

# The True Story of Cosmetics

Exposing the Risks of the  
Smear Campaign

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*By Dana Joel Gattuso*

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### Executive Summary

The Campaign for Safe Cosmetics and its partner, the Environmental Working Group (EWG), are on a crusade to scare consumers away from using cosmetics and hygiene products that contain preservatives and other useful chemicals. As part of their effort to ban the use of synthetic ingredients from skin products, these environmental extremist groups are working to incite fear among consumers, making outrageous and bogus claims that we are poisoning ourselves by using lipstick, makeup, deodorants, skin creams, and even baby products. Specifically, they claim that the additives can cause cancer, create neurological disorders, or cause hormone disruption—even though they are present in trace amounts.

In fact, these preservatives protect users from bacteria. Present in quantities so small—typically, less than 1 percent of a product’s total weight—they are added to prevent contamination and to protect consumers from the buildup of dangerous bacteria that can cause eye infections, skin rashes, and even deadly infections such as *E. coli* and *Salmonella*.

Parabens, for example, are added to makeup, deodorants, moisturizers, and body creams to prevent bacteria, fungi, and mold. According to the Campaign for Safe Cosmetics, parabens are linked to breast cancer and can cause hormone dysfunction. Yet scientists have refuted the claims, arguing that concentrations of parabens in cosmetics are too small to have an adverse effect, and are at levels in our body thousands to millions of times lower than naturally produced estrogens.

Another example is the chemical oxybenzone, used in sunscreens to protect users from the ultraviolet rays that can cause skin cancer. The Environmental Working Group warns consumers to stay away from oxybenzone because it “contaminates the body” and can cause hormone disruption and cell damage. Yet cancer research organizations such as the Skin Cancer Foundation refute EWG’s assertions, arguing that there is no evidence to back the claims of oxybenzone risks. These cancer foundations worry that such fear mongering will scare consumers away from using sun block products that protect consumers from the risks of skin cancer from the sun’s rays.

In spite of the lack of scientific evidence of health risks from these ingredients, the anti-chemical groups have been successful in creating a climate of fear among many consumers—and lawmakers. The legislation they are promoting, the Safe Cosmetics Act of 2011, would ban any cosmetic and skin care ingredients that exceed a one in a million risk of an adverse health impact—which is to say it would ban most ingredients since almost everything carries risk greater than one in a million. While the risks from products not containing these additives would be much higher, those risks would not be considered. In effect, the bill would ban the very chemicals that protect consumers.

In reviewing the claims of the Campaign for Safe Cosmetics and the Environmental Working Group, as well as the scientific literature on the use of these chemical additives, this report finds that these fringe groups are pushing their own anti-chemical agenda at the expense of human health. It shows that consumers are at far greater risk by avoiding these essential ingredients, as backed by sound and peer-reviewed science.

## Introduction

Many environmental advocacy groups, quite simply, want to rid the world of synthetic chemicals. Now they are at war with your makeup. The foundation you put on your face every morning? Full of parabens known to cause breast cancer and hormone disruption, they say. Your lipstick? A “poison kiss,” loaded with lead. What about the cologne you splash on (in the event you’ve been scared away from bathing and using underarm deodorant)? Swimming in phthalates that cause asthma and infertility. No one is safe, least of all your helpless infant, who is a victim of “cancer-causing chemicals” every time you apply baby shampoo.

People for the most part do not get hurt by using cosmetics and other skin care products, save the occasional allergic reaction which can occur among people with sensitive skin or allergies—regardless of whether they are using products with preservatives or so-called “natural” products. Nor is there scientific evidence that chemicals present in personal care products—typically, in trace amounts—can cause cancer, endocrine disruption, asthma, or allergens.

But that is not stopping extremist anti-chemical groups, organized under the umbrella Campaign for Safe Cosmetics, its partner Environmental Working Group, Greenpeace, and others from doing everything in their power to ban these vital ingredients.

That is where the harm is. Chemicals are in cosmetics for a reason. In most cases, they are added to prevent contamination and to protect consumers from the buildup of dangerous bacteria that can cause eye infections, skin rashes, and even deadly infections such as *E. coli* and *Salmonella*. In other cases, they are used to protect us from cancer, as is the case with oxybenzone. The chemical is used in sunscreens because it is the most effective ingredient in protecting users from ultraviolet rays that can cause skin cancer.

These groups’ push for “green consumerism” is couched in fear-mongering and promoted by pseudoscientific reports, videos, and gimmicks to convince consumers that their health is at risk by using these products. It is a fiction that comes at the expense of human health.

This is the true story of cosmetics.

## The Safe Cosmetics Act of 2011

In June 2011, three legislators seized the opportunity in the heat of a controversy involving a product called Brazilian Blowout—a hair salon product that violated U.S. safety laws and caused short-term health effects—to go after chemicals in all cosmetic products. Although the problem was quickly resolved (see full discussion in section on Formaldehyde in appendix), lawmakers used it as justification to introduce legislation that, if passed, will needlessly create a

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mammoth, overreaching, and costly regulatory regime over the manufacturing of cosmetics. (The bill is similar to legislation introduced last year that never gained enough support to advance out of committee.)<sup>1</sup>

The Safe Cosmetics Act of 2011<sup>2</sup> was introduced by Reps. Tammy Baldwin (D-Wis.), Ed Markey (D-Mass.), and Jan Schakowsky (D-Ill.), with strong support from the Campaign for Safe Cosmetics and the Environmental Working Group. It would require all skin care manufacturers to conduct exhaustive and expensive tests on all their products and ingredients and then list every ingredient the product contains on the label—no matter how miniscule its presence.

The bill establishes a new safety standard for cosmetics that is out of whack with any sensible understanding of toxicology. It defines “reasonable certainty of no harm” as not exceeding a “1 in a million risk for any adverse health effect.” That would apply to just about every ingredient since just about everything carries a risk of more than one in a million, including bottled drinking water. This standard is one of the most precautionary standards on the books today, yet it creates greater risks than the ones it purports to address.

It is the same standard used for the Food Quality Protection Act of 1994. When applied to pesticides, it has led to unwarranted bans on numerous and critically valuable products, leaving consumers with few defenses against a host of risks, from West Nile virus to Lyme disease, as well as the psychological stress and uncomfortable and itchy welts associated with emerging bedbug problems.<sup>3</sup>

In fact, regulations governing the foods we ingest allow us to be exposed to far more “harmful” levels of ingredients than what this bill requires of products we apply on our skin. Cosmetics can cause non-threatening skin reactions among some users who are prone to them. Those reactions subside when the cosmetic is no longer used. But this bill would ban such products for all of us. Almost all foods carry a much higher risk than one in a million—yet we do not outlaw those foods.

Furthermore, many of the chemicals that would be banned under this bill are present in many healthy foods we eat, including fruits and vegetables. Apples contain anywhere from 6 to 22 parts per million of natural occurring formaldehyde; pears 39 to 60 parts per million, and dried Shiitake mushrooms as much 100 to over 400 parts per million.<sup>4</sup> Yet this bill would ban formaldehyde-releasing ingredients, which are added as a preservative in cosmetics to fight off deadly bacteria.

The bill also defines the ingredient that must be tested and labeled as any component that is “present at levels above technically feasible detection

limits.” Since scientists can detect the most miniscule levels of almost anything—at one part per billion and even one part per trillion—that would include just about every component of every ingredient of every product, no matter how insignificant.

Some product ingredients contain as many as 100 components, all of which can be detected under today’s measuring standards for chemicals. Under this bill, each of the 100 components must be separated and tested. To pass muster, not a single one of the 100 components, each tested on 1 million people, may cause any kind of adverse reaction, including an allergic reaction, in more than one person.

