery rashes, and choking on phlegm in her sleep. Arce also had "[b]ronchitis for the first time in [her] life and … even cough[ed] up chunks of blood." *Id.* ¶ 6. The WVE website also tells the stories of other salon worker members, identified by first name only, who experienced similar symptoms to Ms. Arce. These include Dawn, who details how she became nauseous and dizzy when applying the straightener to her customers, writing that she was diagnosed with formaldehyde poisoning and developed asthma as a result of inhaling formaldehyde fumes, and Natalija, who details how exposure to formaldehyde left her with chronic sinus and respiratory infections that prevented her from sleeping. *Id.* ¶ 7.

These members would have standing to sue in their own right, as they have suffered actual and threatened concrete injuries to their health and their ability to maintain their livelihood. Thus, WVE satisfies the first requirement of associational standing: that at least one member would have standing to sue in his/her own right. *See Center for Biological Diversity v. EPA*, 861 F.3d at 183 (plaintiff organization suffered injury where agency's decision to permit the use of a certain active ingredient in pesticides impacted insects in natural habitats that were observed and visited by one or two members of plaintiff); *Scenic America, Inc. v. U.S. Dep't. of Transportation*, 836 F.3d 42, 54 (D.C. Cir. 2016) (plaintiff offered sufficient evidence of representational injury in fact for APA § 706 claim where one member suffered a concrete injury because a digital billboard near her home generated flashing lights and marred the view out of her home); *Sierra Club & La. Envtl. Action Network v. EPA*, 755 F.3d 968, 973 (D.C. Cir. 2014) (plaintiffs demonstrated that four of their members faced "substantial and concrete risk of harm," including health and environmental consequences, as a result of their potential exposure to a gasification process due to their proximity to a refinery).

As to the second and third requirements for associational standing, the interest that WVE seeks to protect—the regulation of toxic chemicals in cosmetics—is germane to its purpose as an environmental organization, and neither WVE's claim for relief under the APA nor the relief requested, judicial oversight of FDA's response to the Petition, requires the participation of WVE's individual members as plaintiffs. *See, e.g., Center for Biological Diversity v. EPA*, 861 F.3d at 182 ("no difficulty" holding that plaintiff met second and third elements of associational standing where plaintiff was "dedicated to the protection and enjoyment of the environment" and sought judicial oversight over agency as a result of agency's alleged failure to act).

2. Causation and Redressability

Defendants apparently do not dispute—and cannot reasonably dispute—that plaintiffs satisfy the causation and redressability requirements to establish standing. Where, as here, a plaintiff asserts a "procedural right to protect [its] concrete interests," it may do so "without meeting all the normal standards for redressability and immediacy." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 573 n. 7 (1992). "When a litigant is vested with a procedural right, that litigant has standing if there is some possibility that the requested relief will prompt the injury-causing party to reconsider the decision that allegedly harmed the litigant." *Massachusetts v. EPA*, 549 U.S. at 518.

Thus, plaintiffs need not demonstrate that the ultimate outcome of FDA's decision-making process will be favorable to them in order to have standing to challenge an agency's unreasonable delay. *See Nine Iraqi Allies v. Kerry*, 168 F. Supp. 3d 268, 291-93 (D.D.C. 2016) (injury in fact sufficiently established where government agencies had failed to make final decisions on certain immigrant applications within requisite time period regardless of the substantive results of applications to be adjudicated). Rather, it is sufficient that "there is some possibility" that completion of FDA's review will lead to the requirement of warning labels and/or a ban on the use of formaldehyde in hair-straightening products—either of which would prevent further injury to plaintiffs and their members. *See Massachusetts v. EPA*, 549 U.S. at 518.

B. Plaintiffs' § 706(1) claim is not moot.

FDA's argument that the March 2017 Letter—sent before the filing of the Amended Complaint—somehow moots plaintiffs' claims is simply incorrect. "A case is moot 'when the challenged conduct ceases such that there is no reasonable expectation that the wrong will be repeated' in circumstances where it becomes impossible for the court to grant any effectual relief

whatever to the prevailing party." *United States v. Philip Morris USA, Inc.*, 566 F.3d 1095, 1135 (D.C. Cir. 2009) (internal quotation marks omitted). This is not the case here.

