

BENEATH THE

# SKIN

Hidden Liabilities,  
Market Risk and  
Drivers of Change  
in the Cosmetics  
and Personal Care  
Products Industry

Tim Little  
Sanford Lewis  
Pamela Lundquist





# Table of Contents

Executive Overview and Introduction: <i>Drivers of Change in the Personal Care Products and Cosmetics Industry</i> .....	2
Overview of the Personal Care Products & Cosmetics Industry.....	7
Health Issues and Related Market Risks .....	10
Recommendations.....	18
Appendix A: Reference Chart of Common Cosmetic Ingredients with Known Health Problems.....	21
Appendix B: Thumbnail Descriptions of Selected Companies.....	22
Appendix C: Suggestions for More Information .....	26
Endnotes .....	28

## Acknowledgements

The authors thank Richard Liroff, Erin Neale, Jennifer Snyder, Nathaniel Johnson and Dr. Vesela Veleva for their insight, guidance and advice in researching and writing this paper.

## The Authors

**TIM LITTLE** is co-founder & Executive Director of the Rose Foundation for Communities and the Environment, a grantmaking public charity dedicated to the positive interlock between environmental protection, a healthy economy and livable communities. He has co-authored a series of publications related to fiduciary responsibility and corporate environmental performance. He is also the author of a citizen petition to the Securities and Exchange Commission (endorsed by investors collectively representing over \$3 trillion) calling for increased transparency in corporate environmental disclosures, and is accepted as an expert on environmental disclosure by the Government Accountability Office. [tlittle\\_rose@earthlink.net](mailto:tlittle_rose@earthlink.net)

**SANFORD LEWIS** is a nationally-known attorney with over 20 years' experience in corporate accountability issues. Sanford is counsel for investors and advocacy organizations seeking to promote the substitution of safer alternatives to dangerous chemicals, including pesticides. His clients include the Investor Environmental Health Network, DuPont Shareholders for Fair Value, Health Care Without Harm, the Massachusetts Alliance for a Healthy Tomorrow, and the International Campaign for Justice in Bhopal.

**PAMELA LUNDQUIST** has researched and written on toxicants in cosmetics and personal care products for the Children's Health Environmental Coalition and *The Green Guide*. She is currently pursuing a J.D. at Vermont Law School. [plundquist@vermontlaw.edu](mailto:plundquist@vermontlaw.edu)

This document is a publication of the Investor Environmental Health Network, [www.iehn.org](http://www.iehn.org).

---

## The Rose Foundation

The Rose Foundation for Communities and the Environment is a grant making public charity dedicated to nurturing positive interactions between the environment, the economy and communities. Through its Environmental Fiduciary Project, it advocates the prudent inclusion of environmental and social factors into investment portfolio management.

## Rose Foundation Publications on this Topic

*The Environmental Fiduciary: The Case for Incorporating Environmental Factors into Investment Management Policies*, Goodman, Kron, Little (2002)

*The Gap in GAAP: An Examination of Environmental Accounting Loopholes*, Goodman, Little (2003)

*Fooling Investors and Fooling Themselves: How Aggressive Corporate Accounting & Asset Management Tactics Can Lead to Environmental Accounting Fraud*, Lewis, Little (2004)

*The Prudent Trustee: The Evolution of the Long-Term Investor*, Emerson, Little, Kron (2005)

# EXECUTIVE OVERVIEW

## Introduction

There is good reason, as investors as well as consumers, to be concerned about potentially harmful chemicals in cosmetics. The cosmetics and personal care industry is uniquely vulnerable to consumer backlash as health issues emerge related to the use of their products. Already the evidence has been mounting of health risks associated with commonly used ingredients such as phthalates. Now, new nanotechnologies are being widely deployed in cosmetics products, despite evidence of serious potential health risks. Moreover, the physical application of some of the nanotechnologies to the body in cosmetics makes these uses uniquely prone to skin penetration, inhalation and ingestion of the nanotech materials.

Wall Street is littered with the fallen angels of companies that did not adequately respond to consumer fears. Arguing whether the fears are well-grounded or not and persuading customers to return is a lot harder, and more expensive, than maintaining customer trust and loyalty in the first place.

Under current voluntary controls, many potentially harmful chemicals have been found to make their way into cosmetics and personal care products—from nail polish, to makeup, to shampoo. The threats to health may include, for instance, cancer, harm to developing fetuses and infants exposed to the chemicals through baby products or their mother's cosmetics use, and disruptions of various organ or hormonal systems in the body.

For thousands of years, people have used cosmetics and personal care products to enhance health, comfort and beauty. For example, historians detail the widespread use of scented body oils by ancient Greeks and some credit the Egyptians and Phoenicians with the invention of lipstick.

Today, most Americans use a variety of personal care products such as lotions, powders, shampoos and cosmetics every day. Guided by brand loyalty, social custom and the performance of individual products most Americans apply about 10 cosmetics or other personal care products containing over 126 distinct ingredients to their bodies daily, for uses ranging from routine daily ablutions to peels, waxes and more exotic treatments.<sup>1</sup> Overall, the cosmetics industry accounts for the use of nearly one in seven of the 75,000 chemicals registered for use in the United States. However, unlike many other industries, chemicals used in the cosmetics and personal care industry are intended to be



applied intimately, often daily, to our skin. In many cases, penetrating agents ensure rapid and deep penetration of these substances into our bodies.