Consider one blogger and industry leader’s assessment of what the Safe Cosmetics Act would require:

A product containing what would normally be regarded as five ingredients—olive oil, blue chamomile extract, and essential oils of orange, rose and vetiver—would require an ingredient list looking something like this:<sup>5</sup>

oleic acid, palmitic acid, stearic acid, linoleic acid, linolenic acid, squalene, hydroxytyrosol, tyrosol, oleuropein, ligstroside, elenolic acid, acetoxypinoresenol, oleocanthal,  $\alpha$ -tocopherol, herniarin, hyperoside, umbelliferone, methylumbelliferone, caffeic acid, chlorogenic acid, quercetin, rutin, flavanone, isorhamnetin, quercimeritin, anthemic acid, choline, triacontane, patuletin, patulitricin, apigetrin, apigenin-7-glucoside, apigenin-7-apiosylglucoside, luteolin-7-glucoside, apigetrin-7-acetylglucoside, luteolin-4-glucoside, luteolin, patuletin, matricin, matricarin, galacturonic acid, d-limonene, citronellol, geraniol, myrcene, linalool,  $\alpha$ -pinene, sabinene,  $\beta$ -phellandrene, geranial, neral, decanal, citronellal, (Z)- $\alpha$ -ocimene,  $\beta$ -pinene, valencene,  $\beta$ -elemene, terpinolene, dodecanal,  $\beta$ -terpinene,  $\beta$ -sinensal,  $\beta$ -sinensal,  $\beta$ -cadinene,  $\beta$ -copaene,  $\beta$ -muurolene, nerol,  $\beta$ -3-carene, (Z)-3-hexenol, perillaldehyde, octanol, cis-sabinene hydrate, undecanal, nonadecane, heneicosane, 1-nonadecene, 2-phenylethanol, (E)- $\alpha$ -ocimene, methyleugenol, eugenol, 1-heptadecene, eicosane, trans-linalool oxide,  $\beta$ -caryophyllene, 1-tricosene,  $\beta$ -terpineol,  $\beta$ -farnesene, farnesyl acetate, citronellyl formate, pentadecane,  $\beta$ -guaiene, benzaldehyde, (Z)- $\beta$ -farnesene, terpinen-4-ol, geranyl acetate, isogeranyl acetate, farnesyl propionate, methyl salicylate, citronellyl acetate, hexanol,  $\beta$ -humulene, methyl geranate,  $\beta$ -terpinene, cis-rose oxide, isogeraniol,  $\beta$ -bergamotene,  $\beta$ -2-carene, cis-linalool oxide, octadecane, heptadecane,  $\beta$ -phellandrene, cis-rose oxide,  $\beta$ -maaliene, ethyl

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benzoate, geranyl acetone, 3-methylbutanol, docosane, 1-heneicosene, p-cymene, 1-eicosene, bourbonene, ?-cadinene, hexadecane, 1-tricosene, octanal, nerolidol, 2-undecanone, benzyl benzoate, ?-muurolene, 2-phenylethyl phenylacetate, farnesol, geranyl formate, guaiol, heptanal, allo-ocimene, 1-octadecene, “2-phenylethyl-3-methyl valerate, hexadecanol, hexanal, 3-hexenyl formate, 2-phenylethyl benzoate, khusimol, vetiselinol, cyclocopacamphan-12-ol (epimer A), ?-cadinol, ?-vetivone, ?-vetivenene, ?-eudesmol, ?-vetivone, khusenic acid, ?-vetispirene, ?-vetivenene, ?-amorphene, (E)-eudesm-4(15), 7-dien-12-ol, ?-calacorene, (Z)-eudesm-6-en-11-ol, ?-amorphene ziza-5-en-12-ol, ?-selinene, (Z)-eudesma-6,11-diene, salvial-4(14)-en-1-one, khusinol, cyclocopacamphan-12-ol (epimer B), selina-6-en-4-ol, khusian-ol, ?-amorphene, 1-epicubanol, khusimene, ziza-6(13)-en-3?-ol, ziza-6(13)-en-3-one, 2-epi-ziza-6(13)-en-3?-ol, 12-nor-ziza-6(13)-en-2?-ol, ?-vetispirene, eremophila-1(10),7(11)-diene, dimethyl-6, 7-bicyclo-[4.4.0]-deca-10-en-one, 10-epi-?-eudesmol, ?-calacorene, (E)-opposita-4(15),7(11)-dien12-ol, prekhusenic acid, 13-nor-eudesma-4, 6-dien-11-one, isovalencenol, spirovetiva-1(10),7(11)-diene, 2-epi-ziza-6(13)-en-12-al, (E)-isovalencenal, preziza-7(15)-ene, (Z)-eudesma-6,11-dien-3?-ol, intermedeol, isoeugenol, isokhusenic acid, elemol, eremophila-1(10),6-dien-12-al, juniper camphor, khusimone, eremophila-1(10),4(15)-dien-2?-ol, eremophila-1(10),7(11)-dien-2?-ol, (Z)-isovalencenal, allo-khusiol, methyl-(E)-eremophila-1(10),7(11)-dien-12-ether, (E)-2-nor-zizaene, (Z)-eudesm-6-en-12-al, funebran-15-al

As the following will document, there is no need for new legislation on cosmetics. Manufacturers are already required by law to ensure products are safe for use. Those who violate the law are prosecuted, and anyone who is actually injured from a product has ample opportunity to collect damages—the threat of litigation serves as an additional reason manufacturers take extra care to ensure the safety of their products. Hurting customers is never good business.

In fact, the cosmetics industry has an impressive safety record, thanks in good measure to the independent Cosmetic Ingredient Review. This organization conducts peer-reviewed safety assessments on cosmetic ingredients.<sup>6</sup> It consists of panels of academic scientists, medical researchers, and clinical dermatologists, under the review of the FDA. Legislation that seeks to go way beyond this by banning chemicals is driven my activist campaigns that have no basis in reality.

## Exposing the Smear Campaign

*This is the story of a world obsessed with stuff. It's the story of a system in crisis. We're trashing the planet, we're trashing each other, and we're not even having fun. The good thing is that when we start to understand the system, we start to see lots of places to step in and turn these problems into solutions.*

*(“The Story of Cosmetics: The Ugly Story of Toxins In, Toxins Out,” Campaign for Safe Cosmetics)*

So begins the video by the Campaign for Safe Cosmetics, a coalition group of environmental activists founded in 2004, whose mission is to eliminate the use of chemicals in personal care products by provoking panic among consumers.<sup>7</sup> With the ultimate goal of regulating chemicals out of use, they use sensationalized and alarmist rhetoric, along with misleading and inaccurate information, to scare consumers into believing we are facing a “chemical crisis,” and that we are poisoning ourselves and our children.

The video, geared toward women and particularly mothers of young children, makes the claim that cosmetics, soaps, and shampoos we use everyday are loaded with toxic chemicals that are “linked” to cancer, endocrine disruption, allergies, asthma, and other health problems. Worse, it implies that we are poisoning our children by using products like baby shampoos, diaper rash ointments, and “tubs full of toxic suds.” We are even “pre-polluting” our babies before they are born, they claim, through synthetic fragrances and other chemicals used by expecting mothers.<sup>8</sup>

The Campaign for Safe Cosmetics’ goal is to scare consumers, pressure manufacturers, and move legislators and regulators to overregulate and ban product ingredients its members claim are “deadly chemicals.”

High on the list are synthetics and preservatives in personal care products, the very additives that prevent spoilage, protect consumers from deadly bacteria, and, in the case of sunscreens, are necessary additives that protect us from the sun’s rays and skin cancer.

The Campaign tries to give the impression that it has science on its side, claiming to have “mountains of scientific evidence...[linking] chemicals [consumers are] using to all sorts of problems.”<sup>9</sup> In fact, the body of scientific evidence shows the opposite. For almost every chemical for which the Campaign claims a link to a health risk, scientific panel reviews and peer-reviewed studies have discredited its claims. These include assessments made by scientists from the National Research Council, American Cancer Society, National Cancer

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Institute, European Union Scientific Committee on Consumer Products, National Toxicology Program, and Cosmetic Ingredient Review panel, among others.

The media has also been part of the problem, giving extensive coverage to the sensational health risk claims by the Campaign for Safe Cosmetics, the Environmental Working Group, and Greenpeace, while rarely reporting on the scientific reports and studies that refute their assertions. Often, news stories use inflammatory language and scary images to incite public phobia against the use of “unnatural” cosmetics. For example, in a *Women’s Health Journal* article entitled “Chemicals and Cosmetics: Such Sweet Poison,” the writer asks readers: “Want to feel young, fresh and feminine? Douse yourself in petro-chemicals, and smear your skin with hormone disrupters. And for spring-fresh confidence you didn’t even know you were lacking, wash with our delicate blend of magnesium chloride, triclosan, methylchloro-isothiazolinone and other unnatural essences.”<sup>10</sup>

Toxicologists concur that the media has done a poor job in its coverage of chemical risk. According to a survey by George Mason University of members of the Society of Toxicology, 90 percent believe the media does a poor job of presenting the issue in a balanced manner, 95 percent believe the media does a poor job in explaining risk and the risk-benefit tradeoffs, and 96 percent believe the media does a poor job in explaining the importance of dose.<sup>11</sup> Eight out of 10 toxicologists responded that the Environmental Working Group exaggerates the risks from chemicals; 96 percent said Greenpeace overstates the risks.<sup>12</sup>

***Dose and the degree of exposure.*** Most of us are familiar with the basic foundation of toxicology, that “the dose makes the poison.” The Swiss Renaissance chemist Paracelsus laid out the principle back in the 16th century: “All substances are poisonous, there is none which is not a poison; the right dose differentiates a poison from a remedy.”<sup>13</sup> Yet one of the key approaches of the anti-chemical campaigners—with which the media too often goes along—is to completely disregard the amount of exposure or dose when reporting on the risks of chemicals.

