

# Assessing Consumer Product Safety:

## *How Science Can Be Sidelined in Product Formulations*

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Case Studies on BPA, Phthalates, and Parabens



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# OVERVIEW

Chemicals are all around us – they are a basic human component and are found in both nature and the products we use every day. From plastics to cleaning materials, cosmetics to paints, electronics to automobiles and well beyond, consumers encounter chemical compounds in every facet of life. From the moment we wake up and brush our teeth, to our morning coffee, and the starting of cars, chemicals make our daily lives possible. While the vast majority are safe and improve our quality of life, some substances can have adverse impacts when we interact with them at high levels. As consumers we expect to not be misled when it comes to the safety and science behind these products.

Confusion and misunderstanding are constantly emerging about the safety of products we use every day. Consumers are bombarded with warning labels, marketing campaigns and quasi-governmental endorsements of select products with little information about product testing, government studies, or regulatory decisions. Today, substances that have been meticulously studied by experts, scientists and regulators – and deemed safe for daily use – can still be mischaracterized and targeted by well-intentioned but misdirected campaigns seeking to deter their use in *any* product and push consumers to use different substances.

Efforts to rid products of various substances are often based on the European ‘precautionary principle’ – this is the idea that, when it comes to chemicals, use of any chemical should be restricted in an anticipatory fashion when a potential risk cannot be excluded. While such an approach may appear to be logical, it fails to take into account how often someone is exposed to the chemical. As a result, efforts by interest groups to use this concept as a regulatory benchmark are short-sighted – it can lead to limits on tested chemicals while incentivizing the use of less tested chemicals or products.

Alternatively, the approach used by U.S. regulators is to assess the level of risk. In other words, unlike looking at the chemical in isolation, we should weigh practical considerations like how and how often consumers use products made with certain chemicals.

Consumer marketing campaigns that target against the use of specific chemicals and do not base their findings on scientific data are manifesting themselves with greater frequency. The impact is also greater as technology enables the general public to exert growing influence. When appeals fail to budge the regulatory system, activists often pressure businesses directly.

In January, a *New York Times* article profiled Johnson & Johnson’s efforts to replace key substances in its products due to consumer concerns. Executives noted that, “the company is responding to a fundamental shift in consumer behavior, as an increasingly informed public demands that companies be more responsive to their concerns, especially when it comes to the ingredients in their products.”<sup>1</sup> Johnson & Johnson is not alone. Last year, industry titans like

## How Sideling Science in Product Formulations Can Harm Consumers

Substances that have been meticulously studied by experts, scientists and regulators – and approved for daily use – are often mischaracterized and targeted by groups seeking to deter their use.

Consumers are forced to use alternative products that, largely, have not undergone extensive testing.

### Example:

The Food and Drug Administration<sup>1</sup> banned the use of silicone in cosmetic procedures in 1992 and closely studied the implants in the following years. In 2006, the FDA lifted the ban because links to health concerns could never be proven. For the last 8 years silicone implants have been used again, and a 2011 report has once again confirmed that “silicone gel-filled breast implants are safe and effective when used as intended”.

<sup>1</sup> U.S. Food and Drug Administration, “Regulatory History of Breast Implants in the U.S.,” <http://goo.gl/xbrRoH>

<sup>1</sup> *New York Times*, “The ‘No More Tears’ Shampoo, Now With No Formaldehyde,” <http://goo.gl/iysGR7>

Wal-Mart<sup>2</sup>, Target<sup>3</sup> and Proctor & Gamble<sup>4</sup> all responded to public fervor by pledging to replace or reduce numerous chemicals in their products, including the three classes of chemicals examined in the case studies below.