In addition to frequent, personal, often intimate use, cosmetics and personal care products are also part of the fashion world, which is heavily image-driven. The cosmetics industry keeps pace with fashion trends by introducing new colors and products seasonally, in tandem with the garment industry. Significant product development and marketing dollars are devoted to continually creating and selling new versions of the same personal care products as part of the ingrained and interwoven societal links among fashion, personal attractiveness and romance. Like any other consumer based industry, consumer interest is also maintained by developing products with new and improved features: smudge-proof lipstick, mascara that curls lashes, and quick-dry nail polish are a few examples.





Safety controversies in the cosmetics industry stem in part from insufficient attention to the use of chemicals in intimate cosmetic applications where they may pose a hazard to particularly sensitive populations, such as fetuses developing in the womb. For example, emerging evidence links phthalates—an ingredient of nail polish, shampoo, anti-perspirants and sunscreens—and an array of health effects including malformed or underdeveloped reproductive organs in males exposed to these chemicals during early development. While phthalates are used in a broad range of industries, in cosmetics applications the potential for consumer exposures is heightened. A front page story in the *Wall Street Journal* in 2005, headlined “From an Ingredient in Cosmetics, Toys, a Safety Concern”, focused on the hazards of phthalates to male reproductive development and noted restrictions being imposed in Europe and Japan.<sup>2</sup>

## Drivers of Change in the Cosmetics and Personal Care Industry

This paper examines multiple factors driving what may become a perfect storm of health related concerns that could batter the value of cosmetics and personal care industry stocks:

- Lack of U.S. regulatory oversight
- Emerging health issues that could undercut consumer confidence
- Growing consumer concern in response to these health threats
- Aggressive new European Union standards that are creating a context of notably weaker public health protection practices in the US
- Restrictions global personal care companies may soon face in shipping products worldwide due to various national restrictions on toxic chemicals.

## Lack of U.S Regulatory Oversight

If they think about it at all, most American consumers generally assume that personal care products—many of which are marketed under trusted brands that have been household names for generations such as Avon, Procter & Gamble, Johnson & Johnson or Revlon—are safe. Given the U.S.’s complex framework of governmental regulatory agencies, U.S. consumers assume that federal oversight provides a basic level of assurance that potential health risks associated with such intimate and prolonged usage have been identified, and exposure to carcinogens, mutagens, or other toxic agents eliminated.

But the truth is, there is only a porous and ill-defined regulatory framework to back consumer trust in most personal care products. Although nominally under the purview of the U.S. Food and Drug Administration (FDA), since cosmetics are not classified as drugs unless the manufacturer claims certain pharmaceutical properties, cosmetics are generally exempt from pre-market review. So health threats or actual harms may only be found after widespread penetration into the market and exposure to potentially millions of customers.

## Health Issues Create Liability and Unquantified Market Risk

Therefore, beneath the skin of the glamorous cosmetics industry lurks the ugly specter of undisclosed and unquantified risk—posing problems for investors who need to make portfolio decisions based on financial facts, rather than marketing fragrance. And, since much of the value in the cosmetics and personal care industry is vested in image and brand rather than specific products, unlike many other chemical intensive industries cosmetics companies have a special investment in their reputations and brand value. Consumers buy personal care products they trust will keep them attractive, fashionable and feeling vital. If customers find out that a product, especially one they have long trusted and applied to their bodies, carries hidden chemical hazards, they may even feel betrayed. This may pose a serious threat to brand loyalty with significant implications for profitability and market share. It is difficult to overstate the potential magnitude of this

challenge. As common ingredients such as phthalates—ubiquitous to many cosmetics—become increasingly linked to serious health threats such as impairing the development of the reproductive system in newborn boys, consumers may stampede away—not only from specific products, but from entire brands, creating a potential for dramatic and far-reaching price shocks.

Studies in an array of consumer product markets have examined the linkages between brand loyalty and profitability. Most show a positive relationship, and most importantly, a relationship that is vulnerable to shock. For example, as one recent study points out, “Brand equity is a valuable yet fragile asset. The mounting frequency of product-harm crises and ill-prepared corporate responses to such crises can have profound consequences for brand equity.”<sup>3</sup>

But it’s not just an abstract academic question. Lessons abound for the cosmetics and personal care industry—and for their investors—in pharmaceutical giant Merck’s unfolding disaster with the once-popular painkiller Vioxx. Once heralded as a wonder drug, Vioxx became linked with strokes and heart attacks. More than 6,000 people have already sued Merck, and the total number of suits is projected to reach 100,000. According to published reports, some analysts project that it may take as much as \$50 billion to settle the claims.<sup>4</sup> As soon as this bad news started to hit the press in 2004, Merck’s stock began to dive and investors saw the value of their Merck stock shrink 40% for the year. The \$120 billion New York State Common Retirement Fund has alleged that Merck’s management “knew, yet failed to disclose, that a growing body of evidence demonstrated that patients who used Vioxx were at an increased risk of adverse cardiovascular reactions, including heart attack, stroke and death.”<sup>5</sup> The suit alleges that, by failing to tell investors about these health risks, Merck violated federal securities disclosure laws by withholding financially material information that “put lives at risk and cost shareholders billions of dollars.”<sup>6</sup>