Chemicals are usually added to cosmetics as preservatives to keep out bacteria and other microorganisms that can be harmful to humans. The amount of the compounds present in the product is small—usually measured in parts per million—and found by most toxicologists to be perfectly safe at those levels.

The cosmetic preservative parabens, for example, is said by the Campaign and other environmental groups to be linked to breast cancer and hormone dysfunction. Yet scientists have refuted the claims, arguing that concentrations of parabens in personal care products—ranging from 0.01 percent to 0.3 percent<sup>14</sup>—

are too small to have an adverse effect, and are at levels in our bodies much lower than naturally produced estrogens.<sup>15</sup>

One study, published in *Critical Views in Toxicology*, notes that in considering the impact parabens in cosmetics have on human health, “[I]t is paramount to consider both the doses and the potency of such compounds in comparison to [naturally-produced] estrogen.” The study, which does consider dose and exposure, concludes, “[I]t is biologically implausible that parabens could increase the risk of any estrogen-mediated endpoint, including effects on the male reproductive tract or breast.”<sup>16</sup>

Similarly, the Campaign for Safe Cosmetics and its coalition members have derided formaldehyde-releasing ingredients used in cosmetics to prevent dangerous *E. coli* bacterial growth and other forms of deadly contamination as dangerous and proven carcinogens. They cite as “evidence” studies done on the exposure to formaldehyde in industrial settings where workers inhale the chemical day after day for prolonged periods of time. Some scientists believe there is a risk of nose cancer at those levels of exposure, which go way beyond what cosmetic wearers experience.

The ban-all-chemicals groups even dismiss the findings of the world’s most stringent regulator of chemicals, the European Commission. Its scientific panel on cosmetics, which places strong emphasis on the dose, concluded that when personal care products containing formaldehyde are applied to the scalp or skin, they are safe as long as the chemical does not exceed 2,000 parts per million.<sup>17</sup>

**Studies on rats.** Another misleading approach used by the all-chemicals-are-bad crowd is to suggest that the findings of lab tests on rats can be extrapolated to make conclusions about health impacts on humans. Many of the claims these groups make about the dangers of chemicals in cosmetics are based on lab tests performed on rats where the rodents are typically fed or exposed to enormous doses of an ingredient. Studies in toxicology repeatedly warn readers that these tests cannot necessarily be used to draw conclusions on human impact.

For example, claims by these groups—and repeated in the media—that parabens are linked to endocrine disrupters are based on lab tests on rats. As the European Union’s Scientific Committee on Consumer Safety wrote in its March 2011, “Opinion on Parabens” (the most comprehensive scientific review of the literature to date), “[T]he rat data as such cannot be simply extrapolated to the human situation without additional supportive data. To this respect, no human study results for the parabens...are available that show unchanged levels of hormones which are of importance for the ongoing discussion.”<sup>18</sup>

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Similarly, much of the noise linking the chemical phthalates in fragrances with infertility comes from studies on rats. As with parabens, there has been little to no causal link from tests on humans. The one study that sought—and claimed—to duplicate the results from rats to humans<sup>19</sup> was flatly rejected and discredited by the National Toxicology Program in an article published in *Science*.<sup>20</sup> Furthermore, when scientists attempted to duplicate the results from tests on rats exposed to phthalates to monkeys, they found no defects on reproductive development.<sup>21</sup>

***Balance: a necessary ingredient in cosmetics.*** Contrary to the bleak picture painted by the Campaign for Safe Cosmetics, there is no credible evidence linking cancer to cosmetics.<sup>22</sup> As for other health risks, the most serious health impacts reported from the use of personal care products have been nosebleeds, vomiting, and headaches among some workers when applying the hair smoother Brazilian Blowout on clients at hair salons. None of these conditions persisted after the beauticians stopped using the product. The federal Office of Safety and Health Administration (OSHA) has since warned salons nationwide to stop using the product till more is known about its ingredients and effects, and regulators are currently studying the ingredients and their health impact.<sup>23</sup>

Some users who have allergies or sensitive skin may have a bad reaction to certain types of ingredients in cosmetic products. Should those ingredients be removed from the market, or should that user simply stop using the product? Sadly, 10 people die each year from peanut allergies in the United States.<sup>24</sup> That is distressing, yet no one has seriously suggested banning peanuts. Close to 3,000 children are hospitalized each year from drowning accidents,<sup>25</sup> yet no one suggests outlawing swimming pools.

***Cosmetics not regulated or adequately tested for safety?*** The Campaign for Safe Cosmetics claims that most cosmetics are not tested for adverse health effects, that the industry remains unregulated, and that, “[O]utdated federal law...allows cancer-causing chemicals in baby shampoo.”<sup>26</sup>

That is not the case. The science and risks associated with cosmetics are rigorously evaluated by the Cosmetic Ingredient Review, an independent review panel of scientists and physicians that assesses the ingredients used in cosmetics.<sup>27</sup> The Cosmetic Ingredient Review panel is made up of seven voting members from the fields of medical and scientific research, including the areas of dermatology, pharmacology, chemistry, veterinary medicine, and environmental medicine. Three additional members are selected by the U.S. Food and Drug Administration (FDA), the Consumer Federation of America, and the industry

group, the Personal Care Products Council to serve as “liaison” members. They are not allowed to vote.<sup>28</sup>

The panel conducts extensive analyses and reports on hundreds of ingredients considered “high priority,” based on frequency of consumer use and odds of causing harm, and identifies them as “safe,” “unsafe,” “safe with qualifications,” or “data are insufficient.”<sup>29</sup> All assessments are made available to the public.<sup>30</sup> Reports are peer-reviewed—unlike reports produced by the Campaign for Safe Cosmetics, the Environmental Working Group, and Greenpeace—and published in the *International Journal of Toxicology*.

The FDA enforces the two key laws that govern the cosmetic industry: the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act. Under the Federal Food, Drug, and Cosmetic Act, it is unlawful to manufacture or sell a cosmetic product whose substance causes injury to users. Under the Fair Packaging and Labeling Act, manufacturers are required to label cosmetic products and include a list of ingredients, in descending order of quantity.<sup>31</sup>

While the FDA does not require pre-market approval of cosmetics per se, any marketed product that causes harm to a user would constitute a violation of existing law and would subject the manufacturer to FDA regulatory action.<sup>32</sup> In addition, the agency works closely with the Cosmetic Ingredient Review panel and prohibits or restricts the use of ingredients that have been identified as health risks.<sup>33</sup> FDA also monitors cosmetic product recalls and may request one if a manufacturer has not pulled a product the agency believes is a danger to consumers.<sup>34</sup>

**“Precautionary” approach and its risks.** When pressed to show scientific evidence that cosmetics carry dangerous health risks, the Campaign for Safe Cosmetics and other pro-government regulation groups argue that we do not always know for certain, but why take the risk?

Yet in most cases, removing the ingredients the anti-chemical activists want to ban from products could create enormous risks—or far greater unknowns. Chemical additives are there for a reason. A large number of them are preservatives that have withstood the test of time, protecting consumers from deadly bacteria. Formaldehyde, for example, is one of the most effective compounds in fighting *E. coli*, and it has been used as the main ingredient in vaccines to fight off the deadly infection, *Clostridium*.<sup>35</sup>

Similarly, parabens are added to cosmetics because no other preservative has been anywhere near as effective in warding off bacteria. Yet the anti-chemical organizations, which have been successful in turning consumers off parabens

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based on unsubstantiated charges, have yet to find a safe alternative. Most substitutes are not as effective as synthetic-based preservatives; others carry risks, such as the organic compound phenoxyethanol. Considered by some to be “the new darling” of the anti-paraben movement, phenoxyethanol has been a concern within the FDA. The agency released an alert in 2008, warning mothers not to use the product Mommy’s Bliss Nipple Cream because it contains “potentially harmful ingredients,” including phenoxyethanol which, according to the release, can shut down the central nervous system and cause diarrhea.<sup>36</sup>

Other so called paraben substitutes marketed as “natural,” like grapefruit seed extract (to which, ironically, many consumers are allergic) are anything but natural. Rather, they require even larger quantities of synthetic preservatives than products containing parabens in order to keep the product free from bacteria.<sup>37</sup> Yet most consumers do not know this and are misled into believing they are using a product that is safe and “natural,” or chemical-free.

