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Food and Drug Administration
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Rockville, MD 20852

CITIZEN PETITION FOR REGULATORY ACTION TO)
ADDRESS SAFETY CONCERNS SURROUNDING)
KERATIN HAIR-STRAIGHTENERS THAT CONTAIN)
FORMALDEHYDE AND FORMALDEHYDE-)
RELEASING CHEMICALS AS INGREDIENTS)

Via _____

By the Environmental Working Group and Women’s Voices for the Earth

CITIZEN PETITION

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The undersigned Petitioners EWG, WVE, and the 75 individually named citizen petitioners (collectively “Co-Petitioners”), under 21 C.F.R. § 10.30, the federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301-399, and the Administrative Procedure Act, 5 U.S.C. § 553(e), hereby submit this citizen petition to the U.S. Food and Drug Administration (FDA), through its Acting Commissioner, Janet Woodcock (“Commissioner”). By this petition, Co-Petitioners request through the Commissioner that the FDA ban formaldehyde and formaldehyde equivalents present in and subsequently released from “Brazilian style” or “keratin based” hair-straightening and -smoothing products.

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II. INTRODUCTION

The United States (U.S.) Food and Drug Administration (FDA) is a federal agency responsible for protecting the public's health by ensuring the safety of our nation's cosmetic products.¹

Co-Petitioner Women's Voices for the Earth is a 501(c)(3) nonprofit organization.² WVE was founded over two decades ago, in 1995, to amplify the voices of women in order to help eliminate toxic chemicals that harm the health of communities.³ As part of its praxis, WVE has always specifically recognized and highlighted critical connections among gender, health, class, race, and the environment, to help women increase corporate accountability and transparency, enact health-protective laws, and take steps to reduce toxic exposure in their lives.⁴

Co-Petitioner Environmental Working Group is a nonpartisan, U.S.-based 501(c)(3) nonprofit organization.⁵ For over 25 years, EWG has dedicated itself to protecting public health, as well as the environment, through research, education, and advocacy.⁶ EWG first petitioned the FDA on this issue a decade ago, in 2011. EWG's 2011 petition concerned the same subject matter as this petition – namely, the excessive formaldehyde released by “keratin based” or “Brazilian style” hair-straightening and -smoothing products.⁷

EWG's 2011 petition asked the FDA to investigate deceptive labeling of such products, require appropriate labeling, and consider implementing a complete ban on formaldehyde-releasing chemicals in hair-straightening products. In March 2012, EWG requested an update on the status of the 2011 petition.⁸ On July 27, 2012, the FDA explained to EWG in writing that the 2011 petition remained under review.⁹ Upon receiving no further substantive response from the FDA for more than four years, EWG proceeded to file suit in 2016, along with Co-Petitioner WVE.¹⁰ The case was eventually dismissed, in 2018, due to issues related to constitutional standing. In 2017, the FDA responded to EWG's petition, granting it in part and denying it in part. The FDA

¹ U.S. Food and Drug Administration, *What We Do*, U.S. Food and Drug Administration, <https://www.fda.gov/about-fda/what-we-do> (last visited May 26, 2021).

² EIN: 85-0501011

³ Women's Voices for the Earth, *Who We Are*, Women's Voices for the Earth, <https://www.womensvoices.org/about/who-we-are/> (last visited May 27, 2021).

⁴ *Id.*

⁵ EIN 52-2148600

⁶ Environmental Working Group, *Who We Are*, Environmental Working Group, <https://www.ewg.org/about-us> (last visited May 27, 2021).

⁷ Environmental Working Group, *Citizen Petition For Regulatory Action to Address Safety Concerns Surrounding Keratin Hair-Straighteners That Contain Formaldehyde and Formaldehyde-Releasing Chemicals as Ingredients* (Apr. 12, 2011), https://static.ewg.org/reports/2011/brazil_blowout/PDF/FDA-Petition.pdf?_ga=2.13044020.200611322.1576594206-1753754952.1567216891 [hereinafter EWG's 2011 Citizen Petition].

⁸ Letter from Thomas Cluderay, Assistant General Counsel, Environmental Working Group, and Robert Katsnelson, Law Clerk, Environmental Working Group, to Linda M. Katz, M.D., M.P.H., Director, Office of Cosmetics and Colors, Chief Medical Officer, Center for Food Safety and Applied Nutrition (Mar. 7, 2012), https://static.ewg.org/pdf/EWG-Letter-FDA-Update-Petition-March-7-2012.pdf?_ga=2.1887729.1308437437.1619033951-975890449.1592862015.

⁹ Complaint against Robert M. Califf, United States Food and Drug Administration, by Environmental Working Group, No. 1:2016cv02435-CKK (D.D.C. Dec. 13, 2016), <https://ecf.dcd.uscourts.gov/doc1/04516481812>.

¹⁰ *Id.*

denied EWG's request to require a warning label but agreed to consider implementing a complete ban following the completion of an ongoing scientific risk evaluation.¹¹

Despite promises to consider a ban, the FDA has taken no public action indicating whether a ban is necessary. The FDA has issued two warning letters to manufacturers of keratin hair-straightening products, in 2011 and 2015 – finding the products “adulterated” by reason of their formaldehyde content and “misbranded” based on misleading claims about such formaldehyde content.¹² Public records received by EWG show that the FDA ultimately completed a risk evaluation in 2016 and determined that a ban would be appropriate, but as of the time of filing this petition, the FDA has not proposed any regulatory action.¹³

As such, the FDA's regulation of formaldehyde in hair-straightening and -smoothing products remains as inadequate as it always has been. As a result of the FDA's inaction, such products continue to release toxic formaldehyde in beauty salons, posing a health hazard to salon workers and consumers in these spaces. Furthermore, the hazard posed by these products will certainly continue unabated – unless and until the FDA takes action to ban all forms of formaldehyde in hair-straightening and -smoothing products.

III. ACTION REQUESTED

Co-Petitioners request that the FDA ban the use of formaldehyde, formaldehyde equivalents, and other chemicals that emit high levels of formaldehyde in hair-straightening and -smoothing products. Using formaldehyde or formaldehyde equivalents would render such products adulterated under section 601 (21 U.S.C. § 361) of the Federal Food Drug and Cosmetics Act. Such products may also contain misleading claims about the formaldehyde content and risks of using such products, rendering them misbranded under section 602 (21 U.S.C. § 362) of the FDCA. The FDA is already on record via the warning letters to GIB, LLC dba Brazilian Blowout and Van Tibolli Beauty Corp¹⁴ that hair-smoothing products containing formaldehyde are adulterated under section 601 of the FDCA and may be misbranded under section 602 of the FDCA. However, the FDA has not taken regulatory action to ban formaldehyde and formaldehyde equivalents in hair-straightening and -smoothing products, and such products remain legal and readily available. To adequately protect consumers and the salon workers who administer these dangerous hair treatments, Co-Petitioners request that the FDA swiftly ban the

¹¹ Letter from Steven M. Musser, Ph.D., Deputy Director for Scientific Operations, Center for Food Safety and Applied Nutrition, to Thomas Cluderay and Jane Houlihan, Environmental Working Group (Mar. 28, 2017), <https://www.regulations.gov/document/FDA-2011-P-0276-0006>.

¹² Letter from Michael W. Roosevelt, Acting Director, Office of Compliance, Center for Food Safety and Applied Nutrition, to Mike Brady, CEO, GIB, LLC dba Brazilian Blowout (Aug. 22, 2011), <https://wayback.archive-it.org/7993/20170111100925/http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2011/ucm270809.htm> [hereinafter Brazilian Blowout FDA Warning Letter], and letter from Susan M. Turcovski, District Director, Florida District Office, to Van Tibolli, CEO, Van Tibolli Beauty Corp (Sep. 2, 2015), <https://wayback.archive-it.org/7993/20190908082850/https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/van-tibolli-beauty-corp-09022015> [hereinafter Van Tibolli FDA Warning Letter].

¹³ Melanie Benesh, “*Let’s Just Ban the Damn Ingredient*”: *Inside FDA Scientists’ Failed Attempt To Ban Formaldehyde in Hair Treatments*, Environmental Working Group (Oct. 21, 2020), <https://www.ewg.org/news-insights/news/lets-just-ban-damn-ingredient-inside-fda-scientists-failed-attempt-ban>.

¹⁴ See Brazilian Blowout FDA Warning Letter, *supra*; Van Tibolli FDA Warning Letter, *supra*.

use of formaldehyde and formaldehyde equivalents in hair-straightening and hair-smoothing treatments.

IV. STATEMENT OF FACTUAL GROUNDS

A. Use of formaldehyde in cosmetic products

Formaldehyde is a gas, but manufacturers use mixtures of other ingredients that incorporate formaldehyde into another state (*i.e.*, a liquid or solid) for use in cosmetics.¹⁵ These formaldehyde-containing cosmetic ingredients are further classified as either “formaldehyde equivalents” or “formaldehyde releaser preservatives.”¹⁶ From a regulatory perspective, agencies such as OSHA have long defined formaldehyde as “formaldehyde gas, its solutions, and materials that release formaldehyde.”¹⁷

When in aqueous solution, formaldehyde gas “is almost completely hydrated into methylene glycol,” which is, consequently, “essentially the liquid form of formaldehyde.”¹⁸ At odds with the chemical industry and its official position, cosmetic companies often label the methylene glycol content and not the formaldehyde content.¹⁹ Thus, formaldehyde and methylene glycol are both considered “free formaldehyde” in aqueous solutions, and “[f]or this reason, the hazards associated with an aqueous solution of formaldehyde will be the same as that of gaseous formaldehyde,”²⁰ and methylene glycol is known as a “formaldehyde equivalent.”²¹

Formaldehyde equivalents are distinct from “formaldehyde releaser preservatives” and other formaldehyde-releasing chemicals, which release less formaldehyde over considerable periods of time.²² Formaldehyde equivalents, by contrast, are *continuously* (and often *rapidly*) *converted to formaldehyde and vice versa*.²³ In room-temperature aqueous solutions at neutral pH, there is a dynamic equilibrium between methylene glycol and formaldehyde in the presence of a

¹⁵ National Toxicology Program, *Report on Carcinogens* 6 (14th ed. 2016), <https://ntp.niehs.nih.gov/ntp/roc/content/profiles/formaldehyde.pdf> [hereinafter NTP Report on Carcinogens].

¹⁶ CIR Expert Panel, *Final Amended Report: Formaldehyde and Methylene Glycol* 33 (Dec. 7, 2011), https://www.cir-safety.org/sites/default/files/formy_build.pdf.

¹⁷ 29 C.F.R. § 1910.1048(a) (2021).

¹⁸ Brazilian Blowout FDA Warning Letter, *supra* note 12, at 2.

¹⁹ Bryan Goodman, *ACC Comments on the Use of Formaldehyde in Hair Smoothing Products*, American Chemistry Council (Apr. 13, 2012), <https://www.americanchemistry.com/Media/PressReleasesTranscripts/ACC-news-releases/ACC-Comments-on-the-Use-of-Formaldehyde-in-Hair-Smoothing-Products.html>.

²⁰ CIR Expert Panel, *supra*, at 32.

²¹ Brazilian Blowout FDA Warning Letter, *supra* note 12, at 2.