Perhaps most ominous for cosmetics and personal care investors is the fact that the Vioxx disaster, including the allegations that Merck’s management was slow to react to the adverse health data and may have even deliberately withheld liability information, occurred under the FDA’s drug regulation regime—which is much more stringent than the cosmetic and personal care product self-regulatory

safety process. If problems of the magnitude of Vioxx could slip through the FDA’s relatively tight drug screening process, what kind of liabilities are passing unchecked through the looser cosmetics regulatory screens? The significant and unanswered questions about the health and financial liabilities that may be associated with personal care products represent real threats to reputational value, brand, franchise, market share and profitability in the cosmetics industry. And, just as they did with Merck, investors may find themselves asking—what did cosmetics company executives know and when did they know it?

## Growing Consumer Concern

Consumers are starting to question the health risks associated with personal care products and the press is starting to cover the story. For example, during the summer of 2005, a study was released on a group of chemicals called phthalates, which are widely used in cosmetics. This study showed that phthalate exposure causing negative impacts on reproductive health found in animal studies could be similarly affecting humans.<sup>7</sup> Though the study didn’t prove causation, it demonstrated a correlation between prenatal exposure to phthalates and reproductive effects in newborns.

Although it is difficult to quantify consumer concern on emerging issues such as health threats related to cosmetics and personal care products, one reliable barometer is media coverage. A Lexis-Nexis search of major newspapers and wire stories during the period 1995 – 2005 reveals a dramatic increase in coverage—from one news story during the 5 year period prior to 2000 to 165 stories in the last four years. And the trend is accelerating; there were 75 news and wire stories in 2005 alone.<sup>8</sup>

Many of the consumer questions and related media coverage are being driven by focused efforts of nongovernmental organizations (NGOs). In particular, the Environmental Working Group (EWG), a public interest research and advocacy organization based in Washington DC, has released a series of detailed and influential reports exploring the safety of ingredients in personal care products.<sup>9</sup> One of these reports was the 2002 “Not Too Pretty: Phthalates, Beauty Products and the FDA,” which documented harmful phthalates in nearly 75% of 72 off-the-shelf cosmetics products.



After the release of “Not Too Pretty,” a broad coalition of public health, educational, religious, labor, women’s, environmental and consumer groups began to form, coalescing into the Campaign for Safe Cosmetics (CSC). CSC has the stated goal of protecting the health of consumers and workers by requiring the health and beauty industry to phase out the use of chemicals linked to cancer, birth defects and other health problems and replace them with safer alternatives. A core initiative has been the Compact for Safe Cosmetics, which is a company by company pledge to phase out hazardous materials in cosmetics and personal care products within three years, and to meet the new tough European Union cosmetics ingredients standards worldwide.<sup>10</sup> To date, 500 manufacturers, distributors and retailers have signed the pledge. However, many of the larger companies, including Avon, Estée Lauder, and Procter & Gamble have so far refused to do so. U.S. consumers and investors alike may develop significant concerns about why these companies have chosen not to formally agree to remove potentially harmful chemicals from their U.S. products—especially since these companies must reformulate to remove many of these substances from products sold in the lucrative E.U. marketplace.



## Pressure From European Union and Canadian Regulations

Landmark legislation passed in Europe will have far reaching consequences for cosmetics industry regulation around the world. European Union (E.U.) Directive 2003/15/EEC bans over 1,000 chemicals from use in cosmetics sold in the E.U., on the basis of scientific evidence demonstrating that these chemicals are carcinogens, mutagens, or reproductive toxicants (CMRs). It came into effect in the spring of 2005.<sup>11</sup> Any cosmetic company that wishes to sell its products in the 25 E.U. member states, a market of 457 million people, must comply with this directive by formulating or reformulating its products without these banned chemicals.<sup>12</sup>

Compliance is only one of the far reaching consequences of this new regulatory regime, according to Citizens Advisors’ Social Research Analyst Vesela Veleva, author of the article “New EU Rules for the Cosmetics Industry: What do They Mean for U.S. Companies and Stakeholders?”<sup>13</sup> According to Dr. Veleva, the E.U. directive sets a standard that consumers and NGOs in other countries will demand for products sold in their countries. For example, if products appear to be safer in Europe, then American consumers may desire the same level of safety for the products that they use. Dr. Veleva also predicts that shareholders concerned about potential liabilities from identified CMRs are likely to push companies to reformulate product to remove these chemicals.<sup>14</sup> Otherwise these companies may experience liabilities, including tort lawsuits, and face risks such as market exclusion and damaged reputation—all of which impact the bottom line.