The question arises then, are companies really protecting consumers by responding to these unfounded demands, or are they unintentionally putting consumers at greater risk? The facts demonstrate that in some cases, products on the store shelves may contain replacement substances that are largely untested. When a decision is made to replace a substance with another, manufacturers are forced to use an alternative chemical or product that often has not undergone the same (or any) rigorous safety evaluations. In many cases, companies are not even required to disclose what kind of compounds they are using as a replacement. The alternative substance may actually pose more of a risk to a consumer than the initially tested, regulatory-approved chemical.

To better inform consumers in Texas and nationwide with scientifically backed data, this report is an effort to expose the non-regulatory threats that often exist when campaigns mounted against products or substances are not built on science. We focus on three case studies – Bisphenol A, Phthalates, and Parabens – and take an in-depth look at both the regulatory history and the views in the scientific community. We also have included the messages and approaches often used by non-governmental organizations' (NGO) marketing campaigns aimed at consumers.

## CASE STUDY: BISPHENOL A (BPA)

Bisphenol A, or BPA, is a synthetic chemical used primarily in the production of two plastics: polycarbonate, a rigid plastic (used in kitchen appliances, protective equipment, sports gear, reusable water bottles); and epoxy resin, a strong adhesive and coating (found in food and beverage can liners, drum liners). One of the most common uses of BPA is in canned goods. The chemical forms a barrier between a container and its contents, which prevents corrosion and migration of the metal or plastic into the food or beverage. By doing so, BPA extends shelf-life and protects against dangerous bacteria like E-coli and botulism. There

- 2 *USA Today*, "Wal-Mart announces phase-out of hazardous chemicals," <http://goo.gl/e2whUu>
- 3 Press Release from Target, "introducing the Target Sustainable Product Standard," <http://goo.gl/O7F42S>
- 4 *Business Green*, "Inside P&G's phosphate-free detergent pledge," <http://goo.gl/CPTnk8>

## Scientific Review of BPA Confirms Safety

### 2008: Food and Drug Administration (FDA)

Conducts literature review to examine BPA's safety. Found that food-related materials containing BPA were safe, and "that an adequate margin of safety exists for BPA at current levels of exposure from food contact uses."<sup>1</sup>

FDA also noted that the European Food Safety Authority (EFSA) found BPA to be safe at low levels.<sup>2</sup>

### 2008: The National Toxicology Program (NTP)

The Center for the Evaluation of Risks to Human Reproduction, a U.S. National Institute of Health (NIH) program, reviewed BPA and concluded that there was a basis for concern about the effects of BPA from prenatal and early childhood exposure.

NTP states that additional research is needed to more fully assess the impacts of BPA.<sup>3</sup> The NTP study generates media firestorm, raises public concern and results in a flood of regulatory activity.<sup>4</sup>

### 2009: California EPA's Office of Environmental Health Hazard Assessment (OEHHA)

Panel of California scientists at OEHHA unanimously votes against the listing of BPA on the state's list of toxic chemicals.

Despite the ruling, in April 2013, California's EPA announces a plan to review BPA again. The move would have subverted the state's scientific process by allowing administrative staff to override the panel's 2009 decision. Since then, a California judge issued an injunction against placing BPA on this list.<sup>5</sup>

- 1 U.S. Food and Drug Administration, "Draft Assessment of Bisphenol A For Use In Food Contact Applications," <http://goo.gl/JTM3bg>
- 2 European Food Safety Authority, "Bisphenol A," <http://goo.gl/Exeuoc> vom Saal FS, Akingbemi BT, Belcher SM et al. Chapel Hill bisphenol A expert panel consensus statement: integration of mechanisms, effects in animals and potential to impact human health at current levels of exposure, *Reproductive Toxicology* 2007; 24:131-8.
- 3 See, e.g. vom Saal FS, Akingbemi BT, Belcher SM et al. Chapel Hill bisphenol A expert panel consensus statement: integration of mechanisms, effects in animals and potential to impact human health at current levels of exposure, *Reproductive Toxicology* 2007;24:131-8.
- 4 U.S. Food and Drug Administration, "Bisphenol A (BPA): Use in Food Contact Application," <http://goo.gl/SmRF6y>
- 5 Office of Environmental Health Hazard Assessment delisting of BPA, <http://goo.gl/pED38N>

is a lack of sufficient alternatives available for BPA, and about 6 billion pounds of BPA are produced globally each year.<sup>5</sup>