²² See Jamie McConnell, *Is “Formaldehyde-Free” Really Formaldehyde-Free?*, Women’s Voices for the Earth (Jul. 5, 2016), <https://www.womensvoices.org/2016/07/05/is-formaldehyde-free-really-formaldehyde-free/> (citing R. A. Back and S. Yamamoto, *The Gas-Phase Photochemistry and Thermal Decomposition of Glyoxylic Acid*, *Can. J. Chem* 542 (1984), https://cdnsiencepub.com/doi/pdf/10.1139/v85-088?hc_location=ufi, and GE Silicones, *Regarding the Evolution of Formaldehyde from Polydimethylsiloxanes* (1999), https://imageserv5.team-logic.com/mediaLibrary/99/Formaldehyde_Generation_-_GE_Silicones.pdf) (stating “the chemicals most commonly seen in ‘formaldehyde-free’ hair straighteners are of two different types. The first type includes glyoxylic acid and glyoxyloyl carbocysteine, and the second type includes silicones such as cyclopentasiloxane, dimethicone and phenyl trimethicone. All of these chemicals emit formaldehyde at high heat, such as the 450 F heat of a flat iron.”).

²³ CIR Expert Panel, *supra* note 16, at 47.

polymerization inhibitor.²⁴ This equilibrium is easily shifted through heating, drying, and other conditions, rapidly converting the methylene glycol into formaldehyde gas.²⁵

Formalin, the standard name for a solution of formaldehyde in water, contains 37% to 40% of formaldehyde and 60% to 63% of water (by weight).²⁶ Any aqueous formulation that reportedly contains formalin, formaldehyde, or methylene glycol as a singular ingredient *actually* contains *both* formaldehyde *and* methylene glycol as ingredients.²⁷ Without a polymerization inhibitor such as methanol, the reaction between water and formaldehyde that forms methylene glycol will continue to form polymethylene glycols, eventually becoming a solid mixture of long-chain polymethylene glycols called paraformaldehyde,²⁸ another formaldehyde equivalent, which is sold as a white powder.²⁹

Companies that manufacture products containing formaldehyde equivalents sometimes claim that under ambient conditions, their products “do not contain formaldehyde” or are “formaldehyde-free,”³⁰ even though the FDA has warned that such claims constitute misbranding.³¹

The International Cosmetic Ingredient Dictionary and Handbook (INCI Dictionary) gives the cosmetic functions of formaldehyde as a cosmetic biocide, denaturant, and preservative.³² Formaldehyde plays a highly specialized role in hair-smoothing treatments, due to the way that formaldehyde reacts chemically with keratin, a biological protein. The chemical reforms the disulfide bonds between the keratin molecules that make up the hair strand.³³ Formaldehyde effectively maintains a long-term straightening effect in hair that works by cross-linking together the amino acids in keratin.³⁴

Several hair-smoothing treatments often marketed by the commercial name Brazilian Blowout or “keratin treatments” contain methylene glycol (*i.e.*, “essentially the liquid form of formaldehyde”³⁵). The 2018 material safety data sheets provided by Brazilian Blowout for its

²⁴ R. Golden and M. Valentini, *Formaldehyde and Methylene Glycol Equivalence: Critical Assessment of Chemical and Toxicological Aspects*, 69 *Regulatory Toxicology and Pharmacology* (Issue 2) 178, 180 (2014), <https://doi.org/10.1016/j.yrtph.2014.03.007> (citing Winkelman et al., *Kinetics of the Dehydration of Methylene Glycol*, 55 *Chem. Eng. Sci.* 2065 (2000), [https://doi.org/10.1016/S0009-2509\(99\)00498-4](https://doi.org/10.1016/S0009-2509(99)00498-4), and Winkelman, et al., *Kinetics and chemical equilibrium of the hydration of formaldehyde*, 57 *Chem. Eng. Sci.* 4067 (2002), [https://doi.org/10.1016/S0009-2509\(02\)00358-5](https://doi.org/10.1016/S0009-2509(02)00358-5)).

²⁵ CIR Expert Panel, *supra* note 16, at 47.

²⁶ John A. Kiernan, *Formaldehyde, Formalin, Paraformaldehyde and Glutaraldehyde: What They Are and What They Do*, 00-1, *Microscopy Today*, 8 (2000), <http://publish.uwo.ca/~jkiernan/formglut.htm>.

²⁷ CIR Expert Panel, *supra* note 16, at 32.

²⁸ CIR Expert Panel, *supra* note 16, at 31.

²⁹ John A. Kiernan, *supra*.

³⁰ See, e.g., Kristin L. Frawley, Master Essay, *Formaldehyde Exposure in the Cosmetology Industry from Brazilian Blowouts*, University of Pittsburgh, 4 (2013), <http://d-scholarship.pitt.edu/19728/>.

³¹ Brazilian Blowout FDA Warning Letter, *supra*, and Van Tivoli FDA Warning Letter, *supra*.

³² CIR Expert Panel, *supra* note 16, at 34.

³³ C.F. Cruz et al., *Changing the Shape of Hair With Keratin Peptides*, 7 *Royal Society of Chemistry Advances* 51581 (2017), <https://doi.org/10.1039/C7RA10461H>.

³⁴ *Id.*

³⁵ Brazilian Blowout FDA Warning Letter, *supra* note 12, at 2.

salon product confirms the presence of methylene glycol,³⁶ with methylene glycol listed at 3% to 7%.³⁷ As the FDA explains, “methylene glycol is used in certain cosmetic products that are applied to human hair as part of a combination of chemical and heating tool treatment intended to smooth or straighten the hair,” and “[w]hen heated these products release formaldehyde into the air.”³⁸

Formaldehyde-based hair-straightening and -smoothing products remain readily available in the U.S., and numerous salons still use these products to offer Brazilian Blowout-type treatments, putting salon workers and consumers at risk. Public records show that between 2013 and August 2020, the FDA received hundreds of adverse event reports related to formaldehyde in cosmetics.

B. Health effects of formaldehyde

1. Cancer

The National Toxicology Program first listed formaldehyde in the Second Report on Carcinogens (ROC), in 1981, as “reasonably anticipated to be a carcinogen,” and changed its status to “known to be a human carcinogen” in the 12th ROC, in 2011.³⁹ The NTP’s most recent evaluation of formaldehyde, in the 2016 14th ROC, classifies “[f]ormaldehyde as a known human carcinogen based on sufficient evidence of carcinogenicity from studies in humans and supporting data on mechanisms of carcinogenesis.”⁴⁰ In its report, the NTP further stated:

Epidemiological studies have demonstrated a causal relationship between exposure to formaldehyde and cancer in humans. Causality is indicated by consistent findings of increased risks of nasopharyngeal cancer, sinonasal cancer, and lymphohematopoietic cancer, specifically myeloid leukemia among individuals with higher measures of exposure to formaldehyde (exposure level or duration), which cannot be explained by chance, bias, or confounding.⁴¹

According to the NTP, nasopharyngeal cancer is a rare cancer, with an annual incidence of less than 1 per 100,000 in most parts of the world.⁴² Evidence that formaldehyde causes nasopharyngeal cancer comes from “(1) consistent findings of increased risk among individuals with the highest formaldehyde exposure in numerous case-control studies,”⁴³ along with “(2) excess cancer mortality associated with formaldehyde exposure in the [National Cancer

³⁶ Brazilian Blowout, *Safety Data Sheet*, Salon Services Pro (2018), https://www.salonservicespro.com/msds/brazilianblowout/brazilian_sds_2019.pdf.

³⁷ CIR Expert Panel, *supra* note 16, at 50 (showing the list of ingredients provided by the manufacturer in Table 2).

³⁸ Brazilian Blowout FDA Warning Letter, *supra* note 12, at 2.

³⁹ NTP Report on Carcinogens, *supra* note 15, at 1.

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.*

⁴³ *Id.*

Institute] NCI cohort⁴⁴ of industrial workers,”⁴⁵ and finally “(3) findings of positive exposure-response relationships in a large multi-center case-control study... and in the NCI cohort.”⁴⁶ The associations between occupational formaldehyde exposure and nasopharyngeal cancer remained after adjustment for or consideration of potential confounding by exposure to other sources of excessive formaldehyde, such as tobacco smoking,⁴⁷ or exposure to wood dust.⁴⁸ Risks were significantly elevated for individuals first exposed to formaldehyde at the youngest ages. The NTP noted other studies which also found that the highest risks of nasopharyngeal cancer were associated with individuals exposed to the highest formaldehyde levels and/or longest exposure durations (after lagging exposures for 10 years).⁴⁹

Like nasopharyngeal cancer, sinonasal cancer is also rare, according to the NTP, with an annual incidence of about 1 per 100,000.⁵⁰ The evidence relied on by NTP in its determination that formaldehyde exposure causes sinonasal cancer comes from “consistent findings of increased risk in population-based case-control studies,” as well as from a pooled analysis of 12 case-control studies that found “an excess of sinonasal cancer” occurring in relation to exposure.⁵¹

The NTP also concluded that an association exists between formaldehyde exposure and lymphohematopoietic cancer.⁵² This conclusion was based on evidence of significantly higher risk of developing lymphohematopoietic cancer demonstrated by the NCI cohort of industrial workers, increased risks found in all cohort studies of professional groups, and the significant risk reported in a meta-analysis by Zhang et al. (2009).⁵³ In the NCI cohort study of industrial workers, the risks of Hodgkin’s lymphoma and multiple myeloma were significantly higher among individuals with the highest peak exposures, and a positive exposure-response

⁴⁴ The NCI Cohort Consortium is an extramural-intramural partnership formed by the National Cancer Institute (NCI) to address the need for large-scale collaborations to pool the large quantity of data and biospecimens necessary to conduct a wide range of cancer studies. According to the 14th Edition of the NTP Report on Carcinogens, the most informative occupation-based studies on formaldehyde are the NCI cohort of more than 25,000 men and women who worked at companies that used or produced formaldehyde and the NCI nested case-control study of lymphohematopoietic cancer in embalmers, because these are the only studies that evaluated quantitative exposure-response relationships.

⁴⁵ NTP Report on Carcinogens, *supra* note 15, at 1.

⁴⁶ *Id.*

⁴⁷ NTP Report on Carcinogens, *supra* note 15, at 2.

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *Id.* (but, because the evidence for these two types of cancer was mainly from the NCI cohort study, the NTP could not establish a causal association).

⁵³ *Id.* (citing, respectively, Laura E. Beane Freeman et al., *Mortality From Lymphohematopoietic Malignancies Among Workers in Formaldehyde Industries: The National Cancer Institute Cohort*, 101 J Natl Cancer Inst (Issue 10) 751 (2009), <https://doi.org/10.1093/jnci/djp096>; National Toxicology Program, *Report on Carcinogens Background Document for Formaldehyde* (2010), http://ntp.niehs.nih.gov/ntp/roc/twelfth/2009/November/Formaldehyde_BD_Final.pdf [hereinafter NTP Report on Formaldehyde]; Luoping Zhang et al., *Formaldehyde Exposure and Leukemia: A New Meta-Analysis and Potential Mechanisms*, 681 Mutation Research/Reviews in Mutation Research (Issues 2–3) 150 (2009), <https://www.sciencedirect.com/science/article/abs/pii/S1383574208001002?via%3Dihub>).

relationship was found for Hodgkin’s lymphoma.⁵⁴ And increased risks for leukemia (all types combined) were found in the professional studies and some of the industrial cohort studies.⁵⁵

The International Agency for Research on Cancer (IARC) evaluated the same studies NTP relied on, and it reclassified formaldehyde as a human carcinogen, in June 2004, based on “sufficient epidemiological evidence that formaldehyde causes nasopharyngeal cancer in humans.”⁵⁶ IARC concluded in 2006 that there was strong but not sufficient evidence that formaldehyde causes leukemia.⁵⁷ IARC noted that elevated risks of leukemia have been consistently observed in proportionate mortality studies of professionals exposed to formaldehyde (*i.e.*, embalmers, workers in the funeral industry, pathologists, and anatomists).⁵⁸ IARC also noted that several studies have identified statistically significant positive associations between exposure to formaldehyde and cancer at other sites, including the oral cavity, oro- and hypopharynx, larynx, lung, brain, pancreas, Hodgkin lymphoma, and multiple myeloma, but the results were inconsistent.⁵⁹

The U.S. Environmental Protection Agency’s (EPA) most recent Integrated Risk Information System (IRIS) classifies formaldehyde as a probable human carcinogen, based on limited evidence in humans, and sufficient evidence in animals.⁶⁰ The EPA is currently in the process of updating this assessment.⁶¹

2. Non-carcinogenic effects of formaldehyde

Beyond formaldehyde’s carcinogenic effects, it also causes acute and chronic toxic effects. The Agency for Toxic Substances and Disease Registry’s (ATSDR) toxicological profile for formaldehyde notes that studies indicate exposure to the chemical can cause irritation of the nose, eyes, and throat, among other effects.⁶² ATSDR also indicates that studies show repeated exposure to formaldehyde can cause upper respiratory tract irritation.⁶³

According to the U.S. Occupational Safety and Health Administration (OSHA), in addition to being a cancer hazard, formaldehyde is a sensitizing agent that can cause an immune system

⁵⁴ *Id.* (citing Laura E. Beane Freeman et al., *supra* note 53).