In a mootness inquiry, the issue is not whether the plaintiffs are entitled to the relief requested, but whether they have received that relief. *See, e.g., Fares v. Smith*, No. 16-1730, 2017 WL 1319716, at *3 (D.D.C. Apr. 7, 2017) (Kollar-Kotelly, J.) (case not moot because "although the government contends that Plaintiffs have received all the disclosure that they are entitled to, Plaintiffs have not received all the relief that they have sought in their Complaint"). Here, the relief requested by plaintiffs is not merely that FDA provide some "response" to the petition, but that it act on the petition in a manner that is reasonable in light of the six-year period that has passed since the petition was filed. *See, e.g.*, AC ¶¶ 4, 92 ("alleging that "the response did not act upon EWG's Petition" but "offered only vague assurances that [FDA] would continue to monitor and investigate keratin hair straighteners" and that the March 2017 Letter "did not act on the requests made in the Petition, and the FDA has failed to act on those requests"). Plaintiffs have not received that relief and have expressly alleged that the actions taken by FDA to date are legally insufficient. Therefore, the case is not moot.[3]

C. Plaintiffs have stated a claim under § 706(1) .

The APA imposes a "nondiscretionary duty upon an administrative agency to pass upon a matter presented to it 'within a reasonable time,' 5 U.S.C. § 555(b), and authorizes a reviewing

[3] *Henley v. FDA*, 873 F. Supp. 776 (E.D.N.Y. 1995), on which defendants rely, is inapposite. In *Henley,* FDA denied the plaintiff's petition after concluding that scientific evidence no longer supported granting the relief requested. *Id.* at 778. FDA thus "concluded" the matter, as the APA required. *See* 5 U.S.C. § 555(b). Here, FDA has made no such finding; rather, it has continued to delay completing the review it claims is necessary to conclude the matter raised by the Petition. Similarly, in *Nat. Resources Def. Council v. FDA*, 760 F.3d 151, 156 (2d Cir. 2014), FDA denied petitions to withdraw its approval for sub-therapeutic use of antibiotics in animal feed, explaining that it had decided to pursue a more efficient strategy for combatting the ill effects of such uses. *Id.* at 156-57. Again, FDA's decision, unlike its March 2017 Letter here, concluded the matter.

court to 'compel agency action unlawfully withheld or unreasonably delayed.'" *Mashpee Wampanoag Tribal Council, Inc. v. Norton*, 336 F.3d 1094, 1099 (D.C. Cir. 2003). "Simply put, the APA imposes a duty on Defendants to act within a 'reasonable' time on Plaintiffs' applications . . . ." *Nine Iraqi Allies*, 168 F. Supp. 3d at 293.

FDA contends that it already has "acted" on the Petition by writing a letter, six years after the Petition was filed, that does little more than promise to collect information about keratin hair straighteners. But the Petition requested that FDA review the scientific evidence regarding exposure to formaldehyde in keratin hair straighteners and make a determination about the need for further regulation—whether in the form of required warning labels, or in the form of an outright ban. FDA has neither conducted the review nor determined it to be unnecessary. Thus, FDA has not "acted" on the Petition at all, but has merely promised to do so at some unspecified time.

Courts analyzing claims of unreasonable delay consider six factors:

(1) the time agencies take to make decisions must be governed by a rule of reason;

(2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason;

(3) delays that might be reasonable in the sphere of economic regulations are less tolerable when human health and welfare are at stake;

(4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority;

(5) the court should take into account the nature and extent of the interests prejudiced by the delay; and

(6) the court need not find any impropriety lurking behind agency lassitude in order to hold that an agency action is unreasonably delayed.

Telecom. Research & Action Ctr. v. FCC ("TRAC"), 750 F.2d 70, 80 (D.C. Cir. 1984).