The Food and Drug Administration (FDA) first approved BPA for human consumption in the early 1960s. Repeated review has found low-level exposure does not pose adverse effects to individuals' health. In fact, studies find about 93 percent of adults have trace amounts of BPA in their systems.<sup>6</sup> To date, there have been no studies showing that [BPA] exposure affects human health.<sup>7</sup>

Despite this, concerns about BPA first surfaced in the early 1990s. One study found that trace amounts of BPA leached from plastic and that, BPA might adversely affect human health. Researchers later expressly acknowledged that no definitive studies showed that exposure to BPA affects human health, stating that "although we published our findings in 1993, it was unclear for a long time how much of the [BPA] was absorbed by humans, how fast it accumulated and even whether or not it was damaging to human health."<sup>8</sup> Subsequent studies have failed to find evidence that low levels of BPA exposure have any adverse effects on human health, supporting the safety of BPA. A 2004 Harvard study concluded that, "In the case of BPA, the evidence considered by the panel suggests that the weight of the evidence for low-dose effects is very weak."<sup>9</sup>

Despite repeated confirmation from scientists about its safety, activist groups regularly petition for restrictions on BPA at the regulatory level. While regulators have reiterated previous findings that the compound poses no threat at low levels, health and environmental activists have taken the fight directly to businesses and retailers. Campbell's, Heinz, ConAgra, Del Monte, Kroger and Wal-Mart were among many companies that faced attacks from coalition groups.

Not surprisingly, some companies reacted to the public pressure despite the lack of any substantiated scientific impetus. Following a six month campaign by activist organizations, which accused Campbell's of poisoning children, the soup-maker capitulated and announced it would work to phase out BPA in its products. Activist organizations heralded the announcement as a "victory" and a "major moment for corporate responsibility and the safety of our food."<sup>10</sup> Environmental journalists called it a "huge shift in the canned foods industry."<sup>11</sup>

However, reality set in and their pledge ended up being a 'huge shift' that was actually no shift at all. Like other canned food producers, Campbell's ran into a problem: no sufficient alternatives were available to replace BPA in its products. The company concluded that it is not worth gambling on a possible alternative when the evidence indicates there is no problem with the current product. "We're [also] aware of the science and the conclusions by regulatory agencies around

5 *Washington Post*, "Alternatives to BPA containers not easy for U.S. foodmakers to find," <http://goo.gl/pqNdsM>

6 National Institute of Environmental Health Sciences, Bisphenol A (BPA) Questions and Answers, <http://goo.gl/9TtuFe>

7 Stanford News Release, "Stanford Q&A: David Feldman on risk of bisphenol A in plastic bottles," <http://goo.gl/dMPa3U>

8 Stanford Report, "5 Questions: Feldman on risk of bisphenol A in plastic bottles", <http://goo.gl/vSYtqE>

9 Harvard Center for Risk Analysis, "Weight of the Evidence Evaluation of Low-Dose Reproductive and Developmental Effects of Bisphenol A," <http://goo.gl/RgjRK7>

10 Change.org, "Campbell's: Stop Endangering Our Kids' Health!" <http://goo.gl/3CnBrn>

11 TreeHugger, "Campbell's Says It's Heading BPA-Free," <http://goo.gl/Bzsl1m>

#### 2010: FDA

FDA issues an official update expressing concern about the potential effects of BPA, but says there was no evidence that BPA is unsafe.

FDA observes that all "standardized" tests have thus far supported the safety of BPA. Only recent tests using novel approaches have shown some different results.<sup>6</sup>

#### U.S. Environmental Protection Agency (EPA)

EPA issues a draft rule to place BPA on a list of "chemicals of concern" that subject it to further analysis.