⁵⁵ *Id.* (citing NTP Report on Formaldehyde, *supra* note 15).

⁵⁶ IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, *IARC Monographs, Formaldehyde*, 100F, Chemical Agents and Related Occupations, 401, 406-08 (2012), <https://monographs.iarc.who.int/wp-content/uploads/2018/06/mono100F-29.pdf> (citing IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, *Formaldehyde, 2-butoxyethanol, and 1-tert-butoxy-2propanol*, 88, Monographs on the Evaluation of Carcinogen Risks to Humans 39 (2006), <https://publications.iarc.fr/106>).

⁵⁷ IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, *supra*, at 406-08.

⁵⁸ IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, *supra*, at 409.

⁵⁹ *Id.*

⁶⁰ U.S. Environmental Protection Agency, *IRIS Chemical Assessment Summary, Formaldehyde; CASRN 50-00-0*, 7, https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0419_summary.pdf#nameddest=rfc.

⁶¹ Pat Rizzuto, ‘Vanished’ EPA Formaldehyde Health Effects Probe Reemerges (3), Bloomberg Law (updated March 11, 2021, 4:47 PM), <https://news.bloomberglaw.com/environment-and-energy/vanished-epa-formaldehyde-health-effects-probe-reemerges>.

⁶² Agency for Toxic Substances and Disease Registry, *Toxicological Profile For Formaldehyde* 41-45 (1999), <https://www.atsdr.cdc.gov/toxprofiles/tp111.pdf>.

⁶³ Agency for Toxic Substances and Disease Registry, *supra*, at 46-47.

response upon initial exposure.⁶⁴ Acute exposure is highly irritating to the eyes, nose, and throat and can make anyone exposed cough and wheeze.⁶⁵ Subsequent exposure may cause severe allergic reactions of the skin, eyes and respiratory tract.⁶⁶ A recent meta-analysis by Lam et al. in 2021 indicates there is sufficient evidence supporting an association between childhood and adult exposures to formaldehyde with asthma diagnosis and symptoms.⁶⁷ Ingestion of formaldehyde can be fatal, and long-term exposure to low levels in the air or on the skin can cause asthma-like respiratory problems and skin irritation such as dermatitis and itching.⁶⁸ OSHA considers concentrations of 100 parts per million (ppm) to be immediately dangerous to life and health.⁶⁹ The National Institute for Occupational Safety and Health (NIOSH) considers 20 ppm of formaldehyde to be immediately dangerous to life and health.⁷⁰

OSHA recognizes that airborne concentrations of formaldehyde above 0.1 ppm can cause irritation of the respiratory tract.⁷¹ The severity of irritation intensifies as concentrations increase.⁷² OSHA requires labels on all mixtures or solutions composed of greater than 0.1 percent formaldehyde and materials capable of releasing formaldehyde into the air at concentrations reaching or exceeding 0.1 ppm.⁷³ The agency also requires that employers label all materials capable of releasing formaldehyde at levels above 0.5 ppm during normal use. The label must contain the words “potential cancer hazard.”⁷⁴

Additionally, a broad meta-analysis by Kim et al. in 2011 indicates formaldehyde may cause adverse health effects, including genotoxicity, immunotoxicity, neurotoxicity, and reproductive toxicity.⁷⁵ One case report described a previously unknown autoimmune disease triggered by Brazilian Blowout.⁷⁶

C. Occupational exposure

Workers are especially at risk from the acute and chronic effects of formaldehyde exposure, as they are often exposed to higher concentrations, for longer durations, and face repeat exposures.

⁶⁴ U.S. OSHA, *OSHA Factsheet Formaldehyde 1* (2011), <https://www.osha.gov/sites/default/files/publications/formaldehyde-factsheet.pdf> [hereinafter OSHA Formaldehyde Factsheet].

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ See Juleen Lam et al., *Exposure to Formaldehyde and Asthma Outcomes: A Systematic Review, Meta-analysis, and Economic Assessment*, 16 PLoS ONE (Issue 3) (2021), <https://doi.org/10.1371/journal.pone.0248258>.

⁶⁸ OSHA Formaldehyde Factsheet, *supra*, at 1.

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ Ki-Hyun Kim et al., *Exposure to Formaldehyde and Its Potential Human Health Hazards*, 29 Journal of Environmental Science and Health (Issue 4) 277 (2011), <https://doi.org/10.1080/10590501.2011.629972>.

⁷⁶ James Dahlgren et al., *Case Report: Autoimmune Disease Triggered by Exposure to Hair Straightening Treatment Containing Formaldehyde*, 3 Open Journal of Rheumatology and Autoimmune Diseases 1 (2013), <http://dx.doi.org/10.4236/ojra.2013.31001>.

The 75 named petitioners are examples of citizens coming forward because of the health impacts they have faced from formaldehyde hair straighteners and the concerns they have for their health.

OSHA has a short-term – defined as 15 minutes – exposure limit of 2 ppm formaldehyde gas. The OSHA Permissible Exposure Limit time-weighted average for an 8-hour period is 0.75 ppm.⁷⁷ If workplace formaldehyde levels increase to 0.1 ppm over eight hours, employers must meet OSHA’s hazard communication requirements.⁷⁸ If exposures to formaldehyde rise to 0.5 ppm over an eight-hour period, OSHA requires that certain corrective actions be taken.⁷⁹ However, as OSHA openly acknowledges, these exposure limits were developed nearly 50 years ago and are likely not health-protective.⁸⁰

NIOSH has developed more stringent formaldehyde exposure recommendations primarily to protect workers from irritation of the eyes, nose, throat, and respiratory system.⁸¹ NIOSH’s Recommended Exposure Limits are just 0.1 ppm formaldehyde for short-term exposures and only 0.016 ppm for any given 10-hour period.⁸² Even more health-protective limits are likely needed to protect workers from cancer and other chronic exposure risks.

Formaldehyde-based hair-smoothing treatments contain formaldehyde equivalents in concentrations likely to release formaldehyde gas that exceed OSHA and NIOSH limits. A 2010 report by the Oregon Health and Science University’s Center for Research on Occupational and Environmental Toxicology revealed potentially unsafe levels of formaldehyde in one brand of chemical straightener, Brazilian Blowout,⁸³ and Oregon OSHA’s tests on another brand, Acai Professional Hair Smoothing Solution, detected levels of formaldehyde, some of which were 100 times above those deemed safe by OSHA.⁸⁴

Also, in 2010, the Oregon state OSHA studied the Brazilian Blowout products used in a salon in Oregon to investigate complaints from stylists and hair salon owners about exposure to formaldehyde while using these products.⁸⁵ In particular, these complaints included products labeled “formaldehyde free” on the product label and on the material safety data sheets.⁸⁶ The original container, which was labeled “formaldehyde free,” was delivered to Oregon OSHA for sample analysis on September 1, 2010, along with the safety information.⁸⁷ The Oregon OSHA

⁷⁷ CIR Expert Panel, *supra* note 16, at 47 (citing U.S. OSHA, Title 29, U.S. Code of Federal Regulations §1910.1048, http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10075).

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ U.S. OSHA, *Permissible Exposure Limits – Annotated Tables*, U.S. Department of Labor, <https://www.osha.gov/annotated-pels> (last visited May 28, 2021) (“OSHA recognizes that many of its permissible exposure limits (PELs) are outdated and inadequate for ensuring protection of worker health.”).

⁸¹ CIR Expert Panel, *supra* note 16, at 41.

⁸² *Id.*

⁸³ Rajiv C. Shah and Kelly E. Taylor, *Concealing Danger: How the Regulation of Cosmetics in the United States Puts Consumers at Risk*, 23 *Fordham Environmental Law Review* 203, 205 (2011) (citing, at n.13, Molly Prior and Andrea Nagel, *Salon Industry Grapples with Fallout from Blowout*, *Women’s Wear Daily*, Oct. 8, 2010, at 6).

⁸⁴ Rajiv C. Shah and Kelly E. Taylor, *supra* note 83, at 205-206 (citing, at n.14, Jill U. Adams, *A Closer Look; Brazilian Blowout Questions Continue*, *L.A. Times*, Nov. 29, 2010, at E1).

⁸⁵ Kristin L. Frawley, *supra* note 30, at 11.

⁸⁶ *Id.*

⁸⁷ *Id.*

laboratory analyzed the sample using four different test methods.⁸⁸ Formaldehyde was reported detected by each of the four methods, at concentrations of 10.6%, 6.3%, 10.6%, and 10.4% of the product, respectively.⁸⁹ In addition to OSHA's four testing methods, two separate test methods were also used to analyze the product and detected formaldehyde concentrations at 8.4% and 8.6%, respectively.⁹⁰

Oregon OSHA also took 105 samples of various hair-smoothing products from 54 Oregon salons.⁹¹ Of those samples, 37 samples came from bottles of the Brazilian Blowout Acai Professional Smoothing Solution, which is labeled "formaldehyde free."⁹² The formaldehyde content of these samples ranged from 6.8% to 11.8% and averaged more than 8%.⁹³

Oregon OSHA also monitored formaldehyde in the air in Oregon salons where hair-smoothing treatments are used. They found short-term exposures ranging from a high of 0.108 ppm for one stylist to a high of 1.88 ppm for another.⁹⁴

Based on these findings, Oregon OSHA published a Hazard Alert and a full report in October 2010.⁹⁵ In addition, Oregon OSHA alerted federal OSHA, along with state OSHA programs where these products were manufactured, imported, or distributed, because the hazard information for the product was not correct and did not meet the requirements of OSHA's Formaldehyde and Hazard Communication Standards.⁹⁶

In 2011, federal OSHA investigated three salons and found that stylists using either Brazilian Blowout Acai Professional Smoothing Solution or Cadiveu Brasil Cacau were exposed to formaldehyde above OSHA's short term exposure limit (STEL) of 2.0 ppm, thereby putting their health at risk.⁹⁷ In one salon surveyed, formaldehyde levels during the blow-drying phase of chemical straightening treatment were measured at five times the OSHA STEL.⁹⁸ OSHA issued a hazard alert to salon owners and workers, in April 2011.⁹⁹ The agency recommended that salons stop using products containing formaldehyde, due to dangers such as eye and nose irritation, skin reactions, and the link between formaldehyde and nose and lung cancers.¹⁰⁰ In May 2011, NIOSH released a Health Hazard Evaluation that showed six of seven short-term air quality tests

⁸⁸ *Id.*

⁸⁹ Kristin L. Frawley, *supra* note 30, at 11-12.

⁹⁰ Kristin L. Frawley, *supra* note 30, at 12.