Sunscreen is another example where the environmental organizations are putting the public in harm’s way by pushing their anti-chemical agenda. According to the Environmental Working Group, consumers are at risk from using most—92 percent—sunscreens on the market. Why? Because most contain the synthetic additive, oxybenzone, which the Environmental Working Group says is absorbed through the skin and contaminates the body. It claims the ingredient has been linked to cell damage, hormone dysfunction, and allergies.

However, the Skin Cancer Foundation says there is simply no evidence to support the accusations. The Foundation worries that consumers will be concerned over the findings and avoid sunscreen altogether, increasing their risks of skin cancer. Its scientists also worry that the Environmental Working Group’s “top picks” are less known and their effectiveness at shielding users from skin cancer not as well tested.<sup>38</sup>

It should be noted that these anti-chemical groups are not health-based organizations. For example, the Campaign for Safe Cosmetics’ coalition members include the advocacy groups Alliance for a Healthy Tomorrow and the Massachusetts Breast Cancer Coalition, in addition to the Environmental Working Group, Friends of the Earth, and Women’s Voices for the Earth.<sup>39</sup> By title, one might assume the former groups are run by credentialed physicians or toxicologists whose primary objective is the safety and wellbeing of consumers. Yet, in spite of their mission statements, these groups are fundamentally environmental activists, not health or medical groups, which have put all their efforts into fighting chemicals that, they claim, are destroying the planet.

Their extreme environmental fear mongering comes at the expense of human health, as is the case with their campaign to phase out ingredients in sunscreen products or preservatives that prevent bacteria. Numerous reports produced by these groups have been rejected by cancer foundations and research groups who are concerned about the unintended consequences of doing without chemicals.

Nor is the anti-chemical movement necessarily better for the environment. As *New Scientist* notes:

The creams and soaps we slather on our bodies show how rushing to replace petroleum-based chemicals with renewable alternatives might lead us astray. Most of the moisturizers, grease-busters and lathering agents contained in toiletries are derived from fossil sources. Now manufacturers have started to return to more traditional, plant-derived ingredients such as palm and coconut oil.

Unfortunately, while these materials are renewable, they can be far from environmentally benign, as biodiverse forests around the globe have been cleared and replaced by monocultures of oil palms. A scheme to certify palm oil as sustainable has been in operation since late 2008, but of the 40 million tonnes of palm oil produced annually, only around 1.7 million tonnes is so far covered, according to the industry-led Roundtable on Sustainable Palm Oil.<sup>40</sup>

## Conclusion

There is no credible evidence linking cancer and cosmetics or any other of the activists' outrageous health claims.<sup>41</sup> Instances where consumers have been injured by using a personal care product are minute to nonexistent.

The largest risks to consumers come from non-synthetic preservatives that have not withstood the test of time, or from avoiding products like sunscreen, intended to protect us from real environmental hazards. Efforts in the past to further regulate cosmetics have not been supported by health advocacy organizations, for good reason. The American Cancer Society, for example, chose not to support California's Safe Cosmetics Act, which is similar to the pending federal legislation. According to then-American Cancer Society's senior policy director: "There isn't sufficient evidence to say cosmetics cause cancer."<sup>42</sup>

In most cases, chemicals are added to cosmetics to prevent contamination and to protect consumers against dangerous bacteria. They also are used to protect us from cancer, as is the case with oxybenzone, which is used in

*There is no credible evidence linking cancer and cosmetics or any other of the activists' outrageous health claims.*

sunscreens to protect users from ultraviolet rays that can cause skin cancer. The anti-chemical green groups' push for "green consumerism," couched in fear-mongering and pseudoscience, comes at the expense of human health.

The appendix of this paper offers detailed case studies on just a few of the chemicals that activists maintain appear in dangerous levels in our cosmetics. In addition to a fuller exposition on chemicals already discussed in this paper—parabens and formaldehyde—it addresses lead and phthalates. These case studies show that activists not only fail to offer sound science to warrant the fears they raise, they refuse to recognize the risks associated with elimination of these valuable products.

# Appendix: Close-up on the Ingredients

## Lead

**What:** At issue are tiny amounts of lead found in the pigments of some lipsticks, typically red-based lipsticks. The FDA describes it as “an unintended contaminant or impurity that can be present at very low levels in some color additives and in other common ingredients, such as water, that are used to produce cosmetics.”<sup>43</sup>

Lead is a natural, ubiquitous substance. We are exposed to it every day in the air we breathe, the water we drink, and the foods we eat. In large doses, it is linked to damage to the nervous system and the brain. In trace amounts, it is present in chocolate,<sup>44</sup> vegetables, bottled water, and other items we ingest, as well as some tubes of lipstick. Yet it has not been identified as a health risk in these products.

**Claim:** The Campaign for Safe Cosmetics claims that, based on a lab test it conducted in 2007, 61 percent of the 33 lipsticks tested contained lead “with levels ranging up to 0.65 parts per million.” It claims it pressured the FDA to conduct its own testing and that when the agency complied in 2009, its study showed lead levels in lipstick ranged from 0.09 ppm to 3.06 ppm, “levels four times higher than the levels found in the Campaign study.” The Campaign asserts that, “[R]ecent science indicates there is no safe level of lead exposure.”<sup>45</sup>

**Fact:** The 2009 study conducted for the FDA on the exposure to lead from using lipstick, and published in the peer-reviewed *Journal of Cosmetic Science*, found that minuscule traces of lead found in some lipsticks are not a health risk and fall far below the FDA limit of 20 ppm.<sup>46</sup> The amount detected from extensive lab testing, which ranges from 0.09 ppm to 3.06 ppm, is “only ingested incidentally and in very small quantities”<sup>47</sup> and does not present a concern.

**Discussion:** The mere existence of lead in lipstick may sound absolutely terrifying to some. In reality, that’s less than a two-liter bottle of Coca Cola poured into an Olympic size swimming pool. It not only falls far below the FDA’s limit of 20 ppm, it also falls below California’s standard of five parts per million—the strictest standard for lead content in the country.<sup>48</sup>

There are no cases of traces of lead in lipstick causing harm to users, yet the Campaign for Safe Cosmetics preys on consumer fears by using inflammatory words and images using young children applying it to their lips.

Even California Governor Jerry Brown, one of the nation’s staunchest advocates of zero-tolerance for metals in products,<sup>49</sup> rejected attempts in California, when he was state Attorney General, to regulate lead traces in lipstick and criticized plaintiff attorneys for taking action against its manufacturers. “Lead in lipstick at the levels identified in the CSC Report, and up to 5 parts per million lead, does not raise a reasonable claim of a . . . violation and ought not to be pursued,” wrote California’s former Deputy Attorney General, Edward Weil, on Brown’s behalf.<sup>50</sup>

Note that even this opinion does not make a distinction between lead traces that are ingested and lead



traces that, as is the case with lipstick, are topical. In other words, even if the lead was completely ingested, it would still fall below California's harsh standard. To meet the standard, users would have to eat five tubes of lipstick every day.<sup>51</sup>

The Deputy Attorney General goes further, criticizing the activists for taking action against the manufacturers and pointing out the ramifications these actions could have on retailers and the public interest:

In addition to the public concern about the matter, we are concerned about the potential use of this claim by plaintiffs to pursue matters in a manner that does not promote the public interest. Lipstick is sold in literally thousands of stores throughout the state. In the past, some plaintiff groups have pursued Proposition 65 litigation against large numbers of small businesses, with little evidence of whether the retailer has knowledge of the presence of the listed chemical in the product or on the premises. If this were to occur here, many of those stores would find it more practical to pay a small settlement to the plaintiff than to contest the case. Those stores also might post warnings for products that clearly do not require warnings, which is not in the public interest. Nor would such proceedings result in the "enforcement of an important right affecting the public interest" or confer a "significant benefit" on the general public as those terms are used in Code of Civil Procedure. We hope this objective review of the merits of the issue will discourage your client and any other private plaintiffs from pursuing these matters.<sup>52</sup>