#### 2013: U.S. EPA

The EPA withdraws the draft rule<sup>7</sup> and says that they will pursue additional studies.

#### 2014: FDA

The FDA issues an update reiterating its earlier findings that, "FDA's current assessment is that BPA is safe at the very low levels that occur in some foods. The assessment is based on a review by FDA scientists of hundreds of studies including the latest findings from new studies initiated by the agency."<sup>8</sup>

6 U.S. Food and Drug Administration, "Bisphenol A (BPA): Use in Food Contact Application," <http://goo.gl/SmRF6y>

7 *Plastics News*, "EPA withdraws draft rules on BPA, PBDEs," <http://goo.gl/43nnMB>

8 *Environmental Health News*, "New BPA experiment finds no low-dose effects, FDA says," <http://goo.gl/gCRHEP>

the world that it [BPA] is safe," the company's vice president of Corporate Social Responsibility and Sustainability reported. "Used in cans, it keeps the food from spoiling. We use it. We will follow the science."<sup>12</sup>

Later, Campbell's vice president of Global Communications added, "Our policy hasn't changed... the overwhelming weight of scientific evidence shows that the use of BPA in can lining poses no threat to human health. BPA has been deemed safe by every major scientific body in the world and it continues to be approved for use in our products by every major regulatory authority in the world. We are responsive to public concerns and the debate over this epoxy liner, but the science says it's safe, and we will follow the science."<sup>13</sup> Today, most canned food still contains BPA, especially in acidic items that break down alternative compounds. Yet, public pressure continues.

A closer look at the history of the issue provides insight into why there is confusion about the safety of BPA in common household products. In October 2013, advocacy groups amplified a report linking BPA to breast cancer. Not coincidentally, the report was released during National Breast Cancer Awareness Month to garner attention – even though the researchers were later forced to take back, or "walk back", their assertions.<sup>14</sup> Most of the substance of the report and any close examination of its findings were lost under sensational headlines. Ultimately, experts found the statistical data did not support the claims.

Consumers are stuck in the middle of these safety disputes. Consumer perceptions and buying habits are known to be significantly shaped by headlines from activist organizations, regardless of their legitimacy. Despite approval from the FDA, manufacturers continue to weigh the value of voluntarily deselecting BPA for alternative compounds, not based on health concerns, but instead on the financial effect. For example, in 2009 all major U.S. manufacturers of baby bottles and infant feeding cups discontinued using BPA in their domestic products.<sup>15</sup> A *Washington Post* article reported that replacing BPA is a "goal that is taking years to reach, costing millions and proving surprisingly elusive."<sup>16</sup> As is often the case, according to a research scientist at the New York State Department of Health, it is unclear if BPA's replacement, Bisphenol S (BPS), in store receipts and currency is better or worse than BPA; "Compared with when BPA was more widely used, people may now be absorbing 19 times more BPS through their skin."<sup>17</sup> There are few, if any, practical or reliable alternatives that could serve as a safe, all inclusive alternative to replace BPA-based plastics and resins.

## CASE STUDY: PHTHALATES

First introduced in the 1920s, phthalates are a family of chemicals, used in a variety of industries and consumer products. Phthalates such as dimethyl phthalate (DMP), diethyl phthalate (DEP), and dibutyl phthalate (DBP) are more commonly used in personal care products, such as cosmetics, hairsprays, soaps, and shampoos. These phthalates are what consumers most often hear about in the media regarding safety concerns from interest groups; they are largely being phased out.

Other phthalates that are more commonly used in PVC products to increase flexibility and durability are di-ethylhexyl phthalate (DEHP), diisodecyl phthalate (DIDP), diisononyl phthalate (DINP), and di(2-propyl heptyl) phthalate (DPHP). They are used in vinyl flooring, wire, cable and automotives and have been deemed safe for use in those applications. Despite wide ranging differences in their chemical makeup and toxicity, and varying levels of scientific inquiry, the entire class of phthalates is often lumped together outside of scientific circles. This mischaracterization, in turn, has created greater confusion when discussing their individual uses.