Dr. Veleva points out that “[p]roactive companies” will be in a better position to “gain market share not only in the EU but also in all markets that may later enact similar regulations.”<sup>15</sup> These proactive companies may also avoid fines, expensive litigation and damaged reputations. In fact, Revlon, L’Oréal, and Unilever have announced that they have reformulated products sold worldwide to meet E.U. standards—effectively responding to the main thrust of the Compact for Safe Cosmetics, albeit without





becoming a signatory. Perhaps the most salient point in the article is the prediction that the “longer a company waits to reformulate, the higher the cost of compliance will be.”<sup>16</sup> Indeed, reformulating is not only likely to avoid future costs, but it could also increase revenue by creating a competitive advantage in a slow-growing industry looking for new markets.

But the pressure on U.S. companies and regulators is also being exhibited closer to home. Canada is the United States’ closest neighbor and a major trading partner, so Canadian regulations will inevitably affect many American manufacturers. Canadian cosmetics regulations are stricter than those in the U.S. Existing Canadian ingredient regulations specify that certain substances are prohibited for use in cosmetics and some are restricted for specific uses, or in certain concentrations, or both.<sup>17</sup> The latest “Hotlist” had hundreds of prohibited and restricted chemicals, including formaldehyde, nitrosamines, and 1,4-dioxane.<sup>18</sup> This is far more than the nine ingredients that the FDA bans or restricts<sup>19</sup> and the nine substances that the U.S. Cosmetics Industry Review Panel (CIR) recommends avoiding.<sup>20</sup> Manufacturers must also register all cosmetic products<sup>21</sup> and must inform the Canadian government of the approximate concentration of each ingredient.<sup>22</sup> Any information furnished to the Canadian Cosmetics Program office will be treated as a trade secret if indicated as such by the supplier. Recently, Health Canada (the Canadian equivalent of the FDA) published new labeling regulations that will increase disclosure.<sup>23</sup> As Canadian Health Minister Ujjal Dosanjh explained, “[m]andatory labeling of cosmetic ingredients will increase consumer safety by allowing the public to make more informed choices when selecting cosmetic products.”<sup>24</sup> This change reflects the growing awareness that consumers care what is in the products they buy. All manufacturers and importers must be in compliance with these labeling requirements by November 16, 2006.<sup>25</sup>

There are also changes proceeding at the state level which will inevitably impact U.S. companies and may also influence future federal regulation. For example, the California Safe Cosmetics Act of 2005 requires the reporting of all cosmetic ingredients “identified as causing cancer or reproductive toxicity,” as well as requiring data to back up health effects and safety claims.<sup>26</sup> Although California is just one of 50 states, as the world’s 6th largest economy it casts a long shadow—one that investors may well regard as a portent of change in many industries, including cosmetics and personal care products.

The combination of emerging health risk information, international and state-level regulatory changes and consumer pressure could drive sweeping changes in the American personal care and cosmetics industry—with significant consequences for investors.





# Overview of the Personal Care Products & Cosmetics Industry and the Current the U.S. Regulatory Framework

## Beneath the Skin

This report profiles some of the principal areas of potential risk that have been identified by health researchers, academic institutions, and non-governmental organizations (NGOs). It tracks the growing wave of consumer concern, regulatory initiative and shareholder interest, and suggests that investors should consider the potential effects of these growing drivers of industry change. It closes with an analysis of the advantages to the industry of reformulating product to remove unhealthy or questionable ingredients, and recommendations for how investors can respond to these new challenges. These recommendations include support for greater disclosure of potential risks, reports on opportunities to reformulate products to reduce or eliminate toxics, and closer monitoring of international and U.S. regulatory trends.

## Industry Overview

Depending on how the boundaries of the sector are drawn, the US cosmetic and toiletry market accounts for \$32 billion to \$60 billion in sales. The market, comprised of over 1,000 manufacturing companies, is dominated by large companies, with the 10 largest accounting for 62% of total sales. Estee Lauder, Johnson & Johnson and Limited Brands are the major players in skin care, L’Oreal and Estee Lauder in makeup, and Procter & Gamble and L’Oreal lead in hair care.<sup>27</sup>

Of course, just considering the manufacturers of cosmetics and personal care products doesn’t provide a full overview. The supply chain in this chemical-intensive industry extends to various chemical manufacturers, and also includes a growing natural products element. Generally, these raw materials are mixed in-house at multiple production sites, using closely guarded proprietary

formulae. The finished products are distributed through a broad web that may include local specialty stores, and highly-visible and brand sensitive national drug stores and supermarkets, as well as “big-box” retail outlets such as Wal-Mart. In many cases, cosmetics lines, while important in their own right to retail outlets, may also serve as important draws to entice customers into a store where they may then purchase other goods. For example, cosmetics and personal care products account for only a fraction of CVS’ \$30 billion annual net sales (which are largely driven by pharmaceuticals—more than 70% of CVS’ 2004 net sales were pharmacy items). But the true value of cosmetics and personal care products to CVS’ business strategy is glimpsed by its “unique front store focus on cosmetics, health and beauty.”<sup>28</sup> In other words, cosmetics and personal care products serve as a leader to draw in customers for other merchandise and help create a stronger competitive niche in the very lucrative prescriptions market.