# Appendix: Close-up on the Ingredients

## Parabens

**What:** Parabens are class of chemicals used as preservatives in many deodorants, moisturizers, shampoos, and body creams and are an integral component in preventing bacteria, fungi, and mold from growing in the product.<sup>53</sup> Without it, users would run the risk of applying creams, deodorants, and foundations highly susceptible to *E. coli*, salmonella, and other contaminants that can cause serious infections or irritations.<sup>54</sup> Used for decades in foods, drugs, and hygiene products, parabens were first approved for cosmetics in 1984 by the Cosmetic Ingredient Review.<sup>55</sup> Few other preservatives are as effective as parabens in keeping cosmetics free of bacteria and mold.<sup>56</sup>

Yet parabens have been a target of the anti-chemical crowd since the early 1990s.<sup>57</sup> Back then, their approach was to zero in on instances where users of cosmetics containing parabens reported an irritation or non-threatening allergic reaction. As with any additive, users with sensitive skin conditions can have a bad reaction—though ironically, some of the most common allergy irritants in skin care products are from natural or organic ingredients, such as acacia, benzaldehyde, corn starch, wheat starch, gum arabic, and oil of spearmint, not time-tested synthetics.<sup>58</sup>

In 2004, the anti-chemical greens shifted their focus from allergens to cancer, turning to a new study led by Philippa Darbre, a biochemist at the University of Reading in Great Britain, that linked parabens to cancer.<sup>59</sup> The report was considered controversial and, as the health editor of the London *Observer*, noted at the time, “raises more questions than it answers.”<sup>60</sup>

It also was soundly rejected by most cancer research organizations, including the American Cancer Society, which issued a statement that read: “The study did not show that parabens caused or contributed to breast cancer development—it only showed that they were there,” and warned against any rush to judgment.<sup>61</sup> The National Cancer Institute also rejected the study, pointing to a 2002 study by scientists at the Fred Hutchinson Cancer Research Center. After following and testing 1,600 women for over three years, half of whom had breast cancer and half who did not, scientists at the Research Center concluded there was no link between underarm deodorant or antiperspirant and breast cancer.<sup>62</sup>

But the suggestion of a link between parabens and cancer stuck, creating a global uproar and unleashing a worldwide campaign among the anti-chemical crowd against the preservative.

**Claim:** The claim that parabens can cause breast cancer and endocrine disruption has been spread largely by the media, a handful of closely allied environmental groups, and manufacturers of “green” products out to capitalize on the hysteria. The Environmental Working Group, for example, asserts, “Parabens can disrupt the hormone (endocrine) system and were found in the breast cancer tumors of 19 of 20 women studied.”<sup>63</sup> The Campaign for Safe Cosmetics, which cites and links to the Environmental Working Group (one of its members), makes the similar assertion that parabens in deodorants and other personal care products can be absorbed through the skin and were found in tissues from breast tumors.<sup>64</sup>

Other advocacy groups, dedicated to regulate and eventually ban chemicals in cosmetics, and almost all of whom are members of the Campaign for Safe Cosmetics, state that parabens cause breast cancer and problems to the reproductive system.<sup>65</sup> Meanwhile, the media, often citing press statements from these organizations rather than peer-reviewed studies, have inundated the public with hype and misinformation, claiming parabens contain hormonal ingredients and are a cause of breast cancer.<sup>66</sup>

**Fact:** The source for most claims that parabens are linked to breast cancer is one study published in 2004 that was widely discredited even at the time of its publication. The 2004 Darbre study found after testing the breast tissue of 20 women diagnosed with breast cancer, that “[P]arabens [from underarm deodorants] were found intact in the human breast” in tissues observed from 18 of the 20 women. The study then called for more research, stating, “[T]his should open the way technically for more detailed information to be obtained on body burdens of parabens and in particular whether body burdens are different in cancer from those in normal tissues.”<sup>67</sup>

However, in the same edition of the *Journal of Applied Toxicology*, an editorial by toxicologists warned that the findings “should not be over-interpreted.” The editorial addressed the limitations of the Darbre study and “the need to consider data that is appropriate to human exposures.” They pointed out that other studies on animals suggest that the weak estrogen-mimicking effect is 500 times less potent than the effect on women who take birth control pills or hormone replacement therapy.<sup>68</sup>

Darbre conceded her study’s limitations a few years after its publication, telling the medical-based website WebMD: “Our research certainly does not prove causality, but we believe that in a few of these tumors the level of this chemical was high enough to promote breast cancer cell growth. We don’t know, however, if parabens can cause normal cells to become cancer cells.”<sup>69</sup>

At the time of the study’s release, however, Darbre struck a definitive tone. She told reporters: “[T]here is now evidence to implicate the chemical constituents of underarm cosmetics, including antiperspirant and deodorant products, in the development of breast cancer.” And, “It is another example of how the human body is being increasingly polluted by chemicals used in consumer products.”<sup>70</sup>

The study was quickly and widely discredited as flawed among the medical and science community. Experts pointed out that the study looked at only a tiny sample—that is, of all women diagnosed with breast cancer, only 20 were used for the study. Moreover, the study did not research tissues of women who did not have breast cancer. It showed a mere correlation, not that breast cancer is caused by parabens. Finally, scientists pointed out that the study showed concentrations far lower than naturally-produced estrogens found in the body.<sup>71</sup>

As American Cancer Society Chief Epidemiologist Michael Thun responded: “From a consumer’s point of view, there’s going to be a far greater risk from other sources of estrogen [such as taking hormones after menopause and being overweight, because fat tissue makes estrogen.] The additional risk, if it exists, would be minuscule [from deodorant use].”<sup>72</sup>

**Gender Benders?** Widespread claims that parabens can cause reproductive problems in males can be traced to a 1998 British study on rats. The study found that parabens could have the effect of mimicking the animals’ natural production of estrogen but at extremely weak levels. It found that in rats, the most potent paraben, butylparaben, produced estrogen-like activity 10,000 to 100,000 times less than naturally producing estrogen. The scientists

were careful to say there is no evidence parabens had the same effect on humans and did recommend study on humans.<sup>73</sup>

But that spark ignited an inferno of hype, largely from the media, warning consumers that the synthetic preservative parabens can cause cancer and are “known” endocrine disruptors,<sup>74</sup> “attacking” the male reproductive system. Definitive and frightening statements like this one from the *Townsend Letter for Doctors and Patients*, a magazine on alternative and holistic medicine that claims to “present scientific information,” were common: “Parabens used as preservatives are endocrine disrupters that mimic the hormone estrogen and have been found to accumulate in the tissue of women with breast cancer. (3,15,24)”<sup>75</sup> (Note: The numbers refer to endnotes, citing articles from popular magazines, including *Parade* and *Total Wellness*, a UCLA student publication on health.) An article in London’s *Daily Mail* ominously asked: “Can Cosmetics Give Children Cancer?” and quoted Darbre as warning women to “cut down or cut out” their use of underarm deodorants.<sup>76</sup>

Other groups, mostly working with EWG and the Campaign for Safe Cosmetics, have jumped on the anti-paraben bandwagon. Some of these, such as the Breast Cancer Fund (also a member of the Campaign for Safe Cosmetics), give the impression they are medical groups driven by medical expertise, when in fact they are extreme activist organizations, fighting “exposures to chemicals and radiation in our everyday environment.”<sup>77</sup>

In another example, Dr. Stuart Jeanne Bramhall—a psychiatrist—writes in *The Seattle Examiner*: “It is concerning that millions of Americans may be systematically poisoning themselves with common household products, toiletries and cosmetics....One of the worst offenders is the paraben class of compounds (mostly found as methylparaben or PABA), which is used as a preservative in nearly all commercial toiletries.”<sup>78</sup> Still other dire warnings about parabens come from the organic industry which lobbies against most non-natural preservatives.<sup>79</sup>

Toxicologists emphasize the need to consider dose and potency of consumers’ use of parabens. Scientists Robert Golden, Jay Gandy and Guenter Vollmer, writing in the journal *Critical Reviews in Toxicology*, point out that the estrogen activity of some tests in rats are weak, “many many orders of magnitude less active than [actual] estrogen,” and that, “[T]he presumption that similar risks might also result from exposure to endocrine-active chemicals with far weaker activity is still speculative.”<sup>80</sup> Yet the media coverage of these findings has been non-existent.