⁹¹ Oregon OSHA, "Keratin-Based" Hair Smoothing Products and the Presence of Formaldehyde 2 (2010), <https://osha.oregon.gov/OSHAPubs/reports/keratin-based-hair-smoothing-report.pdf>.

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ Kristin L. Frawley, *supra* note 30, at 12.

⁹⁶ *Id.*

⁹⁷ Kristin L. Frawley, *supra* note 30, at 13.

⁹⁸ *Id.*

⁹⁹ Rajiv C. Shah and Kelly E. Taylor, *supra* note 83, at 206-207 (citing, at n.21, U.S. OSHA, U.S. Department of Labor's OSHA Issues Hazard Alert To Hair Salon Owners, Workers on Smoothing and Straightening Products That Could Release Formaldehyde, Dept. of Labor (Apr. 11, 2011), <https://www.osha.gov/news/newsreleases/national/04112011> [hereinafter U.S. OSHA Hazard Alert]).

¹⁰⁰ Rajiv C. Shah and Kelly E. Taylor, *supra* note 83, at 207 (citing, at n.23, U.S. OSHA Hazard Alert, *supra*).

conducted at a salon during use of Brazilian Blowout products exceeded its recommended formaldehyde STELs.¹⁰¹

Salon work in the U.S. is disproportionately performed by women who may be more vulnerable to the effects of formaldehyde.¹⁰² One New York Times article, “Perfect Nails, Poisoned Workers,” illustrates this point by telling the stories of several salon workers in Ridgewood, Queens, in New York City, who are exposed to chemicals at work, including formaldehyde. According to the Times, “stories of illness and tragedy abound at nail salons across the country, of children born slow or ‘special,’ of miscarriages and cancers, of coughs that will not go away and painful skin afflictions. The stories have become so common that older manicurists warn women of child-bearing age away from the business.”¹⁰³

Supporting the anecdotal evidence presented in the New York Times article, at least three general health studies include findings on menstrual disorders and heavy menstrual flow (menorrhagia) in women who are occupationally exposed to formaldehyde.¹⁰⁴ Several studies also show that formaldehyde exposure is associated with increased risk of babies being born with low birth weight.¹⁰⁵ A Danish study found formaldehyde exposure was associated with increased likelihood of babies being born with “major” congenital malformations.¹⁰⁶ NIOSH has warned that “working with formaldehyde could increase your chances of having fertility problems or miscarriage.”¹⁰⁷

D. The FDA has failed to act

1. Investigations into the safety of formaldehyde in hair-straightening and -smoothing products began more than a decade ago

Around 2007, a hair treatment from Brazil swept American hair salon markets, with the alluring promise of keeping hair straight and smooth for far longer than older methods – up to four

¹⁰¹ Letter from Srinivas Durgam, MSPH, MSChE, CIH, Industrial Hygienist, and Elena Page, MD, MPH, Medical Officer, Hazard Evaluations and Technical Assistance Branch, Division of Surveillance, Hazard Evaluations and Field Studies, to salon owner (May 16, 2011), https://www.cdc.gov/niosh/hhe/pdfs/HETA_11-0014_Interim_Letter_for_web.pdf.

¹⁰² Reports by Zippia, a careers site, estimate that 76.8% of hair stylists and 78.6% of salon assistants are women. See Zippia, *Hair Stylist Demographics in the US*, Get The Job You Really Want – Zippia, <https://www.zippia.com/hair-stylist-jobs/demographics/> (last visited Jun. 1, 2021), and Zippia, *Salon Assistant Demographics in the US*, Get The Job You Really Want – Zippia, <https://www.zippia.com/salon-assistant-jobs/demographics/> (last visited Jun. 1, 2021).

¹⁰³ Sarah M. Nir, *Perfect Nails, Poisoned Workers*, The New York Times (May 8, 2015), <https://perma.cc/ZE7V-48PF>.

¹⁰⁴ Xiaojiang Tang et al., *Formaldehyde in China: Production, Consumption, Exposure Levels, and Health Effects*, 35 Environment International (Issue 8), 1210 (2009), <https://doi.org/10.1016/j.envint.2009.06.002>.

¹⁰⁵ See Anh Duong et al., *Reproductive and Developmental Toxicity of Formaldehyde: A Systematic Review*, 728 Mutation Research (Issue 3), 118 (2011), <https://doi.org/10.1016/j.mrrev.2011.07.003>.

¹⁰⁶ See *id.* (citing J.L. Zhu et al., *Laboratory Work and Pregnancy Outcomes: A Study Within the National Birth Cohort in Denmark*, 63 Occupational and Environmental Medicine 53 (2006), <https://doi.org/10.1016/j.mrrev.2011.07.003>).

¹⁰⁷ NIOSH, *Reproductive Health and the Workplace, Formaldehyde*, Centers for Disease Control and Prevention (last reviewed Nov. 15, 2019), <https://www.cdc.gov/niosh/topics/repro/formaldehyde.html>.

months – all while, it claimed, improving hair health by using the naturally occurring protein keratin and an extremely hot iron to hydrate and relax hair.¹⁰⁸

Not long thereafter, however, Oregon OSHA began receiving numerous complaints from salon workers who – after applying Brazilian hair-straightening treatments – were suddenly suffering from nosebleeds, eye irritation, and breathing problems.¹⁰⁹ Oregon OSHA began to investigate these chemical straightening treatments, in early 2010.¹¹⁰ Although the investigation of chemical straightening products originated in Oregon, its impact extended far beyond Oregon’s borders.¹¹¹ England and Ireland have issued recalls for both Brazilian Blowout and Acai Professional Smoothing Solution.¹¹² In addition, in October 2010, Canada’s public health department issued a warning to consumers not to use Brazilian Blowout.¹¹³ The following month, on November 4, 2010, the Personal Care Products Council (the trade association representing the cosmetics industry) announced that it was working with the FDA to review the use of formaldehyde in professional hair-smoothing products.¹¹⁴

The FDA has known about high levels of formaldehyde in hair-straightening and -smoothing treatments since at least 2008¹¹⁵ but has failed to take meaningful action to protect salon workers and consumers. As a result of the extremely high levels of formaldehyde detected in Oregon salons in 2010, Earl Blumenauer, a congressional representative from Oregon, asked the FDA and the Federal Trade Commission to investigate whether Brazilian Blowout and Acai Professional Smoothing Solution posed safety risks to consumers and whether the products were properly labeled.¹¹⁶

In April 2011, EWG filed a citizen petition to the FDA for regulatory action on formaldehyde in keratin hair-straightening products.¹¹⁷ In August 2011, the FDA sent a warning letter to GIB finding its Brazilian Blowout product was “adulterated” and “misbranded” in violation of the

¹⁰⁸ Rajiv C. Shah and Kelly E. Taylor, *supra* note 83, at 205 (citing, at n.9, Elizabeth Hayt, *Curls, Split! Ringlets, Be Gone!*, N.Y. TIMES, Jul. 19, 2007, at G3).

¹⁰⁹ Rajiv C. Shah and Kelly E. Taylor, *supra* note 83, at 205 (citing, at n.12, Kermit McCarthy et al., *Keratin Based Hair Smoothing Products and the Presence of Formaldehyde*, Oregon OSHA and Oregon Health & Science University’s Center For Research on Occupational and Environmental Toxicology (2010)).

¹¹⁰ *Id.*

¹¹¹ Rajiv C. Shah and Kelly E. Taylor, *supra* note 83, at 206.

¹¹² Rajiv C. Shah and Kelly E. Taylor, *supra* note 83, at 206 (citing, at n.17, Kitty Holland, *Health Briefing*, Irish Times, Oct. 19, 2010, at 2, <https://www.irishtimes.com/news/health/health-briefing-1.665847>).

¹¹³ Rajiv C. Shah and Kelly E. Taylor, *supra* note 83, at 206 (citing, at n.16, Carly Weeks, *With Hair Products, It’s Buyer Beware: It Took Complaints From Consumers Before Health Canada Issued Warning about Brazilian Blowout*, *Globe & Mail*, Oct. 19, 2010, at L4).

¹¹⁴ Rajiv C. Shah and Kelly E. Taylor, *supra* note 83, at 206 (citing, at n.20, Statement by John Bailey, Chief Scientist, *Personal Care Products Council: Industry Concerned About Safety of Ingredient in Professional Hair Smoothing Products*, Personal Care Products Council (Nov. 4, 2010), <https://www.personalcarecouncil.org/tag/preservatives/>).

¹¹⁵ See Mary A. Fischer, *Scared Straight*, *Allure* (July 6, 2008), <https://www.allure.com/story/scared-straight>.

¹¹⁶ Rajiv C. Shah and Kelly E. Taylor, *supra* note 83, at 206 (citing, at n.15, Katy Muldoon, *Blumenauer Asks Feds to Investigate Hair-Care Products with Formaldehyde*, *The Oregonian* (Oct. 6, 2010), https://web.archive.org/web/20210126103609/https://www.oregonlive.com/health/2010/10/Blumenauer_asks_feds_to_invest.html).

¹¹⁷ EWG’s 2011 Citizen Petition, *supra* note 7.

federal Food Drug and Cosmetic Act.¹¹⁸ In January 2012, California settled its lawsuit against GIB. The settlement, among other things, required GIB to cease deceptive advertising describing its products as formaldehyde-free and safe.¹¹⁹ In November 2012, then-California Attorney General Kamala Harris, got a court order for GIB to reformulate Brazilian Blowout to comply with its settlement.¹²⁰ But a subsequent EWG analysis of GIB material safety data sheets found that the company was still using 3% to 7% formaldehyde, down from 11.8%.¹²¹ In September 2015, the FDA sent a warning letter to Van Tibolli Beauty Corp. finding its GK hair-taming system products are “adulterated” and “misbranded,” in violation of the federal Food Drug and Cosmetic Act.

FDA emails, obtained through an EWG Freedom of Information Act request, revealed that a draft scientific assessment of formaldehyde was completed in early 2016 and went through additional edits during the year.¹²² In July 2016, the Center for Food Safety and Applied Nutrition, the FDA office that oversees the Office of Cosmetics and Colors, gave its approval to pursue a ban on formaldehyde. On July 26, Nakissa Sadrieh, Ph.D., director of the cosmetics division of the FDA Office of Cosmetics and Colors, wrote: “[T]he center is proposing to develop regulations to ban the use of formaldehyde in hair smoothing products... This is a very big deal for us, and for the public.”¹²³ However, by October 2016, emails revealed that scientists felt their concerns were being ignored and their efforts stymied by the agency.¹²⁴ Now, a decade

¹¹⁸ Brazilian Blowout FDA Warning Letter, *supra* note 12.

¹¹⁹ Consent Judgment Resolving the People’s Claims Against Defendant GIB, LLC, GIB, LLC Cases (2011) (Judicial Council Coordination Proceeding No. 4657), https://oag.ca.gov/system/files/attachments/press_releases/n2617_consent_judgement.pdf.

¹²⁰ WVE, *California Superior Court Gives Brazilian Blowout 30 Days to Reformulate or Remove Products from Marketplace*, Women’s Voices for the Earth (Dec. 3, 2012), <https://www.womensvoices.org/2012/12/03/california-supreme-court-gives-brazilian-blowout-30-days-to-reformulate-or-remove-products-from-marketplace/#:~:text=Los%20Angeles%E2%80%94The%20California%20Superior,reformulated%20product%20mee>.

¹²¹ Tina Sigurdson and Galen Roth, *Brazilian-style Blowouts: Still Poisonous, Still in Salons*, Environmental Working Group (Aug. 21, 2015), <https://www.ewg.org/enviroblog/2015/08/brazilian-style-blowouts-still-poisonous-still-salons>.