It’s also important for investors to recognize the growing consumer demand for “clean & green” products. According to the Organic Consumers Association, sales of natural personal care products have experienced 52% growth between 1998 and 2004.<sup>29</sup> *CosmeticsDesign.com*, a trade publication, similarly tracks the mounting demand for organic and natural cosmetics and personal care products, reporting a robust sales curve in the U.S.—from \$3.9 billion in 2003 to an estimated \$5.8 billion in 2008.<sup>30</sup> The global market is estimated to be more than double the U.S. share, pegged by the Euromonitor at \$8.7 billion in 2004.<sup>31</sup>

## Regulatory Oversight

The U.S. Food & Drug Administration (FDA) defines cosmetics as, “articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for

cleansing, beautifying, promoting attractiveness, or altering the appearance.” With the exclusion of soap, the FDA’s definition includes the components of cosmetics as well as the final product.<sup>32</sup> The FDA also regulates drugs, which are generally defined as substances intended to diagnose, treat or prevent disease, or to affect the structure or function of the body.<sup>33</sup>

The FDA requires extensive pre-market safety testing for drugs, but not for cosmetics, ostensibly because drugs have a more substantial impact on the body.<sup>34</sup> The key factor determining whether a product is a drug or a cosmetic, however, is what claim the manufacturer makes about it.<sup>35</sup> For example, if a cosmetic company claimed that its product actually changed the structure of the skin, the product could be categorized as a drug and therefore subject to pre-market testing.<sup>36</sup> If the manufacturer made no such claim for the very same product, it would be regulated as a cosmetic, regardless of how it actually affected the body.<sup>37</sup> Therefore, a cosmetic would only trigger the much more rigorous (and costly) pre-market testing regimen used for new drugs if the manufacturer makes claims that it will act like a drug. In short, the current regulatory system has a structural bias towards manufacturer avoidance of the more onerous classifications by simply controlling marketing claims.

The extent of pre-market testing for cosmetics, required by federal law, is that “each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing.”<sup>38</sup> There is no clear definition of what “adequately substantiated” means and who must provide the evidence—the government, the manufacturer, or an independent body.<sup>39</sup> The Environmental Working Group (EWG), a harsh critic of the cosmetics industry and federal regulators, has challenged the FDA in a petition to give practical meaning to the term “adequately substantiated.” In a written response the FDA said it would not undertake rulemaking to define “adequately substantiated” but would look into the possibility of issuing guidance in the future. If a product violates this provision, it must only display a conspicuous warning statement

There is also a federal prohibition on the manufacture or delivery of a cosmetic that is “adulterated” or

“misbranded”—that is, if it contains a poisonous or deleterious substance that may render it temporarily or permanently injurious to users, under “customary or usual” conditions of use.<sup>40</sup> However, whether many substances of concern are deemed “poisonous or deleterious” is sufficiently vague, and premarket testing sufficiently spotty, that there is no real mechanism translating the health protective spirit of the law into clear and enforceable policy and regulation.

## Fox Guarding the Hen House

Exacerbating the regulatory uncertainty, the laws governing cosmetics are enforced in a self-policing manner. For example, cosmetics regulatory actions by the FDA are typically only triggered by adverse reaction reports. Manufacturers, packers, and distributors are “requested” to file a certain form with respect to all reportable adverse experiences.<sup>41</sup> These types of experiences include any allergic reactions or bodily injuries sustained by a customer as a result of use of the cosmetic. The agency may then follow up these reports with inspections of the cosmetics maker, and analysis taken from persons filing the complaints and from the firm’s product samples. However, these adverse reaction reports are considered voluntary. Therefore, for enforcement to occur under the current regulatory regime, a company must file the bureaucratic equivalent of a “kick me here” sign with an oversight agency which otherwise is largely content to leave the company alone—hardly a recipe for accurate, timely, foresighted weeding out of dangerous elements in personal care products.

Ingredients in cosmetics and personal care products are reviewed and assessed by a committee funded by the Cosmetic, Toiletry & Fragrance Association, the Cosmetic Ingredient Review (CIR) panel (in addition to whatever testing individual cosmetics companies may elect to do).<sup>42</sup> The CIR Expert Panel classifies ingredients as either (1) safe as currently used; (2) safe with qualifications; (3) unsafe; or (4) insufficient information for a determination.<sup>43</sup> The CIR makes its determinations based principally on published scientific data, but can call on individual companies for unpublished data.<sup>44</sup> The EWG reported in “Skin Deep” that only 11% of the 10,500 ingredients the FDA has documented in products had been



assessed for safety by the CIR panel.<sup>45</sup> EWG calculated that only 28 of the 7,500 products evaluated in its report “Skin Deep” had been fully assessed before placed on the market for sale.<sup>46</sup>