Golden and his colleagues found when dose and potency are considered, using data on humans rather than rats, that, “[I]t is biologically implausible that parabens could increase the risk of any estrogen-mediated endpoint, including effects on the male reproductive tract or breast cancer.”<sup>81</sup>

The findings of the European Commission’s Scientific Committee on Consumer Products<sup>82</sup> are the most definitive. Its extensive “Opinion on Parabens,” released December 2010 and updated March 2011, is the most comprehensive scientific review of peer-reviewed literature on parabens to date. The report is particularly relevant as the European Commission regulates chemicals in cosmetics more aggressively than any other government entity. The Scientific Committee found no risk to parabens used in cosmetics.

Regarding breast cancer, the Committee writes that the studies “have proven parabens to be...not carcinogenic.” It states: “After thorough study of the available knowledge, the SCCP concluded that there was insufficient data to establish a link between the use of cosmetics and breast cancer.”<sup>83</sup>

On endocrine disrupters, the Committee writes: “[N]o human study results for parabens under discussion (with the exception of butylparaben) are available that show unchanged levels of hormones which are of importance

for the ongoing discussion.” Regarding the most potent of the family, butylparabens, the Committee found that neither of the two studies most commonly cited on butylparabens—one that shows a strong link between butylparabens and endocrine disruption, and one that refutes it—are “considered to be scientifically acceptable” and “no unequivocal conclusion [on butylparabens] can be drawn.” The Committee then recommended using an extremely “conservative value” as a safeguard, finding that “the use of [butylparabens and propylparabens, the two most potent forms of parabens] as preservatives in finished cosmetic products [is] safe to the consumer, as long as the sum of their individual concentrations does not exceed 0.19 percent.” This is actually a revision of their recommendation in an earlier report of 0.4 percent. The Committee concluded that methylparabens and ethylparabens are safe at current levels.

**Risks of going paraben-free:** Ironically, as the amount of peer-reviewed literature discrediting any dangers of parabens has increased over the past decade, so has the hysteria. What has been the impact of all this on users of cosmetics? To the detriment of consumers, some manufacturers of cosmetics are reformulating their products to contain no or fewer parabens.

Manufacturers who sell products globally, for example, are limiting the amount of parabens in products in order to meet the European Union’s stringent requirements on cosmetics.<sup>84</sup> To sell in EU member nations, products must not exceed a daily concentration of 0.4 percent of parabens<sup>85</sup>—even though the European Scientific Committee on Consumer Safety concluded in its 2010 review that parabens as used in cosmetics do not pose a danger.<sup>86</sup>

Other producers are merely responding to public fears—and what is quickly developing into a type of marketing snob appeal. If it is paraben-free, it must be healthy for you, so goes the currently fashionable view.<sup>87</sup> Product descriptions like “luxury with a conscience” and “chic-ological” are examples of the moralizing tone some marketers are using.<sup>88</sup> Typically, these products are more expensive, adding to the snob appeal. These marketers know consumers will pay more if they are getting cosmetics they believe are “natural.”

But, in spite of the hype and misinformation, most manufacturers are fully aware that “paraben-free” is problematic and carries far greater risks than products containing parabens. No manufacturer knows this better than Arbonne International, which was forced to recall its “vegan,” paraben-free “Seasource Detox Spa Foaming Sea Salt Scrub” in 2009, after bacteria were discovered in one of its lots.<sup>89</sup>

The fact is that parabens have been used since the 1930s for an essential reason—they keep out mold, fungus, and bacteria. No other ingredient on the market has proven to be as effective.

Even the Environmental Working Group, which warns consumers on its website that, “Parabens can disrupt the hormone (endocrine) system and were found in the breast cancer tumors of 19 of 20 women studied,”<sup>90</sup> acknowledges that parabens are the safest preservative known. EWG scientist Rebecca Sutton told *The Los Angeles Times*: “You certainly don’t want parabens to be pulled out and a more dangerous preservative to be put in.... Sometimes cosmetic companies might jump on the paraben-free bandwagon without really doing a proper assessment of...the safer preservatives that they ought to be adding.” She added, “We have limited data to evaluate. We’ve been unable to create a list of safer preservatives at this time based on existing publicly available scientific literature.”<sup>91</sup>

Yet some manufacturers are using other lesser known preservatives in order to be able to call their products “paraben-free.” One example, as noted in the body of this paper, is the organic compound phenoxyethanol, used in some skin creams and other cosmetics. The FDA says it is “potentially harmful” and “can depress the central nervous system and may cause vomiting and diarrhea, which can lead to dehydration in infants.”<sup>92</sup>

Another example is chlorphenesin, a muscle relaxer used in some creams and cosmetics to keep out bacteria. It also reportedly has potentially dangerous side effects, particularly for small children. The FDA warns, “chlorphenesin relaxes skeletal muscle and can depress the central nervous system and cause slow or shallow breathing in infants.”<sup>93</sup>

In small doses in actual application, these ingredients, like parabens, may be harmless. But the point is they have not been around as long as parabens or as thoroughly tested and deemed safe as have parabens.

For this reason, most products do contain parabens—even when they are advertised and marketed otherwise. For example, one of the most popular and widely promoted alternatives to parabens is grapefruit seed extract, marketed widely as a “natural” ingredient that kills bacteria.<sup>94</sup> GreenHealthResearch.com—a website that calls itself an “online resource for information about healthy living and lifestyle choices for women” and sells products it claims “promote healthier living and are produced by companies that have proven that women’s well-being is first on their list of priorities”—is typical in its propaganda about parabens and the extract: “There are alternatives to using products that contain parabens! Grapefruit seed extract is a natural preservative that many cosmetic companies are turning to in an effort to rid their products of parabens.” And: “Grapefruit seed extract and other forms of ascorbic acid, a.k.a. vitamin C, is a natural antimicrobial and is not an endocrine disruptor like parabens are. It is also gentler on the skin and less likely to cause skin reactions and negative health effects.”<sup>95</sup>

Not so. While the seeds themselves are certainly natural, nothing else about the extract is. Almost all personal care products that contain grapefruit seed extract must use parabens or some kind of synthetic preservative to keep it safe from contamination. In fact, most cosmetics and lotions with grapefruit seed extract contain more synthetic preservatives than products containing parabens. Some makers of grapefruit seed extract even add parabens,<sup>96</sup> misleading consumers into believing they are getting only natural products.

In summary, consumers have been led to believe by the “green” anti-synthetic, anti-preservative movement that they are a lot better off if they avoid any products containing parabens. The good news is that many products contain parabens even when they are advertised as paraben-free.

# Formaldehyde

**What:** Formaldehyde is a chemical preservative that has been used for over a century. It is an essential component of a wide range of industrial products, including building materials, fertilizers, wood-pressed products, and household products, including glues, adhesives, and disinfectants.

Formaldehyde is also a natural substance and is present in the air we breathe, indoors and out.<sup>97</sup> Furthermore, as noted earlier, various vegetables we eat release formaldehyde gas when cooked, including Brussels sprouts, cabbage, and Shiitake mushrooms—at 400 parts per million.<sup>98</sup>

Trace amounts of formaldehyde, in the form of formaldehyde-releasing preservatives, are used in numerous personal care products, including shampoos, soaps, and cosmetics to keep consumers safe from fungi, mold, and bacterial growth. It has been found to be one of the most effective preservatives, particularly in preventing Gram-negative bacteria such as *E. coli*.<sup>99</sup> Formaldehyde is also used in numerous vaccines to prevent deadly diseases such as *Clostridium*,<sup>100</sup> influenza, and diphtheria.<sup>101</sup>

**Claim:** The source of hysteria over trace amounts of formaldehyde in cosmetics comes largely from misinformation spread by the Campaign for Safe Cosmetics and its partner, the Environmental Working Group. The Campaign's 2009 non-peer-reviewed report, "No More Toxic Tub," focuses on small children's shampoos, body washes, and body creams. It asserts, based on lab tests it commissioned, that these products "are commonly contaminated" with formaldehyde, which EWG warns can cause cancer and skin allergies. It cites the EPA's classification of formaldehyde as a "probable human carcinogen" and a report by the World Health Organization on long-term industrial exposure, not the trace amounts present in cosmetics, as the basis for its conclusion.<sup>102</sup>

**Fact:** The studies cited by the Campaign that link formaldehyde to carcinogenic risks pertain to long-term and airborne exposure occurring almost exclusively in industrial settings from workers who inhale the preservative on a daily basis.

The World Health Organization study, which was produced in 2005 and is one of the key sources the Campaign uses in its release, does not contain new findings, but merely confirmed the findings of earlier WHO studies linking continuous exposure in industrial, workplace settings—where workers inhaled large quantities of formaldehyde vapors day in and day out—to a potential risk of developing nasopharyngeal, or nose, cancer. They found, however, that for the general population, typical low-level exposure to formaldehyde is not a risk<sup>103</sup>—though this is not mentioned anywhere in the Campaign for Safe Cosmetics' report.