¹²² Email from Nakissa Sadrieh, Ph.D., Director, Cosmetics Division, FDA, to Linda Katz, M.D., M.P.H., Director, Office of Cosmetics and Colors, FDA (Mar. 30, 2016, 1:42 PM), http://static.ewg.org/reports/2020/BrazilianBlowoutPDFs/Link5.pdf?_ga=2.87635921.835454761.1616417194-1202074806.1601303277; email from Nakissa Sadrieh, Director, Cosmetics Division, FDA, to Linda Katz, Director, Office of Cosmetics and Colors, FDA (Jun. 2, 2016, 4:28:57 PM), http://static.ewg.org/reports/2020/BrazilianBlowoutPDFs/Link6.pdf?_ga=2.87635921.835454761.1616417194-1202074806.1601303277; email from Nakissa Sadrieh, Director, Cosmetics Division, FDA, to Linda Katz, Director, Office of Cosmetics and Colors, FDA (Oct. 5, 2016, 5:12:32 PM), http://static.ewg.org/reports/2020/BrazilianBlowoutPDFs/Link7.pdf?_ga=2.87635921.835454761.1616417194-1202074806.1601303277.

¹²³ Email from Nakissa Sadrieh, Ph.D., Director, Cosmetics Division, FDA, to CFSAN-OCAC-COS-CAT (Jul. 26, 2016, 1:32:17 PM), http://static.ewg.org/reports/2020/BrazilianBlowoutPDFs/Link2and8.pdf?_ga=2.73939803.835454761.1616417194-1202074806.1601303277.

¹²⁴ See Email from Kapal Dewan, Lead Biologist, FDA, to Nakissa Sadrieh, Ph.D., Director, Cosmetics Division, FDA (Oct. 18, 2016, 8:02:53 AM EDT), http://static.ewg.org/reports/2020/BrazilianBlowoutPDFs/Link10.pdf?_ga=2.152441840.835454761.1616417194-1202074806.1601303277, and E-mail from Nakissa Sadrieh, Ph.D., Director, Cosmetics Division, FDA, to Kapal Dewan, Lead Biologist, FDA, and Linda Katz, M.D., M.P.H., Director, Office of Cosmetics and Colors, FDA (Oct. 18, 2016, 8:20:09 AM),

since EWG's original citizen petition, the FDA still has not acted to ban formaldehyde in hair-smoothing products.

2. Reports of adverse events associated with chemical straightening products persist

More recent data indicate that formaldehyde in hair straighteners and smoothers continues to harm consumers and salon workers. A 2015 study published in the peer-reviewed journal *Regulatory Toxicology and Pharmacology*, for instance, surveyed 72 heated cosmetic products and found that in 42%, formaldehyde released was very close to or above the threshold value suggested by the Cosmetic Ingredient Review, whereas 11 products, negative using the official method of reference, were close to or above the threshold value (0.074 g/100 g calculated as pure formaldehyde).¹²⁵

New reports of adverse events associated with hair-straightening and -smoothing products have also emerged since EWG filed its 2011 petition.

FDA adverse event reports (AER), dated between 2011 and 2019 and made available to EWG through a 2020 FOIA request, show the severe effects of formaldehyde on salon workers and their customers. Some of the effects are so horrific that they seem unreal, but they are very real for those affected. The following are excerpts from the AERs:

- “It was reported that the patient got sick due to formaldehyde poisoning of her whole body. She lost her hair and her teeth were removed due to the damage the product caused in her mouth and formaldehyde pockets were found in her gums which were not going away.”¹²⁶
- “I got a Brazilian blowdry treatment on my hair and the salon stylist used a product on me that mainly contained methylene glycol. As soon as the procedure began I had redness in my eyes and my eyes started watering profusely. My head started hurting ...[and] my skin developed itchiness. I also felt an extreme irritation in my nostrils and the symptoms have not stopped even though it has been two hours post treatment. I also experienced bronchoconstruction [sic] and could not swallow food for some time period.... [T]his was the worst adverse reaction I have ever encountered.”¹²⁷
- “I was working in my salon on Saturday while one of my coworkers was performing a Brazilian blowout. Now I am having chest pains and trouble breathing ... my symptoms are gradually getting better.... [N]ow it's more of a stinging, raw feeling in my lungs.”¹²⁸

http://static.ewg.org/reports/2020/BrazilianBlowoutPDFs/Link10.pdf?_ga=2.152441840.835454761.1616417194-1202074806.1601303277.

¹²⁵ Corrado Lodovico Galli et al., *Novel Analytical Method to Measure Formaldehyde Release From Heated Hair Straightening Cosmetic Products: Impact on Risk Assessment*, 72 *Regulatory Toxicology and Pharmacology* (Issue 3), 562 (2015), <https://doi.org/10.1016/j.yrtph.2015.05.010>.

¹²⁶ FDA Adverse Event Reports, Part 1, 1 of 4, CTU No.: FDA-CDER-CTU-2019-125387, RCT No.: RCT-639058, at 15 (Oct. 25, 2019) (on file with EWG) [hereinafter AERs].

¹²⁷ AERs, Part 1, 1 of 4, CTU No.: FDA-CDER-CTU-2018-74354, RCT No.: RCT-185863, at 40 (Aug. 11, 2018) (on file with EWG).

¹²⁸ AERs, Part 1, 1 of 4, CTU No.: FDA-CDER-CTU-2018-94908, RCT No.: RCT-208263, at 72 (Oct. 15, 2018) (on file with EWG).

- “My wife uses Brazilian blow at work. After an especially long day at work, she came home feeling very sick. Usually [she] comes home with headaches and trouble breathing[,] period[;] this time she vomited blood on two occasions. It is of my understanding that Brazilian blowout is unregulated. The formaldehyde is killing my wife, I'm sure of it. Please ban this poison!”¹²⁹
- “Had a Brazilian blowout at my salon. Nobody mentioned any potential side effects, but the day of treatment, they put me in a room with [a] window open due to “fumes.” A week later, I have blisters on my neck and forehead, and raised hives with intense itching on my scalp. Washing my hair is painful.”¹³⁰
- “Complainant stated that she had her hair treated with Coppola Keratin Smoothing Therapy Complex by her hairdresser. She stated she started losing her hair the next day and to date has lost 60% of her hair. She has seen a doctor who did [a] blood test and stated she is healthy and the hair loss is probably due to the product.... [S]he has looked on the Internet and seen several other references to this problem.”¹³¹
- “42 year old female complainant with no known allergies and no medical conditions believes Peter Coppola Keratin Smoothing Treatment is cause for her symptoms. Complainant worked at a salon for one year and two months and was a very active person. From 12/09 to 08/11 complainant serviced clients with smoothing treatments on an average of twice per week. After about a year, complainant developed symptoms of coughing up brownish/yellowish flem [sic], a continuous cough, raspy voice and chest pains. Complainant noted that other stylists were experiencing similar symptoms and determined that symptoms must be related to product in question due to the amount of excess fumes involved with the smoothing treatments [sic][.] Complainant discontinued use of product in question on 08/11[,] however her symptoms persist. In 09/12 complainant was diagnosed with [an] autoimmune disorder. She has persistent chest pains and requires steam to improve her breathing. She has also developed swelling in her legs and was recently approved for disability due to her ongoing conditions.”¹³²
- “Consumer states that she is a professional hairdresser and was hospitalized twice approximately one week after giving a keratin smoothing treatment to a client. Consumer went to the emergency room on 10/21/2013 complaining of difficulty breathing, and a productive cough with blood in the sputum. Consumer was treated with a cough suppressant and antibiotics and then released. Consumer returned to the emergency room the next day complaining of worsening symptoms. At that time she was admitted to the hospital. Consumer was hospitalized from 10/22/2013 until 10/26/2013. Consumer states that while hospitalized a lung biopsy was performed which indicated blood, fluid and unidentified white matter. Additionally she states that her liver function test came back elevated. CT scan and xrays were normal. She is scheduled for a pulmonary function test next month.”¹³³

¹²⁹ AERs, Part 1, 1 of 4, CTU No.: FDA-CDER-CTU-2018-103645, RCT No.: RCT-218975, at 80 (Nov. 18, 2018) (on file with EWG).

¹³⁰ AERs, Part 1, 1 of 4, CTU No.: FDA-CDER-CTU-2019-60721, RCT No.: RCT-376450, at 98 (May 24, 2019) (on file with EWG).

¹³¹ AERs, Part 1, 2 of 4, FACTS Complaint# 122631, CAERS #166590, at 49 (Oct. 3, 2011) (on file with EWG).

¹³² AERs, Part 1, 2 of 4, FACTS Complaint# 135401, CAERS #173404, at 81 (Dec. 24, 2013) (on file with EWG).

¹³³ AERs, Part 1, 2 of 4, FACTS Complaint #134917, CAERS #175122, at 98 (Nov. 8, 2013) (on file with EWG).

- “My salon has been using the Brazilian Blowout product for a couple of years. After all the complaints a couple years ago, we were informed by the employer that the product was safe and the level of formaldehyde was within FDA's ‘safe’ levels. We have no ventilation system in the salon, even after repeatedly asking for one. I am still required to do the service and I have been having to do about one a week for the past two months. Normally, I experience burning, watering eyes, blurred vision, sore throat, loss of taste/smell afterwards, migraines, nausea, and chest discomfort. I have been sick and put on antibiotics for throat/chest infections more in the past year alone than in the past 10 years combined. After the most recent treatment, last Wednesday, I had chest pain, chest tightness, shortness of breath, and labored breathing constantly. It has been almost five days. I have an appointment with the doctor tomorrow morning. It has prevented me from doing normal daily activities for five days. I have no prior medical concerns involving lung function, asthma, allergies, or fatigue. I cannot understand how hairstylists are still having to be subjected to this torture! When is the FDA going to step in and stop the release of this poison to salons? Even with a doctors note for me to be excused from performing the service, I still have to be in the salon while others perform this service. The one I did on Wednesday sent a co-worker in her 60s to the bathroom vomiting. It's hurting all of us. We have had enough of this company jumping through loopholes, it needs to be banned.... [b]efore someone gets permanent medical damage. Thank you.”

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The AERs describe symptoms consistent with the non-carcinogenic effects previously discussed.¹³⁵ Some of the most commonly reported symptoms were: nose and throat irritation, headache, respiratory system harm, allergic reactions, difficulty breathing, eye irritation, skin irritation, blistering, hair loss, nose bleeds, dizziness, and vomiting. These gut-wrenching descriptions reflect the experiences of real people using these dangerous chemical hair-straightening products.

In addition to the AERs, some named petitioners described the health effects they experience due to occupational exposure to formaldehyde-based hair-straightening and -smoothing products. The following are excerpts of the health effects they described:

- Corrie Sweat reported experiencing “[h]eart arrhythmia, irritation around nostrils, unexplained rashes on my face, hand tremors, shortness of breath, confusion, eye irritation, environmental illness, liver issues – inability to detox naturally, auto immune disease” from exposure to Brazilian Blowout and Keratin Complex.¹³⁶
- Dawn Landers reported suffering “[f]ormaldehyde poisoning and extreme sensitivity to minor exposures following [her initial exposure].”¹³⁷ She stated, “I now have asthma ... forever. It’s hard to breathe ... forever. If I’m exposed to this toxic product, I feel as if I’m

¹³⁴ AERs, Part 1, 3 of 4, Triage Unit Sequence #559723, at 26 (Jun. 22, 2014) (on file with EWG).

¹³⁵ Some AERs not included above also described carcinogenic symptoms such as acute myeloid leukemia e.g., AERs, Part 1, 1 of 4, CTU No.: FDA-CDER-CTU-2017-60683, RCT No.: RCT-85212, at 1 (Sep. 20, 2017) (on file with EWG).