<sup>12</sup> *Forbes*, "Campbell's Big Fat Green BPA Lie," <http://goo.gl/h9LIAV>

<sup>13</sup> *Forbes*, "Campbell's Big Fat BPA Lie," <http://goo.gl/Mol1j4>

<sup>14</sup> *Forbes*, "USA Today Spins Breast Cancer Scare Out Of Retracted Study Claim As New EPA Study Dismisses Risk," <http://goo.gl/2ja6uH>

<sup>15</sup> U.S. Food and Drug Administration, "Bisphenol A (BPA): Use in Food Contact Application," <http://goo.gl/Jw0YYk>

<sup>16</sup> *Washington Post*, "Alternatives to BPA containers not easy for U.S. foodmakers to find." <http://goo.gl/5okoCZ>

<sup>17</sup> U.S. News and World Report, "BPA Substitute Lurks in Paper Money, Receipts," <http://goo.gl/Dpr3Ql>

In the past decade there has been a steady call from activists to add phthalates to federal and state lists of banned hazardous substances. Yet the debate about phthalate safety has been in the press for much longer than that. In 1983, a panel established by the U.S. Consumer Product Safety Commission (CPSC) concluded that DEHP could be a health risk for children who came in contact with it. DEHP was found in infant mouthing devices like pacifiers, rattles and teethers.

As a result, the industry voluntarily removed DEHP and began using DINP, a tested phthalate that had stronger chemical bonds and was less likely to leach than DEHP.<sup>18</sup>

Environmental groups then raised concerns about DINP in the late 1990s.<sup>19</sup> However, following an assessment that began in 1998, the CPSC reported that toys containing DINP posed few, if any, risks to children. The CPSC also convened a panel of scientists to continue to review DINP and proposed additional testing on mouthing exposure. Due to the increased attention, some companies voluntarily removed DINP from children's toys, as they had with DEHP.<sup>20</sup>

In 2001, as a result of the additional testing of mouthing exposure, the CPSC panel of scientists concluded that the risk posed to the majority of children would be "minimal to nonexistent."<sup>21</sup> A further review was completed in 2002 and concluded that exposure to DINP in children's devices was substantially less significant than reported by the earlier studies.

Even before these studies were conducted, a number of environmental groups petitioned the CPSC to ban phthalates in any products intended for children under five years of age, and to issue a national advisory about the public health concerns related to the use of phthalates in PVC. In 2001, the CPSC unanimously denied the petition.<sup>22</sup> Furthermore, in response to the petition, the CPSC scientist in charge of the review emphasized that banning DINP might actually lead to the use of more brittle plastics, which could create a choking hazard for children.<sup>23</sup>

18 U.S. Consumer Product Safety Commission, Petition HP 99-1 Vote Sheet, <http://goo.gl/vEycGa>

19 Fox News, "Consumer Watchdog: Vinyl Toys are Just Ducky," <http://goo.gl/tgdLuv>

20 U.S. Consumer Product Safety Commission, "Memo on Toxicity Review of Diisononyl Phthalate (DINP)," <http://goo.gl/9nLVDG>

21 U.S. Consumer Product Safety Commission, "Chronic Hazard Advisory Panel on Diisononyl Phthalate (DINP) Report, June 2001," <http://goo.gl/xGCLWM>

22 U.S. Consumer Product Safety Commission, "Petition (HP 99-1) Requesting Ban of Use of PVC in Products Intended for Children Five Years of Age and Under," <http://goo.gl/5av8R2>

23 U.S. Consumer Product Safety Commission, Petition HP 99-1 Vote Sheet, <http://goo.gl/vEycGa>

## Scientific Review of Phthalates Confirms Safety

**1998 U.S. Consumer Product Safety Commission (CPSC) Review of DINP**  
CPSC convenes a Chronic Hazard Advisory Panel (CHAP) to review phthalates. Industry voluntarily removes DINP from children's products and toys.