Similarly, as the National Cancer Institute confirms, EPA's classification of formaldehyde as a "probable human carcinogen" refers to near-nonexistent conditions where workers in industries that use formaldehyde continuously breathe the airborne gases "under conditions of unusually high or prolonged exposure."<sup>104</sup> It does not refer to the tiny traces used in cosmetics to prevent bacteria.

Over the past few years, however, EPA officials and some in Congress have attempted to elevate the classification of formaldehyde from a "probable" to a "known" carcinogenic risk. In June 2010, EPA released a preliminary assessment on the health risks of inhaling formaldehyde present in numerous products, claiming evidence of a causal relationship between formaldehyde exposure and leukemia, as well as cancers of the upper

respiratory tract.<sup>105</sup> EPA is using the report as a basis for new, stringent regulations on the use of formaldehyde which, if implemented, would limit its use in myriad products, including as an essential preservative.

The assessment has been widely criticized by experts for its subjective approach and shoddy research. In particular, the National Academy of Sciences' National Research Council rebuked EPA's assessment and methods in reaching its conclusions on the dangers of formaldehyde:

Overall, the committee found that EPA's draft assessment was not prepared in a logically consistent fashion, lacks clear links to an underlying conceptual framework, and does not sufficiently document methods and criteria used to identify evidence for selecting and evaluating studies. Moreover, many of the general problems with the EPA formaldehyde health assessment have been identified by other Research Council committees that reviewed other EPA chemical assessments in recent years. For instance, there have been recurring problems with clarity and transparency of the methods, even though the documents have grown considerably in length.<sup>106</sup>

Most significantly, the National Research Council found insufficient evidence and a biased approach to EPA's claim that formaldehyde causes leukemia and cancer in the respiratory track:

Conclusions appear to be based on a subjective view of the overall data, and the absence of a causal framework for these cancers is particularly problematic given the inconsistencies in the epidemiologic data, the weak animal data and the lack of mechanistic data.<sup>107</sup>

While the National Research Council did not find fault with EPA's findings that high levels of formaldehyde exposure can cause irritation to the eyes, nose, and throat, and has been linked in some studies to nasopharyngeal cancer, these effects have been known for decades and have been addressed by stringent regulations on formaldehyde use in the work place. Since 1991, OSHA has limited exposure of formaldehyde to 0.75 parts per million within an eight-hour work period, up from one part per million. It also requires labeling of any product exceeding 0.1 percent of formaldehyde."<sup>108</sup>

Formaldehyde's use in cosmetics, to protect consumers from E. coli and other bacteria, has been found to be perfectly safe in low levels.<sup>109</sup> Even the Campaign for Safe Cosmetics' lab tests reveal that the amount of formaldehyde they reported present in products—ranging from 54 to 610 parts per million<sup>110</sup>—is far below the European Union's safety threshold for formaldehyde use in cosmetics, the most stringent standard used anywhere in the world.

The EU has concluded, based on extensive research by its scientific panel on cosmetics, that when personal care products containing formaldehyde or formaldehyde-releasing preservatives are applied on the skin or scalp, they are safe as long as the chemical does not exceed 2,000 parts per million<sup>111</sup>—the same standard recommended by the Cosmetic Ingredient Review Panel.<sup>112</sup>

***Blowup on Brazilian Blowout.*** As discussed in the body of this paper, formaldehyde has recently come under assault for what appear to be violations of existing law by a product manufacturer. Samples of the hair smoother Brazilian Blowout, keratin treatments marketed and sold for professional use in hair salons, have been tested and found to contain levels of formaldehyde as high as 11 percent. Some of these products, bizarrely, are labeled "formaldehyde free."<sup>113</sup>



The Campaign for Safe Cosmetics, along with the Environmental Working Group, wasted no time in propagandizing this case of a manufacturer's impropriety in order to propel their agenda to ban all formaldehyde and other crucial preservatives from cosmetics. Along with Reps. Jan Schakowsky (D-Ill.), Ed Markey (D-Mass.), and Tammy Baldwin (D-Wis.), who have reintroduced the stalled Safe Cosmetics Act, now their approach is to use the Brazilian Blowout case as a justification to ban thousands of ingredients that are added to products precisely to keep us safe.<sup>114</sup>

However, the issue is over the manufacturer's violation of existing law, not the need for more regulations. The immediate and thorough responses by federal and state regulatory agencies, as well as litigation filed against the producer GIB, LLC, show just how effectively existing federal and state laws and regulations governing cosmetic content are working.

The uproar began in 2010, after workers at several beauty salons in Portland, Oregon, complained of illness, including headaches, nosebleeds, and breathing problems, after using the product Brazilian Blowout on clients.<sup>115</sup> (It should be noted that none of these workers reported any health symptoms once they stopped using the product, though in some reports, clients experienced some loss of hair.)

Oregon's Occupational Safety and Health Division tested samples of Brazilian Blowout and found levels of formaldehyde ranging from 6.3 to 11.8 percent, including those labeled "formaldehyde free."<sup>116</sup> The Oregon OSHA immediately released a "Hazard Alert" warning salon owners, workers, and clients about the lab findings and advising them to either discontinue use or install air monitoring devices to ensure they are not exposing workers to levels above the 0.75 parts per million limit.<sup>117</sup> Similarly, the federal OSHA and agencies in other states have released hazard warnings alerting hair salons and clients that the agency has found the hair straightening product in some tests to exceed OSHA's permissible levels in the workplace, and that businesses and consumers should stop using the product until more is known.<sup>118</sup>

Around the same time, the California attorney general filed a lawsuit against the Hollywood-based manufacturer of Brazilian Blowout for failing to warn hair salon workers and consumers of the high levels of formaldehyde in the product. Users of the product have filed dozens of individual lawsuits against the manufacturer.<sup>119</sup>

The FDA also is working with other federal and state agencies to determine the ingredients of the product and to what degree it is sold to consumers, even though it is marketed for "professional use only." If in fact the product has been sold at the retail level, the manufacturer would be required by law to include the ingredients on the label.<sup>120</sup>

The Cosmetic Ingredient Review Expert Panel also is reviewing the product's ingredients and health impacts. In preliminary assessments, the panel reported concerns over the levels of formaldehyde gas released into the air when the treatment is applied. When formaldehyde mixes with the chemical methylene glycol, which is the case with Brazilian Blowout, the panel believes it is "unsafe for use in hair smoothing products, the use of which involves application of high temperatures."<sup>121</sup>

These concerns have been addressed in the federal OSHA's alert to hair salons that they stop using any hair treatment products that contain formaldehyde or any formaldehyde-equivalent ingredients, such as methylene glycol or formalin.<sup>122</sup> The Panel did find and confirm that formaldehyde is safe in minimal concentrations when

used in cosmetics as a preservative and does not emit vapors.<sup>123</sup> Their final report is expected to be released before the end of the year.

In short, numerous federal and state regulatory agencies are warning hair salons and consumers to stop using the product. Along with scientific panels, they are assessing the risks of using keratin-based hair smoothers. The cause for the controversy, however, appears to be the illegal activity by GIB LLC, the company that markets the Brazilian Blowout product in the United States. Violations could include the failure to list all its ingredients, disregard for OSHA requirements in the workplace, failure to include warning labels, and failure to follow requirements of the Fair Packaging and Labeling Act if, in fact, the product is being sold at the retail level.

Calls by some members of Congress for the FDA to require “better labeling practices and warnings”<sup>124</sup> are redundant, as these requirements already exist.<sup>125</sup> Similarly, efforts to ban the use of formaldehyde and other preservatives in personal care products actually increase health risks by doing away with the very ingredients that protect consumers from dangerous bacteria.

## Phthalates

**What:** “Phthalates” is a generic term that refers to a very broad, ubiquitous group of compounds found in a huge range of products, including those used in construction, homes (such as vinyl floors, wall covering, shower curtains), clothes, toys, packaging, and medicines. They are present in many plastics to make the product soft and flexible for consumer use, including medical equipment used in hospitals such as IV bags and tubing.