Many of these issues involve questions of fact. "Resolution of a claim of unreasonable delay is ordinarily a complicated and nuanced task requiring consideration of the particular facts and circumstances before the court." *Mashpee Wampanoag Tribal Council, Inc. v. Norton*, 336 F.3d at 1100. In *Shinnecock Indian Nation v. Kempthorne*, No. 06-5013, 2008 WL 4455599 (E.D.N.Y. Sept. 30, 2008), after "reviewing the allegations in the complaint—and particularly in light of the highly fact-based nuanced review required for unreasonable delay claims," the court declined "to conclude as a matter of law at the motion to dismiss stage" that there had been no unreasonable delay. *Id.* at *22; *see also Tummino v. Von Eschenbach*, 427 F. Supp. 2d 212, 231 (E.D.N.Y. 2006) ("given that a 'rule of reason' ultimately governs the issue of unreasonable delay, some inquiry into the reasons offered for the delay must be permitted").

The Amended Complaint sufficiently alleges that a six-year delay in beginning to conduct even basic research is unreasonable. Plaintiffs have alleged in detail the health risks associated with exposure to formaldehyde in keratin hair straighteners, including "eye, nose and throat irritation, anosmia, increased upper respiratory disease, dry and sore throats, respiratory tract irritation, cough, chest pain, shortness of breath and wheezing." AC ¶ 15. Plaintiffs have further alleged that several government agencies consider formaldehyde a known or suspected carcinogen. AC ¶ 16. These allegations support plaintiffs' claim of unreasonable delay, as "delays that might be reasonable in the sphere of economic regulations are less tolerable when human health and welfare are at stake." *See TRAC*, 750 F.2d at 80.

Plaintiffs have further alleged that FDA is already aware of overwhelming scientific evidence of the harmfulness of formaldehyde-containing keratin hair straighteners, including:

- CIR – a cosmetic industry organization supported by the FDA and dedicated to the safety of cosmetic ingredients – has concluded, in a report made available to FDA, that "formaldehyde and methylene glycol are unsafe for use in the present practices of use and concentration in hair smoothing products" (AC ¶¶ 21-22);
- At a CIR expert panel meeting attended by FDA, scientists observed that the leave-on concentrations in certain keratin hair products rendered them "like an explosive" (AC ¶ 23);
- Half a dozen members of Congress have urged FDA—twice, given FDA's inaction after the first request—to take action to protect workers and consumers from formaldehyde-containing keratin hair straighteners, noting that six countries had banned the products altogether due to their effect on human health (AC ¶¶ 45, 48);
- The Commissioner of the New York State Department of Health similarly requested that FDA take action, citing product tests conducted by the Oregon Department of Consumer and Business Services and the European Directorate-General of Health and Consumer Affairs (AC ¶ 47);
- OSHA issued a "hazard alert" warning stylists against the use of formaldehyde-containing keratin hair straighteners, citing, *inter alia*, air tests showing formaldehyde above permissible limits in salons using certain such straighteners (AC ¶ 51);

- FDA received numerous letters from salon workers, who subsequently met with FDA and other agencies, describing the adverse health effects they suffered in connection with their exposure to the hair-straightening products (AC ¶¶ 56-58); and
- FDA received nearly 200 adverse event reports documenting ill effects relating to the use of hair-straightening products (AC ¶ 59).

Against this backdrop, plaintiffs have alleged ample facts to support their claim that FDA has unreasonably delayed, and unlawfully withheld, acting on the Petition. Rather than collect any information necessary and reach a final determination as to what, if any, action is appropriate, FDA has barely begun the information-gathering process. In six years, FDA has admitted that it has merely (i) requested "literature searches for scientific publications concerning the toxicity of formaldehyde-releasing hair smoothers"; (ii) begun "market research" in order "to gain a better understanding of the prevalence" of the product; and (iii) begun "analyzing" its own internal information and publicly available information. Def. Opp., Ex. B, Dkt. 20-3, at 5. Defendants offer no explanation why six years has been an insufficient period of time for FDA to collect and analyze the information it deems necessary to act on the Petition. Indeed, defendants do not so much as even hint at when FDA will complete its analysis and reach a final decision about what, if any, action to take.