**2002 U.S. Consumer Product Safety Commission (CPSC) Review<sup>1</sup>**  
CPSC determines that there is "no demonstrated health risk" from use of DINP in toys.

**2002 Cosmetics Ingredient Review (CIR)<sup>2</sup>**  
CIR reaffirms its original conclusion that DBP, DMP and DEP are safe for use in cosmetics

**2002 Food & Drug Administration (FDA)<sup>3</sup>**  
FDA reviews the safety and toxicity data for phthalates in cosmetics and concurs with the CIR findings.

**2003 National Toxicology Program's Center for the Evaluation of Risks to Human Reproduction (CERHR)<sup>4</sup>**  
CERHR concluded that there was "minimal risk to non-existent risks of injury" from mouthing toys containing DINP.

**2005 U.S. Centers for Disease Control (CDC)<sup>5</sup>**  
CDC (2005) report indicates that exposure is well within safe limits for phthalates.

1 Consumer Product Safety Commission (CPSC) (2001) Chronic Hazard Advisory Panel on Diisononyl Phthalate (DINP). U.S. CPSC, Bethesda, MD 20814. June 2001

2 "Annual Review of Cosmetic Ingredient Safety Assessments 2002/2003," International Journal of Toxicology (Supplement 1), 1-102, 2005., <http://goo.gl/WjCP4S>

3 U.S Food and Drug Administration, "Phthalates and Cosmetic Products," <http://goo.gl/CO0Pk4>

4 Center for the Evaluation of Risks to Human Reproduction (CERHR 2003) NTP-CERHR Expert Panel Report on Diisononyl Phthalate. National Toxicology Program, Center for the Evaluation of Risks to Human Reproduction, Research Triangle Park, NC. March 2003. NIH Publication No. 03-4484.

5 U.S. Centers for Disease Control and Prevention, "National Biomonitoring Program: Phthalates," <http://goo.gl/VHefKv>

Analysis and reviews produced in 2002, 2003, 2005 and 2010<sup>24</sup> confirm little to no concern for the health effects of this widely-used phthalate in humans.

In 2008 – following a series of high profile toy recalls, a European focus on chemicals in toys and pressure from activist organizations – the U.S. took action on phthalates at the federal level despite little empirical data to support such a move. At that time, the U.S. Congress passed, and President Bush signed, the Consumer Product Safety Improvement Act (CPSIA) which permanently banned three phthalates (DEHP, DBP, BBP) in children’s toys and required temporary restrictions on the use of three other phthalates (DINP, DIDP, DnOP) in children’s products that can be placed in the mouth, pending further study of the safety of phthalates and alternatives to phthalates. Interestingly, DPHP, a phthalate similar to DIDP, was not included in this Act even though less is publicly available for this phthalate compared to others. To date, DPHP has not received the same interest group scrutiny and review. As for the current CPSC phthalate review mandated by the passage of the CPSIA, that process is still ongoing today, more than five years later.

The law largely ignored the previous findings of the CPSC<sup>25</sup> and the National Toxicology Program (NTP), which found no significant concerns from the use of DINP.

The interim ban that Congress put in place on DINP, DIDP, and DnOP created new problems. Manufacturers were forced to dispose of a variety of items and spend large amounts of money to re-test their products – even for toys or parts that children could not or would not likely put in their mouths. In one example, a manufacturer spent \$8,600 to test a telescope. As the manufacturer put it, “No one’s gonna eat the telescope.”<sup>26</sup>