¹³⁶ *Named Petitioners’ Descriptions of Health Effects of Formaldehyde from Jan. 27, 2020, to May 19, 2021* (May 20, 2021) (on file with WVE) [hereinafter *Petitioners’ Descriptions of Health Effects*] (statement of Corrie Sweat, Jan. 30, 2020).

¹³⁷ *Petitioners’ Descriptions of Health Effects, supra* (statement of Dawn Landers, Oct. 5, 2020).

being choked immediately, then it moves on to sinus infection, bloody noses, wheezing, salt like taste in [my] mouth as my body detoxes the poison, vomiting, shaking, swelling of eyes and throat and sore throat.”¹³⁸

- Heidi Hartt: “My symptoms are increasingly severe and consistent with others exposed to this treatment ... [s]kin lesions and blisters, shortness of breath and feeling like my throat is swelling closed and raw. Severe brain fog, dizziness, nausea, vomiting, loss of appetite, weight loss. Blurry vision and watery eyes, numbness in fingers and swelling of legs, headaches, skin sensitivity and itchiness, sinus inflammation and runny nose. Joint sensitivity and muscles inflammation.”¹³⁹
- Jaci Munoz: “I started having 30 sec seizures when coworkers started using Brazilian Blowout, along with a ‘turned on flight or fright nervous system’.”¹⁴⁰ In addition to the seizures, Munoz also reported suffering from “[autonomic] dysfunction, chronic low glutathione levels, chronic low B vitamins, poor gut health, chronic state of flight or fright, diagnosed CFS [chronic fatigue syndrome] due to toxic exposure.”¹⁴¹ After eight years of occupational exposure to Brazilian Blowout, beginning in 2005, Munoz had symptoms so serious she was forced to retire, in 2013.¹⁴²
- Kazia Pfunter: “I’ve been a stylist for 6 years and performed straightening services for 4 of them. Directly after giving a service I would have extremely bad headaches, feel nauseous, and have trouble concentrating for several hours after. Long term I would say my migraines can be traced back to when I first started using keratin straighteners on myself and my clients.” Pfunter reported using Brazilian Blowout- and Keratin Complex-brand straighteners.¹⁴³
- Kristi Ramsburg: “I have auto immune hepatitis from environmental factors [doctors] believe. At one point my liver was found to have collapsed over my gall bladder.... [T]hey are monitoring for cirrhosis [sic]... sinus infections eye changes.”¹⁴⁴ Kristi reported that as a result of the liver collapsing, doctors had to remove her gallbladder.¹⁴⁵ Ramsburg reported being exposed to Brazilian Blowout Keratin Complex straighteners, in particular.¹⁴⁶
- Larinda Pentakota: “While working in two separate salons they used the Brazilian blowout products and each time my lungs burned and [I] had problems breathing [for] days after each straightening service. OSHA came out and put a stop to the last salon [I] was in for using the Brazilian blowout because my client and myself had bad reactions. Then 10 days after [I] was issued a quit work notice because [I] contacted OSHA. I could not put my clients and myself in [harm’s] way. This product has to stop!!!”¹⁴⁷ Pentakota also reported suffering from “[l]ungs burning, coughing, nose burning, nose running,

¹³⁸ *Id.*

¹³⁹ Petitioners’ Descriptions of Health Effects, *supra* note 142 (statement of Heidi Hartt, Feb. 11, 2020).

¹⁴⁰ Named Petitioners’ Descriptions of Health Effects, *supra* note 142 (statement of Stephanie Houlias-MacDonald, Jan. 29, 2020).

¹⁴¹ *Id.*

¹⁴² Petitioners’ Descriptions of Health Effects, *supra* note 142 (statement of Kazia Pfunter, Jan. 30, 2020).

¹⁴³ *Id.*

¹⁴⁴ Petitioners’ Descriptions of Health Effects, *supra* note 142 (statement of Kristi Ramsburg, Jan. 30, 2020).

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

¹⁴⁷ Petitioners’ Descriptions of Health Effects, *supra* note 142 (statement of Larinda Pentakota, Oct. 10, 2020).

eyes watering...” and a painful sensation from deep in her lungs when taking deep breaths.¹⁴⁸

- Laurette Thinger: “I have such a serious reaction, my nose eyes and throat burn, my throat swells up like it’s shutting[,] my hands burn. I stopped doing them, however I can’t even work in many salons because they do them and I have such a horrible reaction to them followed by being sick for a week or two once exposed[.] Once the chemical has seeped into my pores my eyes nose throat skin burns[.] I then get an anxiety attack and have to run out of the salon.... I now have [an] issue with even finding a salon to work in.”¹⁴⁹ Thinger listed Brazilian Blowout as the brand responsible for her symptoms.¹⁵⁰
- Marissa Doherty: “I developed MCS [multiple chemical sensitivities] and had to drastically change my life [or] die to formaldehyde exposure in the salon... I have severe Multiple Chemical Sensitivities, to the point of going into anaphylaxis. I also have struggled the past two years with lung issues including pneumothorax. I also had severe brain fog and fatigue. It completely turned my life upside down. It has been such a struggle to resume any normalcy to my life and for my husband and 3 kids. It has caused a strain in my finances, due to my inability to go in public for over a year. As well as the financial burden of trying to pay for treatments not covered by insurance.”¹⁵¹ Doherty further described suffering from lung bullas and partial lung collapse, asthma, brain fatigue and damage, and exhaustion.¹⁵²
- Meredith Pedack: “I was diagnosed with severe Multiple Chemical Sensitivities. A toxic load [b]rain and nervous system injury, and also tipped me into other diagnoses. I had a long list of symptoms that developed into [severe] chronic illness. Nausea, tinnitus, difficulty concentrating, inappropriate crying, brain fog, fatigue, hoarseness, blinding headaches, increased acute sense of smell, panic attacks, full blown crash, [toxicant-induced loss of tolerance,] total loss of tolerance, inability to do basic tasks like feed myself or bathe.... I became house bound for about a year because I couldn’t handle going into any public spaces or be around anyone with fragrance or off gassing, photophobia, ptsd, chronic fatigue syndrome due to the chronic stress of the total toxicity, etc.”¹⁵³ Pedack reported that her symptoms arose from being exposed to Brazilian Blowout and various keratin treatment brands.¹⁵⁴
- Stephanie Houlias-MacDonald: “I used to manage a hair salon that did a lot [of] keratin/straightening treatments.... [M]y eyes well up, I get a headache and start to feel sick. My throat starts to burn and I have a hard time breathing. During the busy season I feel the effects after I go home for the day. Even the products that claim to be ‘safe’ bother me and I often wonder what else is in the bottle that is slowly making everyone sick.”¹⁵⁵ Houlias-MacDonald also reported suffering from headaches, vomiting, bloody

¹⁴⁸ *Id.*

¹⁴⁹ Petitioners’ Descriptions of Health Effects, *supra* note 142 (statement of Laurette Thinger, Jun. 10, 2020).

¹⁵⁰ *Id.*

¹⁵¹ Petitioners’ Descriptions of Health Effects, *supra* note 142 (statement of Marissa Doherty, May 19, 2021).

¹⁵² *Id.*

¹⁵³ Petitioners’ Descriptions of Health Effects, *supra* note 142 (statement of Meredith Pedack, Jan. 28, 2020).

¹⁵⁴ *Id.*

¹⁵⁵ Petitioners’ Descriptions of Health Effects, *supra* note 142 (statement of Stephanie Houlias-MacDonald, Jan. 28, 2020).

nose, sore throat, and dizziness, and being exposed to several brands of formaldehyde hair-straightening products, including Lasio and Brazilian Blowout.¹⁵⁶

- Sydney Fair: “I was on a steroid for swelling in my inner ears, I suffered breathing issues, and new sensitivities to things because of formaldehyde toxicity in my body. I have been out of work for 3 months and traveling many miles to visit an environmental MD who specializes in the detoxification of formaldehyde. I have pictures of my scalp lesions, full body rash, blood in eye, facial swelling, etc.”¹⁵⁷ Fair reported that her formaldehyde exposure was from Brazilian Blowout.¹⁵⁸
- Terri Kemnitz: “I am no longer able to work in a salon atmosphere – I am allergic to or sensitive to almost all mainstream haircare/treatments... I also have a list of autoimmune conditions that may or may not be related to this. I am working on getting my bloodwork done.”¹⁵⁹ Kemnitz described symptoms of migraines, breathing issues, swollen red eyes, itchy hands, and an itchy throat from formaldehyde hair-straightener exposure.¹⁶⁰

In deciding whether to ban formaldehyde-releasing hair-straightening products, the FDA should take into consideration the impact those products have on the health of salon workers. The experiences shared by the named petitioners are very recent anecdotal evidence of the ongoing acute harm caused by formaldehyde hair straighteners to the salon worker community – primarily women – but all the health effects described by the petitioners were too numerous to include in the petition. The petitioners’ original statements, dated between January 2020 and May 2021, and those not quoted above, described numerous symptoms ascribed to formaldehyde-releasing hair straighteners, including sore throat, burning eyes, coughing, nasal and lung irritation, asthma, nose bleed, headache/migraine, dizziness, rash, chronic sinusitis, allergic reactions, trouble breathing, chemical sensitivity, tremors, anxiety, confusion, and vision problems.¹⁶¹

V. STATEMENT OF LEGAL GROUNDS

The 1938 FDCA grants the FDA authority to regulate cosmetic products and their ingredients.¹⁶² The FDCA specifically prohibits “The adulteration or misbranding of any... cosmetic in interstate commerce,” as well as the “introduction or delivery for introduction into interstate commerce,” and “receipt in interstate commerce” of any adulterated or misbranded cosmetics.¹⁶³

¹⁵⁶ *Id.*

¹⁵⁷ Petitioners’ Descriptions of Health Effects, *supra* note 142 (statement of Sydney Fair, Dec. 22, 2020).

¹⁵⁸ *Id.*

¹⁵⁹ Petitioners’ Descriptions of Health Effects, *supra* note 142 (statement of Terri Kemnitz, Jan. 29, 2020).

¹⁶⁰ *Id.*

¹⁶¹ See Petitioners’ Descriptions of Health Effects, *supra* note 142 (statements of Afton May, Alisha, Bettina Bourdens, Brittney Delo Martinez, Cassie Irwin, Chelsea Stephens, Elizabeth Burns, Emily Baedeker, Erin Nelson, Gabriella, Heather Watkins, Holly Dabkowski, Jamie Powers, Jennifer Deer, Jessica Ross, Katie Wall, Krista Varnum, Lauren, Lynnae Duley, Marita, Megan Weaver, Melissa, Nicole Cohea, P. Johnson, Robyn Lozano, Russell Powell, Sadie Gasparini, Sofie Conroy, Stephanie Altman, Sungmi Choi Yoon, Tara Brown, and Teresa Mockler, Jan. 27, 2020 to May 19, 2021).

¹⁶² Congressional Research Service, *FDA Regulation of Cosmetics and Personal Care Products*, at Summary (2012),

https://www.everycrsreport.com/files/20120709_R42594_f2c0c94e9b027987b246daa1c2b2ae9defe309c5.pdf.

¹⁶³ 21 U.S.C. § 331(a)-(c).

A. Formaldehyde renders hair-straightening and -smoothing treatments adulterated

A cosmetic product “shall be deemed to be adulterated” under the FDCA if it “bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual.”¹⁶⁴ The serious health harms of formaldehyde exposure are well documented, as are numerous instances of workers and consumers exposed to dangerous levels of formaldehyde in the air of salons where formaldehyde-based hair-straightening and -smoothing treatments are used.