FDA's dilatory pace infects both plaintiffs' request that FDA review whether to ban the use of formaldehyde or formaldehyde-releasing chemicals in the manufacture of keratin hair straighteners—a review that has not occurred, despite FDA's claim that it has "granted" plaintiffs' request—and plaintiffs' request that FDA require such products to contain labels disclosing their formaldehyde-containing content. While FDA denied the latter request "at this

time," its basis for doing so was its own failure to act on plaintiffs' request that it review whether to ban the products altogether. Dkt. 20-3 at 7.

Such a denial is tantamount to an unreasonable delay. "At some point administrative delay amounts to a refusal to act, with sufficient finality and ripeness to permit judicial review." *Environmental Defense Fund, Inc. v. Hardin*, 428 F.2d 1093, 1100 (D.C. Cir. 1970). The APA empowers courts to order an agency to act to carry out its statutory mandates when "agency recalcitrance is in the face of a clear statutory duty or is of such magnitude that it amounts to an abdication of statutory responsibility." *Public Citizen Health Research Group v. Commissioner, Food & Drug Admin.*, 740 F.2d 21, 32 (D.C. Cir. 1984). More importantly, "even when agency delay or recalcitrance does not rise to a level that justifies either of the above courses, APA empowers the court to evaluate the pace of the agency decisional process and to order expedition if the pace lags unreasonably." *Id.*

In *Public Citizen Health Research Group v. Auchter*, 702 F.2d 1150 (D.C. Cir. 1983), a citizen petitioner challenged OSHA's denial of a petition for an emergency standard regulating industrial exposure to ethylene oxide. The district court directed OSHA to issue such a standard. On appeal, the D.C. Circuit held that the district court had improperly substituted its evaluation for that of OSHA. *Id.* at 1157. The court also, held, however, that in light of "[a]mple evidence in the record indicat[ing] a significant risk" that some workers were encountering serious danger to their health, OSHA's refusal to assign the rulemaking "any priority status" constituted an unreasonable delay of agency action. *Id.* Given the potential harm at issue, the court stated, "a more than three-year span from [plaintiff's] petition to projected final regulation is not tolerable." *Id.* at 1154.

Similarly, plaintiffs here have alleged substantial evidence of the risk posed by formaldehyde-containing keratin hair straighteners to the health of salon workers and customers who are exposed to them. FDA itself has acknowledged this risk, noting in the March 2017 Letter that its website provides "detailed safety information regarding such products," including "the fact that formaldehyde released into the air can cause serious irritation to the eyes, nose, and lungs, and the fact that studies of workers exposed to high levels of formaldehyde . . . found that formaldehyde causes certain cancers." Dkt. 20-3 at 4. Plaintiffs have sufficiently alleged that, as in *Auchter*, "[a]mple evidence in the record indicates a significant risk" of serious harm to the health of salon workers and customers exposed to formaldehyde-containing keratin hair straighteners. *See Auchter*, 702 F.2d at 1157. And the pendency of FDA's action on the Petition is now at six years and counting, or approximately twice the period the court in *Auchter* found "not tolerable." *See id.* at 1154.

FDA's argument that it cannot be compelled by a court under § 706(1) to undertake a particular investigation misses the point. FDA could have denied the Petition in its entirety, refused to undertake any investigation at all, and attempted to articulate a non-arbitrary basis for its refusal—and plaintiffs could have challenged FDA's decision and the underlying reasoning under the APA. But by purporting to "grant" the Petition's request for a review, without actually completing the review, or even committing to a time frame within which it will do so, FDA is delaying action on the Petition. "Judicial review of decisions not to regulate must not be frustrated by *blind* acceptance of an agency's claim that a decision is still under study." *Sierra Club v. Gorsuch,* 715 F.2d 653, 659 (D.C. Cir. 1983) (emphasis in original). And plaintiffs have adequately alleged that FDA's six-year delay in this case is unreasonable, particularly in light of the minimal progress to date.