If DINP is banned in all children’s products, experts say it could cause unintended consequences. According to a federal CPSC scientist, “manufacturers might choose another plasticizer that may or may not be as well characterized toxicologically as DINP. They might choose to use another plastic other than PVC which may release a more toxic chemical and which may or may not be toxicologically characterized. The new plastic may not have the same level of flexibility, a characteristic which currently minimizes the risk of choking hazards.”<sup>27</sup>

Following Congress’ intervention in 2008, some states and environmental groups have continued to push for even more regulation. In 2013, the Mind the Store campaign was launched to urge retailers against the use of chemicals that the campaign deemed harmful, including phthalates. In response to this and similar campaigns, some retailers have asked suppliers to use alternative chemicals, but in many cases they have been unsuccessful in identifying a alternative that has the safety and performance characteristics of phthalates.

24 See box on right

25 U.S. Consumer Product Safety Commission, Petition (HP 99-1) Vote Sheet, <http://goo.gl/Qv8Fof>

26 CBS News – 60 Minutes, “Phthalates: Are they safe?,” <http://goo.gl/CxVGmQ>

27 Testimony of Dr. Michael Babich, U.S. Consumer Product Safety Commission, Hearing Before the Subcommittee on Consumer Affairs, Insurance and Automotive Safety, June 10, 2008.

#### 2006 European Union<sup>6</sup>

EU Risk Assessments find (DINP & DIDP) safe for use in current applications

#### 2010 U.S. Environmental Protection Agency (EPA)

EPA issues draft rule to add 8 phthalate to a list of “chemicals of concern” for further analysis, and then withdraws the draft rule, saying it was “no longer necessary.”

#### 2012 Australia’s National Industrial Chemicals Notification Assessment Scheme (NICNAS)<sup>7</sup>

Australia concludes, “Current risk estimates do not indicate a health concern from exposure of children to DINP in toys and childcare articles even at the highest (reasonable worst-case) exposure scenario considered.”

#### 2014 European Chemical Agency (ECHA)<sup>8</sup>

European Commission endorses ECHA’s findings that “no unacceptable risk has been characterized for the uses of DINP and DIDP in articles other than toys and childcare articles which can be placed in the mouth”.

6 European Chemicals Bureau (ECB) (2003) European Union Risk Assessment Report. 1,2-benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9 rich and di-“isononyl” phthalate (DINP). CAS # 68515-48-0 and CAS # 28553-12-0; EINECS # 271-090-9 and EINECS # 249-079-5. 2nd Priority List, Volume 35. Institute for Health and Consumer Protection, European Chemicals Bureau, European Commission.

7 National Industrial Chemicals Notification and Assessment Scheme (NICNAS) Existing Chemical Hazard Assessment Report No.35. Diisononyl Phthalate. Australian Government, Department of Health and Aging. Sydney, Australia. September 2012. <http://goo.gl/HbP778>

8 European Chemical Agency, “Consultations on draft review report,” <http://goo.gl/DxJX7t>

At the federal level, DINP, DIDP and DnOP do not face prohibitions in any current use. The temporary prohibition on children's toys and mouthing items is still under review at the CPSC.

## CASE STUDY: PARABENS

Parabens are a class of chemicals used in a wide variety of cosmetics and in foods and pharmaceuticals. Parabens are among the most common and most reliable preservatives in personal care products. They fight bacteria and fungus growth, both protecting consumers and extending the shelf life of many beauty products. Parabens are commonly found in makeup, moisturizers, hair care and shaving products, and other cosmetics. The most common parabens are methylparaben, propylparaben, and butylparaben. Typically, products use more than one paraben, which are combined with other preservatives.

In 1984, the Cosmetic Ingredient Review (CIR), an independent panel of scientific and medical experts, reviewed the safety of several parabens (methylparaben, propylparaben, and butylparaben) and found they were safe for use in cosmetic products at levels up to 25 percent of the total content. Typically, parabens are used at much lower levels – ranging from 0.01 to 0.3 percent.