The FDA is already on record in warning letters to GIB, LLC dba Brazilian Blowout and Van Tibolli Beauty Corp. that hair-smoothing products containing formaldehyde are adulterated under § 601 of the FDCA. Public records obtained by EWG show that FDA scientists completed a risk assessment in 2016 and recommended that the FDA ban these products.¹⁶⁵

FDA has ample scientific evidence – consistent with evidence the FDA has relied on to prohibit or restrict other ingredients – to make a finding that formaldehyde is a “poisonous or deleterious substance” and its presence in hair-straightening or -smoothing treatments renders such products “injurious to users.”

1. Formaldehyde is carcinogenic

As discussed *supra*, studies have found formaldehyde to be an animal and human carcinogen. Formaldehyde was definitively demonstrated to cause cancers of the nose, nasal cavity, and nasopharynx in animals.¹⁶⁶ Without strong evidence to the contrary, finding a chemical to be an animal carcinogen is enough for the FDA to infer human carcinogenicity, as the it did when it banned methylene chloride, in 1989,¹⁶⁷ and chloroform, in 1976.¹⁶⁸

¹⁶⁴ 21 U.S.C. § 361(a) (2021) (the only exception to the adulteration law is that it “shall not apply to coal-tar hair dye” meeting certain labeling requirements).

¹⁶⁵ Melanie Benesh, *supra* note 13.

¹⁶⁶ NTP Report on Carcinogens, *supra* note 15, at 1.

¹⁶⁷ Proposed Ban on the Use of Methylene Chloride as an Ingredient of Aerosol Cosmetic Products, 50 Fed. Reg. 51,551, 51,552 (proposed Dec. 18, 1985) (to be codified at 21 C.F.R. § 700.19), <https://www.govinfo.gov/content/pkg/FR-1985-12-18/pdf/FR-1985-12-18.pdf> (“It has been the agency’s policy that substances that cause cancer in laboratory animals should be considered potential human carcinogens unless there is clear epidemiological evidence to the contrary or unless there is other evidence that the effects observed in animals are not relevant to humans.”); see also Ban on the Use of Methylene Chloride as an Ingredient of Aerosol Cosmetic Products, 54 Fed. Reg. 27,328 (Jun. 29, 1989) (to be codified at 21 C.F.R. § 700.19), <https://www.govinfo.gov/content/pkg/FR-1989-06-29/pdf/FR-1989-06-29.pdf>.

¹⁶⁸ Chloroform as an Ingredient of Human Drug and Cosmetic Products, 41 Fed. Reg. 26,842, 26,844 (Jun. 29, 1976) (to be codified at 21 C.F.R. § 700.18), <https://www.govinfo.gov/content/pkg/FR-1976-06-29/pdf/FR-1976-06-29.pdf>.

Beyond animal studies, human studies have found an association between formaldehyde exposure and sinonasal, nasopharynx, and lymphohematopoietic cancers.¹⁶⁹ Thus, the evidence available for banning formaldehyde is stronger than the evidence relied on by the FDA to ban methylene chloride and chloroform, because formaldehyde's carcinogenicity is evidenced not only by animal studies but also by human studies.¹⁷⁰ Formaldehyde-based hair straighteners and hair smoothers containing formaldehyde present a significant cancer risk to salon workers. Based on this carcinogenicity, the FDA should consider hair-straightening and -smoothing products containing formaldehyde to be adulterated and ban them.

2. Formaldehyde is acutely toxic

More than a century of experience with formaldehyde, including numerous studies and reported adverse events, show that formaldehyde is acutely toxic. There is ample evidence that formaldehyde exposure from hair-straightening and -smoothing products can cause chemical burns, acute allergic reactions, and other serious health effects in people.¹⁷¹ Studies show that using formaldehyde-based hair-straightening and -smoothing treatments in salons exposes workers to dangerous levels of formaldehyde, often in excess of short-term occupational exposure limits established by OSHA and NIOSH.¹⁷² Formaldehyde's acute toxicity is a sufficient basis for the FDA to find that chemical hair straighteners are adulterated and ban formaldehyde's use in chemical hair straighteners. In 1974, the FDA restricted vinyl chloride's use in aerosols, based on its acute toxicity and carcinogenicity.¹⁷³

3. Adverse health effects of long-term formaldehyde exposure

Long-term exposure to low levels of formaldehyde has been associated with adverse health effects, including genotoxicity, cancer, blood changes, and reproductive harm.¹⁷⁴ Several studies

¹⁶⁹ NTP Report on Carcinogens, *supra* note 15, at 2.

¹⁷⁰ See Ban on the Use of Methylene Chloride as an Ingredient of Aerosol Cosmetic Products, *supra*, at 27,340; Chloroform as an Ingredient of Human Drug and Cosmetic Products, *supra*, at 26844.

¹⁷¹ See, e.g., AERs including those from 2011 and earlier (see AERs, FDA Keratin Reports (Feb. 11, 2011), https://static.ewg.org/reports/2011/brazil_blowout/PDF/FDA_keratin_reports.pdf?_ga=2.43761893.176577446.1619043256-1202074806.1601303277 (on file with EWG)), and Felicity de Vere et al., *A Severe Case of Methaeglobinaemia in a Brazilian Hairdresser*, 13 *BMJ Case Reports* CP e232735 (2020), <http://dx.doi.org/10.1136/bcr-2019-232735> (a case report of a severe case of methemoglobinemia in a Brazilian hairdresser in the United Kingdom exposed to multiple volatile chemicals, including formaldehyde, during Brazilian Blowout hair treatment).

¹⁷² E.g., J. S. Pierce et al., *Characterization of Formaldehyde Exposure Resulting From the Use of Four Professional Hair Straightening Products*, 8 *Journal of Occupational and Environmental Hygiene* (Issue 11) 686 (2011), <https://doi.org/10.1080/15459624.2011.626259>; Yulia B. Monakhova et al., *Formaldehyde in Hair Straightening Products - Rapid 1H NMR Determination and Risk Assessment*, 35 *International Journal of Cosmetic Science* 201 (2013), <https://doi.org/10.1111/ics.12027>; and Marcelo E. Pexe et al., *Hairdressers Are Exposed to High Concentrations of Formaldehyde During the Hair Straightening Procedure*, 26 *Environmental Science and Pollution Research* 27319 (2019), <https://doi.org/10.1007/s11356-019-05402-9>.

¹⁷³ Vinyl Chloride as an Ingredient of Drug and Cosmetic Aerosol Products, 39 Fed. Reg. 14,215, 14,216 (proposed Apr. 22, 1974) (to be codified at 21 C.F.R. § 700.14), <https://www.govinfo.gov/content/pkg/FR-1974-04-22/pdf/FR-1974-04-22.pdf>; see also Vinyl Chloride as an Ingredient of Drug and Cosmetic Aerosol Products, 39 Fed. Reg. 30,830 (Aug. 26, 1974) (to be codified at 21 C.F.R. § 700.14), <https://www.govinfo.gov/content/pkg/FR-1974-04-22/pdf/FR-1974-04-22.pdf>.

¹⁷⁴ Ki-Hyun Kim et al., *supra* note 75, at 285-88.

found that formaldehyde causes direct damage to DNA in nasal epithelial cells and blood lymphocytes, as well as cellular changes to mucosa cells.¹⁷⁵ Other studies have linked long-term formaldehyde exposure with some types of leukemia.¹⁷⁶ Studies have also linked low-level formaldehyde exposure to low white blood cell counts.¹⁷⁷ Several studies found a clear association between long-term formaldehyde exposure and abnormal menstrual cycles and low-birth-weight babies.¹⁷⁸ The levels of formaldehyde exposure in most of these studies was consistent with the long-term exposure experienced by salon workers. Alone, long-term effects like genotoxicity, carcinogenicity, blood changes, and reproductive harm are enough for the FDA to find that chemical hair straighteners using formaldehyde are adulterated. But, because formaldehyde likely causes *all* of these effects, the evidence is even stronger that chemical hair straighteners and smoothers using formaldehyde are adulterated and the FDA should immediately ban them.

4. Professionals and consumers are considered “users” under the FDCA

Section 601 of the FDCA establishes that a product is rendered adulterated when it contains a substance that would render it “injurious to users.” 21 U.S.C. § 361(a). In its 1985 proposed rule banning methylene chloride in hair sprays, the FDA considered risks to hair care specialists, which it considered a high-risk population. Specifically, the FDA said:

In calculating the risk from exposure to methylene chloride, the agency considered two population groups. One group, hair care specialists, represents the group with the highest

¹⁷⁵ Ki-Hyun Kim et al., *supra* note 75, at 284 (citing F. R. Cassee et al., *Sensory Irritation to Mixtures of Formaldehyde, Acrolein, and Acetaldehyde in Rats*, 70 *Archives of Toxicology*, 329 (1996); S. D. Hester et al., *Formaldehyde-induced Gene Expression in F344 Rat Nasal Respiratory Epithelium*, 187 *Toxicology (Issue 1)* 13 (2003); L. M. Appelman et al., *One-year Inhalation Toxicity Study of Formaldehyde in Male Rats With a Damaged or Undamaged Nasal Mucosa*, 8 *Journal of Applied Toxicology (Issue 2)* 85 (1988); G. M. Rusch, *A 26-week Inhalation Toxicity Study With Formaldehyde in the Monkey, Rat, and Hamster*, 68 *Toxicology and Applied Pharmacology (Issue 3)* 329 (1983)).

¹⁷⁶ Ki-Hyun Kim et al., *supra* note 75, at 287 (citing L. Pinkerton, *Mortality Among a Cohort of Garment Workers Exposed to Formaldehyde: An Update*, 61 *Occupational and Environmental Medicine (Issue 3)* 193 (2004); M. Hauptmann et al., *Mortality From Lymphohematopoietic Malignancies and Brain Cancer Among Embalmers Exposed to Formaldehyde*, *J Nat Cancer Ins.*, 101: 1696–1708 (2009); J. H. Dreyfuss, *Occupational Formaldehyde Exposure Linked to Increased Risk of Myeloid Leukemia and Death*, 60 *CA: A Cancer Journal for Clinicians (Issue 3)* 135 (2010); M. Hauptmann et al., *Mortality From Lymphohematopoietic Malignancies Among Workers in Formaldehyde Industries*, 95 *Journal of the National Cancer Institute (Issue 21)* 1915 (2003)).

¹⁷⁷ Ki-Hyun Kim et al., *supra* note 75, at 285 (citing L. X. Tang and Y. S. Zhang, *Health Investigation on Workers Exposed to Formaldehyde*, 19 *Journal of Occupational Health (Issue 7)* 34 (2003); Z. M. Tong, *Effect of Formaldehyde on Blood Component and Blood Biochemistry of Exposed Workers*, 20 *Chinese Journal of Industrial Medicine (Issue 6)* 409 (2007); W. H. Yang, *Hemogram of Workers Exposed to Low Concentration of Formaldehyde*, 14 *Practical Preventative Medicine (Issue 3)* 792 (2007)).

¹⁷⁸ Ki-Hyun Kim et al., *supra* note 75, at 286 (citing Y. Lu et al., *A Survey of the Effect to Teachers’ Health From Formaldehyde Contact*, 30 *Journal of Xinjiang Medical University (Issue 3)* 234 (2007); H. K. Taskinen et al., *Laboratory Work and Pregnancy Outcome*, 36 *Journal of Occupational Medicine (Issue 3)* 311 (1994); Ligita Marozienė and Regina Grazulevičienė, *Maternal Exposure to Low-level Air Pollution and Pregnancy Outcomes: A Population-based Study*, 1 *Environmental Health (Issue 1)* 6 (2002), <https://doi.org/10.1186/1476-069x-1-6>; Anh Duong et al., *Reproductive and Developmental Toxicity of Formaldehyde: A Systematic Review*, 728 *Mutation Research (Issue 3)* 118 (2011), <https://doi.org/10.1016/j.mrrev.2011.07.003>).

exposure level expected from aerosol hair sprays. The other group is the segment of the population that routinely uses aerosol hair sprays as part of their grooming practices.¹⁷⁹

When the FDA finalized the ban, in 1989, it based its decision on upper bound risk estimates that the use of methylene chloride in hair sprays would render those sprays “injurious to the health of consumers and of hair care professionals.”¹⁸⁰ Thus, the FDA has established in previous regulations that it considers *both* workers and consumers to be “users” under section 601(a) and should consider both consumers and salon workers to be “users” of chemical hair-straightening and -smoothing treatments containing formaldehyde. Given the significant risks to both groups, and the heightened risks to salon workers, such products are adulterated.