Based on the weight it places on this topic in panel discussions and written reviews, the CIR appears to consider allergic reactions to be its top concern. The CIR bases most use recommendations on ingredient sensitization properties rather than carcinogenic potential. For example, of the ingredients approved by the CIR for use in cosmetics based on sensitization, 14% also had some data indicating cancer risks, yet the panel still chose sensitization as the area of concern. The industry uses the CIR’s findings, but is not bound specifically to follow them.<sup>47</sup>

Also, the FDA has found it difficult to police misleading cosmetic labels because it bears the burden of proof—it must demonstrate that the product is adulterated or misbranded before it can act.<sup>48</sup> For example, although it might be unethical, in light of the burden of proof the FDA might not take enforcement action against a manufacturer

that markets a cosmetic containing known allergens, even if there was no warning on the label. Also the FDA is not authorized to require recalls of cosmetics but it may “request” and monitor the recall of a companies’ product from the market when a firm has been unwilling to remove a harmful cosmetic without FDA’s written request.<sup>49</sup> This general absence of government oversight may lead to companies marketing products with ingredients that are, in the words of the Environmental Working Group, “poorly studied, not studied at all, or worse, known to pose potentially serious health risks.”<sup>50</sup>

The cosmetics industry, in response to the groundswell of advocacy and public concern about the health effects of its products, has begun touting a new initiative known as the Consumer Commitment Code (CCC). CCC appears principally shaped to defend the industry’s Cosmetics Ingredient Review process and to support the industry’s voluntary transmission of adverse event information to the Food and Drug Administration. The industry also says it is ready to provide additional information if and when requested by the FDA. Yet, in our opinion, the code appears to do little if anything to encourage cosmetics companies to eliminate the array of substances of concern for long term health issues such as reproductive, cancer and endocrine impacts that are being flagged in the scientific literature.

In summary, the current U.S. federal regulatory system for cosmetics and personal care products contains structural flaws which largely allow manufacturers to control many of the circumstances under which they are regulated. Through careful marketing, manufacturers may generally avoid the onerous and expensive pre-market testing required for drugs—even if the product may be incidentally ingested or otherwise intimately introduced to the body in the same way as a drug. Although manufacturers are under a vaguely-stated burden to “adequately substantiate” the safety of their products, there appears to be minimal enforcement of this mandate—no bright lines that provide industry, consumers and investors alike with the certainty needed to accurately forecast risk or cost. The result is a system that encourages the widespread penetration of products that by their very nature involve significant human exposure into markets before any rigorous safety testing is conducted—ultimately, a game of roulette which places consumers, manufacturers and investors at risk.





# Health Issues Create Potential & Unquantified Market Risk

Concerns about the safety of cosmetics and personal care products involve certain key ingredients, preservatives, “fragrance” (a catch-all term which can include any number of compounds) and impurities. Due to the tremendous number of ingredients used in cosmetics and personal care products, a comprehensive treatment is beyond the scope of this paper. However, readers may wish to consult Appendix A for a quick reference chart of common ingredients with identified health concerns.

## Key Ingredients

Many ingredients in cosmetics and personal care products may cause adverse health reactions. However, it is far beyond the scope of this paper to catalogue and describe all of these controversies. Instead, we focus attention on an ingredient which has received some of the greatest notoriety in recent years, a class of chemicals called phthalates. The mounting health controversy around phthalates in cosmetics—an issue first flagged by the Environmental Working Group in the report “Beauty Secrets” in 2000—is perhaps the best example of both the risks facing the cosmetics and personal care products industry, and the differences between the U.S. and E.U. approaches to product safety.

## What are Phthalates?

Phthalates are a class of chemicals widely used in cosmetics, perfume, nail polish, skin lotion, and hair styling products.<sup>51</sup> They are also used in shampoos, conditioners, deodorants, antiperspirants and sunscreens.<sup>52</sup> Phthalate exposure from cosmetic or beauty products can happen by inhalation or absorption through the skin.<sup>53</sup>

One phthalate in particular, dibutyl phthalate (DBP), is a common constituent of nail polish, where it helps reduce brittleness and cracking, and enhances consistency.<sup>54</sup>

According to the Skin Deep website 89 products contain DBP, including nail polish shades by Orly, Maybelline, Wet’n’Wild, Covergirl and Avon; nail treatments by Nailtechniques, Barielle, Nutra Nail, Black Radiance; and polishes and treatments by Lippmann Collection and Custom Nails.

Phthalates have an oily texture, so when they are used in lotions, they make skin feel softer.<sup>55</sup> Phthalates also lubricate all the other ingredients in a formula and help lotions penetrate the skin.<sup>56</sup> The Skin Deep website shows that diethyl phthalate (DEHP) was found in three Chanel face moisturizers and a perfume by Royal Secret. Phthalates have also been found in beauty products manufactured by Avon, Chanel, Maybelline, Covergirl and Wet’n’Wild.<sup>57</sup> In fact, according to the American Chemistry Council, phthalates are essential to perfume and scented products because phthalates help fragrances last longer.