Like the other chemicals discussed in this paper, parabens have come under fire from public attacks alleging they are linked to breast cancer and fertility issues. In response, many leading manufacturers have committed to removing parabens from their products, which ultimately will affect consumer pocketbooks. Reformulations of any product are expensive and many times manufacturers choose to pass along the burden to customers.

Concerns about a correlation between breast cancer and parabens stem largely from a 2004 study published in the *Journal of Applied Toxicology* that identified parabens in breast tumors. Many posited that the compounds were introduced through antiperspirants and interpreted the findings to indicate that the presence of parabens caused the cancer. Today most major brands of deodorants and antiperspirants do not contain parabens.

Important to note, however, is the fact that the 2004 study failed to identify causality between the presence of parabens and breast cancer and failed to examine paraben levels in non-cancerous tissue. Following a broader, similar study in 2008, the author, Dr. Philippa Darbre, stated, "The fact that parabens were detected in the majority of the breast tissue samples cannot be taken to imply that they actually caused breast cancer in the 40 women studied."<sup>28</sup>

After reviewing the 2004 study, the FDA made a similar conclusion, writing: "the study did not show that parabens cause cancer, or that they are harmful in any way." The FDA's website also noted, "there is no reason for consumers to be concerned about the use of cosmetics containing parabens."<sup>29</sup>

In 2006, after offering interested parties the chance to submit safety assessments of four main parabens, the CIR determined there was no need to change the panel's position that parabens are safe as used in cosmetics. The American Cancer Society also concluded there was insufficient evidence to support a claim that the use of cosmetics containing parabens increases an individual's risk of developing breast cancer.<sup>30</sup>

Although effectively given a clean bill of health by regulators, some cosmetic manufacturers – particularly those in the "all natural" and "organic" business – have reacted to consumer perceptions by experimenting with paraben alternatives. EMagazine notes a senior coordinator for Whole Foods Market confirmed that, "the number of paraben-free items has increased dramatically."<sup>31</sup>

28 "Parabens in Breast Tissue not Limited to Women who Have Used Underarm Products," <http://goo.gl/jVAEQM>

29 U.S. Food and Drug Administration, <http://goo.gl/ZDlc8U>

30 American Cancer Society, "Antiperspirants and Breast Cancer Risk," <http://goo.gl/pPXAsO>

31 EMagazine, "The Perils of Parabens," <http://goo.gl/B5qzSf>

Consumers should refrain from knee-jerk reactions to speculation about the effects of parabens, experts caution. In an interview with the LA Times, a scientist from the Environmental Working Group notes, “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.”<sup>32</sup>

## CONCLUSIONS

Consumer and industry scrutiny is not a bad thing. In fact, regularly assessing the substances in marketed goods ensures consumers’ welfare. An official from the Vinyl Institute, a trade group representing manufacturers of vinyl, captured the dynamic well when stating that market pressure helps “focus this industry on studying and mitigating our impacts and improving the material and products.”<sup>33</sup> Yet, public outcry should not supersede science, and concerns based on inconclusive information should not determine policy, no matter how loudly trumpeted.

To best protect consumers, regulators should utilize parameters that assess risk based on chemical make-up. Additionally, using rigorous scientific testing, regulators should also factor in a consumer’s exposure to a chemical.

Advocating for the replacement of a certain chemical based solely on fear, opens the door to alternative substances that may pose an even greater risk. Even very similar chemicals are not created equal, and often little is known about the effects a replacement might have in every application under every condition. Instituting quick replacements in response to unscientific outcry spells needless uncertainty and potential danger for the public.

For that reason, it is important that consumers encourage that all regulation be grounded in objective science and a system of uniform standards are followed for substantiating differing scientific opinions – not on marketing campaigns of popular opinion by activists alone.

32 *Los Angeles Times*, “‘Paraben Free’: Should You Care?,” <http://goo.gl/hfcFAf>

33 *Plastics News*, “Environmental group shuts down anti-PVC campaign,” <http://goo.gl/klzjBZ>



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