In cosmetics, phthalate compounds are typically used in colognes and perfumes to help blend the ingredients, ensure the fragrance lasts longer after it is applied and, as a denaturant, to discourage its consumption as alcohol.<sup>126</sup> Diethylphthalate (DEP) is the most common type of phthalate compound used in personal care products, followed by dibutylphthalate (DBP), and dimethylphthalate (DMP). Concentrations are typically less than 10 percent in cosmetic personal care products.<sup>127</sup>

**Claim:** Again, the source of allegations that consumers are in grave danger from using perfumes, body sprays, and other fragrances comes largely from the Campaign for Safe Cosmetics, the Environmental Working Group, the Canadian chapter of Environmental Defense, and Greenpeace. The Campaign’s most recent report, *Not So Sexy: The Health Risks of Secret Chemicals in Fragrance*, claims that perfume manufacturers use “secret” ingredients that are not safe for use in their fragrances. Specifically, the report argues that the cosmetic industry is using a chemical “cocktail” of phthalates and other compounds that, when inhaled or absorbed through the skin, can stunt genital development and is linked to sperm and hormonal damage.<sup>128</sup>

Furthermore, these groups argue most of the “complex mix of clandestine compounds” has never been tested by the FDA, the International Fragrance Association, or “any other publicly accountable institution.”<sup>129</sup>

**Fact:** As with other essential chemical compounds targeted for phaseout by these green groups, the claims against the family of phthalates used in fragrances are egregiously inaccurate and invalid. The charges that phthalates are a health risk have been completely and directly refuted by experts. Every regulatory agency and science panel that has ever studied the data has concluded there is no evidence that phthalates are an endocrine disrupter or safety risk. This includes the National Toxicology Program at the U.S. Department of Health and Human Services,<sup>130</sup> Consumer Product Safety Commission, Food and Drug Administration, National Institute of Environmental Health Sciences, the European Union’s Scientific Committee on Consumer Products, Norwegian Scientific Committee for Food Safety, Cosmetic Ingredient Review, and Research Institute for Fragrance Materials.

The earliest suggestions that there could be a link between ingested phthalates and endocrine disruption date back to lab tests conducted on rats in the 1980s.<sup>131</sup> Tests have shown that in rats, phthalates can cause birth defects in offspring and infertility problems in adults. However, tests on other species—including hamsters, guinea pigs, fish, and monkeys—have shown no adverse health impacts from these compounds.<sup>132</sup>

Most recently, however, the public outrage over phthalates has swirled around a 2005 study by Dr. Shanna Swan, a biostatistician at the University of Rochester Medical School, who attempted to show the same health impact of phthalate exposure on rats could be duplicated on humans. Her study linked the amount of phthalate “metabolites,” or traces of metabolized phthalate found in urine samples of expecting mothers, to the size of genitalia in infant boys, claiming that boys born from mothers who had the highest levels of phthalates

in their urine were seven time more likely to have stunted genital development than those with lower levels. The study concluded that prenatal exposure to phthalates “can adversely affect male reproductive development in humans.”<sup>133</sup>

The impact from the study was explosive. Reports flooded the news that pregnant mothers using cosmetics and mothers that allow their baby boys to play with plastic toys put their sons at risk of stunted genital development. Environmental groups and lawmakers in Congress called for banning phthalates in cosmetics, children’s toys, and other products containing the compound.

Nor was widespread fear over phthalates abated when, as reported in *Science*, an expert panel from the National Toxicology Program “[threw] cold water on a widely publicized study suggesting that hormone-like chemicals in consumer products are warping the reproductive systems of baby boys.” After thoroughly reviewing the “Swan Study” and other related studies, the panel of scientists concluded, “[T]here is no solid human evidence that [phthalates] are harming babies,” and that the study’s “data are insufficient.”<sup>134</sup>

Pointing to the lack of a significant association with DEHP metabolites, the panel noted that Swan’s AGD [anogenital distance] measure is a “novel index” whose relevance in humans “has not been established.” Two toxicologists on the panel questioned Swan’s data on other phthalates as well.<sup>135</sup>

The National Toxicology Program’s unanimous rejection of the Swan study got no media coverage. Instead, the fear mongering by these groups and the media escalated, culminating in calls for the elimination of phthalates. In 2008, Congress, responding to public fears, passed into law limits to concentrations of phthalates in children’s toys at 0.1 percent.<sup>136</sup>

Around the same time, Greenpeace in Europe released the report, *Perfume: An Investigation of Chemicals in Perfumes*. The environmental group commissioned lab tests on 36 brands of colognes and perfumes manufactured in Europe and found the DEP compound in 34 of them. Though it acknowledged that the data is limited, it nonetheless called on the European Union to phase out the “hazardous chemicals,” claiming, “This suggests that regular use of perfumes could substantially contribute to individuals’ daily exposure to these chemicals, some of which have already been recorded as contaminants in blood and breast milk.” And: “Although data remain limited, there is evidence to suggest [DEP] may present us with diverse health and environmental hazards. New evidence is emerging all the time.”<sup>137</sup>

Following the Greenpeace report, the European Union’s Scientific Committee on Consumer Products released its review, *Opinion on Phthalates in Cosmetic Products*, which directly refuted the Greenpeace publication. The 2007 study found that seven of the 10 phthalates identified in the 36 tested products were “when present at all, in such small amounts that they probably are not used intentionally as ingredients in the perfumes, but rather are present as traces and/or impurities.”<sup>138</sup>

On DEP, the scientific committee backed its earlier findings, reporting “a positive opinion on the safe use of DEP in cosmetics.”<sup>139</sup> Again, the scientists found traces in the Greenpeace lab tests so small—with a maximum range of 2.23 percent—that they “are within the range allowed for DEP use in perfumes” which they have found permissible up to 50 percent.<sup>140</sup>

The EU scientific committee concurred with the Norwegian Scientific Committee for Food Safety’s 2005 finding that that the Swan Study did not establish a credible cause and effect between phthalates and irregular genital development, and that DEP was safe in cosmetics.<sup>141</sup>

In spite of overwhelming scientific findings that phthalates as used in cosmetics and other consumer products present no risk, environmental groups, along with researchers who have devoted a lifetime of work in attempting to prove a link to health hazards, continue to insist they are a danger and call for their ban.

When Leslie Stahl of *60 Minutes* asked Dr. Shanna Swan if she is convinced phthalates are harmful to humans, she said, “I’m convinced that they pose a substantial possibility of harm. I cannot conclude they are harmful without confirmation of my study and additional data.” She added that she needs more data to be sure. And yet, earlier in the interview, she offered a worrisome betrayal to any parent of a male child: “We found that the baby boys were in several subtle ways less completely masculine.”<sup>142</sup> When Stahl commented that “the Consumer Product Safety Commission said that these toys have minimal to non-existent risk for these children,” Swan replied, “I don’t think we have the data to confirm that.” And:

*Stahl: So, how can you look at the same data and come out with such different conclusions?*

*Swan: I think that the interpretation of the data is difficult and changing. And at each point in time we have to decide, “What is the action we as a society want to take. Do we want to be more cautious? Do we want to be less cautious?”<sup>143</sup>*

In the same story on *60 Minutes*, Dr. Richard Sharpe of the Medical Research Council’s Human Reproductive Sciences Unit at the University of Edinburgh in Scotland—and one of the world’s leading researchers on phthalates—presented Stahl with a frightening portrayal of his lab test results: “We see un-descended testes. We see this penis abnormality, hypospadias. We see smaller testes in adulthood, which means lower sperm counts.”<sup>144</sup>

But when Stahl mentioned a similar experiment by Dr. Sharpe on monkeys that showed none of the effects, he replied, “Yeah. I would say take the species that’s closest to man, and place more emphasis on that.” And:

*Stahl: If I said to you, “Are phthalates harmful to humans?” what would you say?*

*Sharpe: I don’t know. It’s as simple as that.*

*Stahl: Well, I think that the public understandably get a bit fed up with people, like myself or other people saying, “Well, look, you know, these chemicals might cause effects. But, on the other hand, they might not.” And they say, “Well, look, what can I do for my baby in case they do?”*

*Sharpe: So don’t use body creams. Don’t go out and spray insecticide in your garden. Don’t even do painting in the house. Get your husband to do it.*

*Stahl: Phthalates are in all those things?*

Sharpe: *I'm not saying it's phthalates. I'm saying that what you want to do is avoid environmental chemicals in total as much as you can.*<sup>145</sup>

Sharpe's overly precautionary assertions about avoiding phthalates or other chemicals ignore all tradeoffs associated with replacements as well as the value these products bring to quality of life and public health. In fact, in addition to use in cosmetics, phthalates have critically valuable applications in medical devices, vinyl tubing used in hospitals, and blood bags. If consumers and industry followed Sharpe's advice, many patients would surely die.<sup>146</sup>

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