Phthalates are not solely used in cosmetics—thus creating difficulties for the personal care industry, regulators, investors or the medical profession in accurately assessing cosmetic-related exposures. According to the Phthalate Information Center,<sup>58</sup> in addition to cosmetics, phthalates are also known as plasticizers, because they make PVC and other plastics stronger and more flexible. Therefore, phthalates are often found in soft vinyl items like shower curtains and toys, as well as in insecticides, adhesives, flooring, and plastic plumbing pipes. Phthalates’ oily texture also makes them a valuable industrial lubricant. About a billion pounds of phthalates are manufactured around the world every year.

Phthalates first came to consumers’ attention in 1998 when it was discovered that vinyl toys contained diisononyl phthalate (DINP).<sup>59</sup> The soft plastic toys—including teething and other toys made specifically to be put in the mouth—were exposing kids to very high levels of DINP because it was released from the toys when children mouthed them.<sup>60</sup> Despite the evidence of this exposure route, the U.S. Consumer Product Safety Commission



continues to allow the use of DINP in children's toys in the U.S.<sup>61</sup> In contrast, the same information almost immediately prompted bans on similar products in Europe, and in 2005 the European Parliament permanently banned six phthalates from use in children's toys. Under the E.U.'s action, three phthalates (DINP, DIDP, and DNOP) are banned in toys that are intended to be sucked or chewed by children under three, and three more (DEHP, DBP, and BBP) are banned in all children's products sold in the European Union.<sup>62</sup>

## Why are People Concerned About Phthalates?

Recent scientific studies indicate that phthalates are suspected hormone disruptors, which can seriously harm human reproductive health. In male animals, phthalate exposure before or after birth has been linked to damaged, shrunken, undescended, or atrophied testicles, reduced sperm production and other damaging effects to the reproductive system. A June, 2005, study published by Environmental Health Perspectives was the first one to support the hypothesis that exposure to environmental levels of phthalates in the womb can negatively affect human male reproductive development.<sup>64</sup> The study found that higher levels of phthalate exposure correlated to reduced anogenital distance (the distance between the anus and the scrotum). This condition is considered predictive of other genital abnormalities and factors of reduced virility, such as smaller scrotum and penis, and an increased likelihood of undescended testicles. Another study, also looking at human males, associated exposure to some phthalates with decreased sperm counts and damaged sperm.<sup>65</sup> A few years ago, a study in Puerto Rico found phthalates at six times the concentration in girls between six months and eight years old with premature breast development as compared to girls without any breast development.<sup>66</sup>



In 2000, a U.S. Center for Disease Control and Prevention study found one phthalate in the urine of all 289 people tested, and women of childbearing age had the highest levels of all phthalates combined.<sup>67</sup> Researchers theorized that the higher level of phthalate exposure in this population might be attributed to the fact that this population uses more cosmetics and personal care products than any other group.<sup>68</sup> Industry critics such as the Environmental Working Group argue that further study seems to confirm this hypothesis. For example, in 2005, the Department of Health and Human Services released results from the Third National Report on Human Exposure to Environmental Chemicals, which tested thousands of people for presence of phthalates.<sup>69</sup> According to the Environmental Working Group, the data revealed that the "majority of [phthalate] exposure comes from personal care products and not things like plastics."<sup>70</sup>

Cosmetics industry trade publications reveal the sharp difference in how the U.S and E.U. are responding to the phthalate evidence. For example, even as Cosmetics International reports that the director of the American Chemistry Council's Phthalate Esters Panel hailed a Cosmetic Industry Review Panel report that found "a tremendous margin of safety" in relation to widespread phthalate usage in cosmetics, the E.U. was already in the process of banning various phthalates due to health concerns.<sup>71</sup> As of 2006, the E.U. has banned over 1,000 chemicals from use in cosmetics sold in the E.U., including



## Nanotechnologies

Nanomaterials first began to be applied in consumer products such as cosmetics and sunscreens about ten years ago.<sup>73</sup> Nanotechnology involves the manipulation of particles on the scale of molecules and atoms. Because nanoparticles exist at a scale smaller than that of human cells, nanoparticles exhibit different chemical and biological properties than the same materials in larger size.

This allows the possibility of remarkable and useful qualities to be added to materials - new elements of color, penetration, solubility, transparency, and chemical reactivity, for instance. However, this differential behavior also raises unique and heretofore unexplored health and regulatory questions.

## Serious Evidence of Risk and Health Concerns

Scientists and consumers have expressed concern that nanoparticles may penetrate past human skin cells into the bloodstream and the lymphatic system, and damage many forms of tissue. However, since the use of nanoparticles in cosmetics and personal care products is regulated in the U.S. under the FDA's relatively lax cosmetics regimen, these health impacts have received little official scrutiny, even though cosmetics products are applied to the skin, and therefore easily enter the body. Despite the lack of close FDA regulation, substantial evidence exists of real health impact concerns:

### Emerging Nanotechnology Applications in Personal Care Products

While questions about the health impact of nanotechnology are certainly broader than the cosmetics industry, their usage in cosmetics and personal care products represents a source of concern to investors since cosmetics companies are already deploying nanotechnology in various applications. Examples of new nanotechnology applications in personal care products include:<sup>74</sup>