5. Industry recognizes the dangers of formaldehyde in hair straightening and smoothing treatments

Even the industry-funded Cosmetic Ingredient Review (CIR) panel has found that formaldehyde in hair-straightening and -smoothing treatments are harmful to human health (but CIR only reviewed the safety of formaldehyde and methylene glycol at the request of the FDA).¹⁸¹ The Personal Care Products Council (PCPC) established the CIR program to review the safety of cosmetic product ingredients, based on published and unpublished data on individual ingredients.¹⁸² The purpose of the CIR program “is to determine those cosmetic ingredients for which there is a reasonable certainty in the judgment of competent scientists that the ingredient is safe under its conditions of use.”¹⁸³

As of September 2020, CIR has found 2,512 ingredients “safe as used”; 3,023 ingredients safe with qualifications; 66 ingredients with insufficient data to support safety; and only 12 ingredients “unsafe for use in cosmetic products.”¹⁸⁴ The CIR Expert Panel published its original safety assessment of formaldehyde *more than 30 years ago*, in 1984, and found that *in no case was formaldehyde in a product to exceed 0.2% of a finished product*.¹⁸⁵ CIR also found that “it cannot be concluded that formaldehyde is safe in cosmetics products intended to be aerosolized.”¹⁸⁶ In December 2011, CIR released a Final Amended Report on Formaldehyde and Methylene Glycol (“Final Amended Report”), which incorporated data from PCPC, FDA’s adverse event reporting system, FDA’s laboratory product analyses, the Nail Manufacturer’s Council (NMC), the Professional Keratin Smoothing Council (PKSC), and the American

¹⁷⁹ Proposed Ban on the Use of Methylene Chloride as an Ingredient of Aerosol Cosmetic Products, *supra* note 140, at 51,552.

¹⁸⁰ Ban on the Use of Methylene Chloride as an Ingredient of Aerosol Cosmetic Products, *supra* note 140, at 27,328.

¹⁸¹ See Memo from F. Alan Andersen, Ph.D., Director, Cosmetic Ingredient Review, to CIR Expert Panel Members and Liaisons (Nov. 18, 2010), https://www.cir-safety.org/sites/default/files/117_Buff1.pdf (“FDA has asked CIR to look at these two ingredients and consider how to address the safety of not-yet-reviewed methylene glycol.”).

¹⁸² Congressional Research Service, *supra* note 136, at 14.

¹⁸³ *Id.*

¹⁸⁴ Cosmetic Ingredient Review, *CIR Findings*, Cosmetics Ingredient Review, <https://www.cir-safety.org/cir-findings> (last visited Jun. 2, 2021).

¹⁸⁵ CIR Expert Panel, *supra* note 16, at 31.

¹⁸⁶ *Id.*

Chemistry Council.¹⁸⁷ In its Final Amended Report, CIR determined that “the present practices of use and concentration (on the order of 10% formaldehyde/methylene glycol, blow drying and heating, inadequate ventilation, resulting in many reports of adverse effects), hair smoothing products containing formaldehyde and methylene glycol are unsafe.”¹⁸⁸ To put these “present practices of use and concentration” – which are “on the order of” “10% formaldehyde/methylene glycol” – into perspective, this 10% concentration exceeds by more than **50 times** the limit CIR’s 1984 mandate that *in no case was formaldehyde in a product to exceed 0.2% of a finished product.*¹⁸⁹

PCPC has publicly supported the findings of CIR on formaldehyde in hair straighteners and advocated for more regulation since at least 2016. In a public statement, Beth Jonas, the organization’s chief scientist, said:

In 2011, CIR issued a final conclusion on the safety of formaldehyde and methylene glycol as used in hair straightening products and found them to be unsafe under present conditions of use. The Expert Panel noted that the safety of methylene glycol and formaldehyde in hair straightening products depends on a number of factors, including the concentration of formaldehyde and methylene glycol, the amount of product applied, the temperature used during the application process, and the ventilation provided at the point of use. They concluded that under present practices of use and concentration, formaldehyde and methylene glycol are unsafe in hair straightening products . . . The Council fully supports the Expert Panel’s findings. It’s important to note that FDA has clear authority to regulate the safety of these products under the Food, Drug & Cosmetic Act, which requires that every product and its individual ingredients be substantiated for safety before they are put on the market, and that those products’ labels be truthful and not misleading.¹⁹⁰

6. States have banned formaldehyde in cosmetics

FDA’s lack of action in banning formaldehyde from hair-straightening products has prompted the states to act unilaterally to ban formaldehyde from cosmetics. On May 13, 2013, Minnesota banned formaldehyde and formaldehyde-releasing ingredients in certain children’s products.¹⁹¹ Minnesota’s ban took effect on August 1, 2014.¹⁹² On September 30, 2020, California passed the Toxic-Free Cosmetics Act (AB 2762).¹⁹³ In California, beginning on January 1, 2025, cosmetic products intentionally containing formaldehyde, methylene glycol, and other banned chemicals are banned from commerce.¹⁹⁴ On May 30, 2021, Maryland enacted a law, virtually identical to California’s law, banning formaldehyde-containing cosmetic products from commerce in the

¹⁸⁷ CIR Expert Panel, *supra* note 16.

¹⁸⁸ CIR Expert Panel, *supra* note 16, at 31 (emphasis added).

¹⁸⁹ *Id.*

¹⁹⁰ Beth Jonas, Statement by Beth Jonas, Ph.D., Chief Scientist Personal Care Products Council, in Response to Formaldehyde in Hair-Straightening Products, Personal Care Products Council (Dec. 15, 2016), <https://www.personalcarecouncil.org/statement/statement-by-beth-jonas-phd-chief-scientist-personal-care-products-council-in-response-to-formaldehyde-in-hair-straightening-products/>.

¹⁹¹ MINN. STAT. §325F.177 (2021).

¹⁹² *Id.*

¹⁹³ CAL. Health & Safety Code § 108980 (2021).

¹⁹⁴ Health & Safety § 108980(a)(3) thru (5).

state starting on January 1, 2025.¹⁹⁵ The FDA should join California and Maryland and ban formaldehyde and formaldehyde releasers from cosmetic products like hair-straightening and -smoothing products.

B. Many formaldehyde-based hair straightening and smoothing products are misbranded

Under section 602(a) of the FDCA (21 U.S.C. § 362(a)), “A cosmetic shall be deemed to be misbranded” if *inter alia* “its labeling is false or misleading in any particular.”¹⁹⁶ Section 201(n) (21 U.S.C. § 321(n)) provides that, “in determining whether a product’s labeling or advertising is misleading there shall be taken into account (among other things) the extent to which the labeling or advertising fails to reveal facts material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.”

Formaldehyde hair straighteners usually contain methylene glycol, which is the liquid form of formaldehyde. Yet several brands fail to warn consumers about the risks of formaldehyde exposure or falsely claim that their products are “formaldehyde free,” even if they contain methylene glycol. As stated in the FDA’s warning letter to GIB:

Brazilian Blowout is misbranded because its label and labeling (including instructions for use) makes misleading statements regarding the product's ingredients and fails to reveal material facts with respect to consequences that may result from the use of the product. Specifically, Brazilian Blowout contains the liquid form of formaldehyde, methylene glycol; however, the product label declares that the product contains ‘No Formaldehyde’ or is ‘Formaldehyde Free.’ This declaration renders your product misbranded because it is a false and misleading statement.¹⁹⁷

Additionally, the FDA’s warning letter to GIB noted these products failed to include information on the release of formaldehyde into the air when these products are used as prescribed by the labeling or advertising, or used in the customary or usual fashion.¹⁹⁸

The FDA also found Van Tibolli Beauty Corp’s GK Hair Taming System with JUVEXIN® Curly and Resistant hair-smoothing products to be misbranded. According to the FDA’s 2015 warning letter, despite containing instructions and a warning label, Van Tibolli’s products were misbranded because the labels failed to reveal material facts with respect to consequences that may result from use of the product.¹⁹⁹ Specifically, the FDA found that:

“1. They fail to inform the user of the adverse effects that may result from the release of formaldehyde into the air during the heating process, which can have both short term and

¹⁹⁵ MD. CODE ANN., HEALTH–GEN. § 21-259.2 (2021).

¹⁹⁶ 21 U.S.C. § 362(a).

¹⁹⁷ See Brazilian Blowout FDA Warning Letter, *supra* note 12.

¹⁹⁸ *Id.*

¹⁹⁹ See Van Tibolli FDA Warning Letter, *supra* note 12.

long term health effects (e.g., eye and throat irritation, headache, dizziness, burning sensations, breathing problems, nosebleeds, chest pain, skin irritation and certain cancers), particularly for those who are sensitive to formaldehyde. Long term exposure may potentially cause certain cancers.

2. They fail to inform users that concurrent uses of these products in the same facility may increase the concentration of formaldehyde in the air, which could increase the risk of adverse effects.”²⁰⁰

The FDA noted that although Van Tibolli’s products targeted primarily salon professionals in a salon setting, the products were also available for home use and could be purchased by the general public on the internet and from retail beauty stores.²⁰¹

Although the FDA only targeted two brands, Brazilian Blowout and Van Tibolli, with warning letters, such deceptive practices are ongoing.²⁰² These misbranded products mislead consumers and salon workers into thinking that the products are safe and will not result in formaldehyde exposure. Such misleading practices render formaldehyde hair straighteners misbranded under section 602 and, consequently, the FDA should consider these products misbranded.

VI. ENVIRONMENTAL IMPACT

This citizen petition is categorically excluded from the need to prepare an Environmental Assessment under 21 C.F.R. § 25.32(m) as an “Action to prohibit or otherwise restrict or reduce the use of a substance in food, food packaging, or cosmetics.” The citizen petition is further categorically excluded from the need to prepare an Environmental Assessment under 21 C.F.R. § 25.30(b) as a “recommendation for an enforcement action to be initiated.” The requested regulations codify an existing FDA position on formaldehyde and formaldehyde equivalents in hair straighteners.

We have identified no extraordinary circumstances as defined at 21 C.F.R. § 25.21 for the action requested in this petition that would require the submission of an Environmental Assessment.

VII. ECONOMIC IMPACT

Not requested by the FDA.

²⁰⁰ *Id.*

²⁰¹ *Id.*

²⁰² See EWG, *Brands That Hide Formaldehyde*, Environmental Working Group (Apr. 2011), <https://www.ewg.org/hair-straighteners/our-report/hair-straighteners-that-hide-formaldehyde/> (EWG’s April 2011 analysis found 15 out of 16 claiming little to no formaldehyde contained substantial amounts of formaldehyde and Women’s Voices for the Earth’s Safety Data Sheet analyses for formaldehyde); see also WVE, *Hair Straightening Products Containing Formaldehyde*, Women’s Voices for the Earth (updated Jan. 2018), <https://www.womensvoices.org/safe-salons/brazilian-blowout/hair-straightening-products-containing-formaldehyde/> (WVE identified numerous examples of misbranded formaldehyde releasing hair-straightening products still on the market).

VIII. CERTIFICATION

The undersigned certify, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner that are unfavorable to the petition.

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