When a court finds unreasonable delay, an appropriate remedy may include "ordering rulemaking to begin immediately and proceed expeditiously, and ordering periodic reports to the court concerning the pace of the rulemaking." *Public Citizen v. FDA*, 740 F.2d at 35; *see also TRAC*, 750 F.2d at 81 (unreasonable delays "clearly warrant[ed] retaining jurisdiction" and imposing ongoing reporting requirements on FCC). Plaintiffs have sufficiently alleged facts constituting an unreasonable delay and warranting, at a minimum, a similar remedy here.

D. FDA's March 2017 Letter Is Arbitrary and Capricious.

To the extent that FDA's March 2017 Letter constitutes agency action—and thus is not subject to challenge under § 706(1) —plaintiffs have adequately alleged a claim for relief under 5 U.S.C. § 706(2)(A). Under § 706(2)(A), a reviewing court shall hold unlawful and set aside agency action that is found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." For purposes of this analysis, a *failure* to act constitutes "[a]gency action." 5 U.S.C. §§ 551(13), 701(b)(2).

Defendants argue that plaintiffs have made only conclusory allegations that the March 2017 Letter is arbitrary and capricious. But defendants ignore the Amended Complaint's voluminous allegations of scientific and anecdotal evidence of harm to human health resulting from exposure to formaldehyde-containing keratin hair straighteners; of actions taken by other U.S. agencies and foreign governments to protect the public against these products; and of numerous pleas for action from members of the public, as well as public officials. They ignore allegations that FDA has recognized, since at least 2011, that these products present serious health and safety concerns. AC ¶ 62. They ignore their own admission, in their memorandum before this Court, that "formaldehyde released into the air can cause serious irritation to the eyes, nose, and lungs and . . . studies of workers exposed to high levels of formaldehyde, such as

industrial workers and embalmers, found that formaldehyde causes certain cancers." Dkt. 20-1 at 5.

In short, the Amended Complaint alleges that FDA has known for years that a cosmetic product has an indisputably serious adverse impact on human health, has watched other agencies and foreign governments take responsive action, and purports to have responded to a citizen petition to take action of its own—*after six years*—by taking only minimal steps to begin studying the issue. Moreover, the Amended Complaint alleges that FDA has actually denied a request to require warning labels for these products—not because it has concluded that they are unnecessary, but because it has only just begun to conduct the review necessary to determine whether the products should be banned altogether. These allegations, far from conclusory, are sufficient to state a claim under § 706(2)(A).

The "arbitrary and capricious" standard requires "an agency to examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made . . . . . In reviewing that explanation, [the court] must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment . . . " *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (citations omitted). Plaintiffs have sufficiently alleged that, given the length of the delay and the clear evidence of harm to human health, the March 2017 Letter was not based on an adequate consideration of the relevant factors, and reflects a clear error of judgment by the agency. The Amended Complaint thus states a claim for an order setting aside the March 2017 Letter and directing FDA to complete, by a date certain the review that plaintiffs requested in the Petition.

E. If Defendants' Motion Is Granted, Plaintiffs Should Be Given Leave to Amend.

The "decision whether to grant leave to amend or supplement a complaint is within the discretion of the district court, but leave should be freely given unless there is a good reason, such as futility, to the contrary." *Wildearth Guardians v. Kempthorne*, 592 F. Supp. 2d 18, 23 (D.D.C. 2008); *see also Willoughby v. Potomac Elec. Power Co.*, 100 F.3d 999, 1003 (D.C. Cir. 1996). Plaintiffs respectfully request, should the Court grant defendants' motion, that they be permitted leave to further amend their complaint.

CONCLUSION

For all the foregoing reasons, plaintiffs respectfully request that this Court deny Defendants' motion to dismiss the Amended Complaint.

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Respectfully submitted,

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