- PENETRATION ENHANCER - Encapsulating or suspending key ingredients in so-called nanospheres or nanoemulsions, increases their penetration into the skin:
- L'OREAL (which ranks No. 6 in nanotechnology patent holders in the U.S.)<sup>75</sup> has used polymer nanocapsules to deliver active ingredients, e.g. retinol or Vitamin A, into the deeper layers of skin. In 1998 the company unveiled Plentitude Revitalift, an anti-wrinkle cream using nanoparticles.
- FREEZE 24/7, a new anti-wrinkle skincare line is planning to incorporate nanotechnology in future products.
- LA PRAIRIE's product, the Dollars 500 Skin Caviar Intensive Ampoule Treatment, claims to minimize the look of uneven skin pigmentation, lines and wrinkles in six weeks using nanotechnology. La Prairie's vice president of retail marketing and training, Holly Genovese, says the nanoemulsions in the product "optimize the delivery of functional ingredients into the skin and allow these materials to get to the site of action quicker".
- PROCTER & GAMBLE's OLAY brand was designed with nano-emulsion technology in 2005.<sup>76</sup>
- Other companies using nanotech in their skin products as of 2005 include: MARY KAY and CLINIQUE from LAUDER; NEUTROGENA, from JOHNSON & JOHNSON; AVON; and the ESTEE LAUDER brand.<sup>77</sup>
- HAIR PRODUCTS – using nanoemulsions to encapsulate active ingredients and carry them deeper into hair shafts.
- PUREOLOGY began experimenting with nanoemulsions in 2000 when the company's founder set out to create a product line especially developed for color treated hair.
- SUNSCREENS – the zinc and titanium in sunscreens are "micronized", making them transparent, less greasy, less smelly and more absorbable into the skin.
- DDF planned more nanotech-enhanced anti-aging products as of 2004.
- COLORESCIENCE markets a product named Sunforgettable, a powder which contains titanium dioxide nanoparticles.
- Paris-based CAUDALIE launched its Vinosun Anti-Aging Suncare, a sunscreen and anti-aging treatment that relies on "nanomized" UV filters and antioxidants, in the US in 2003.





- **PASSAGE INTO THE BODY.** Preliminary experiments in animals have found nanoparticles capable of moving into and damaging the lungs, brain and other organs.<sup>78</sup> Scientists are unsure whether particles penetrate diseased or broken skin, such as acne lesions, or whether they enter the body through mucous membranes of the eyes or nose. Particles of 70 nanometers can be inhaled into the deepest recesses of the lungs, where titanium dioxide has proved to be toxic in numerous studies. Inhalation of nanoparticles would be a particular concern for aerosols, such as foot sprays and moisturizing facial mists now on the market that use nanotechnology.
- **ENTRY INTO CELLS.** The smallest nanoparticles can pass through cell walls and damage DNA. In animals they have moved from the nostrils along the olfactory nerve and across the blood-brain barrier - the last line of defense against brain damage.
- **CANCER CONCERNS.** Inhaled nanoparticles can cause lung tumors in rats. Some lab tests showed nanoscale metal oxides in sunscreens to spark changes within skin cells that could lead to cancer.
- **LONGEVITY OF PARTICLES.** Some of the particles are virtually indestructible, much like asbestos fibers that cause lung disease.

Nano-sized carbon fullerenes (“buckyballs”) are currently in some facial moisturizers and creams. Professor Robert F. Curl Jr., winner of the 1996 Nobel Prize in Chemistry for the discovery of fullerenes, stated that he would avoid the use of personal care products containing fullerenes until the risks were better understood: “I would take the conservative path of avoiding using such cosmetics while withholding judgment on the actual merits or demerits of their use.”<sup>79</sup>

In addition to potential human health impact, some scientists have also expressed concern about potential environmental toxicity. Nanoparticles have been shown to bind to soil and sediment particles. In addition, Rice University’s Center for Biological and Environmental Nanotechnology has pointed out the tendency of nanoparticles to bind to contaminating substances already pervasive in the environment, e.g. cadmium and petrochemicals. Thus, it is possible that nanoparticles may be a potential mechanism for long-range and widespread transport of pollutants in groundwater.<sup>80</sup>

Reflecting these concerns, many scientists are recommending a precautionary approach while more data is collected. In July 2004, a joint study by Britain’s Royal Society and Royal Academy of Engineering strongly warned that nanoparticles behave in unpredictable ways and in some cases appear surprisingly toxic, and recommended to the British government that nanoparticle-laden cosmetics, including those containing zinc oxide and iron oxide, be kept off market until proven safe for use on skin. It also recommended clearly labeling products made with nanomaterials to enable consumers to make informed decisions about using these products.<sup>81</sup>

In 2004, the FDA and the National Institute for Environmental Health Sciences, in cooperation with the National Toxicology Program, began a two-year study investigating the skin absorption and phototoxicity of titanium dioxide and zinc oxide preparations used in sunscreens and cosmetics. The NTP is also investigating the toxicity and skin uptake of fullerenes.<sup>82</sup>

The FDA held a meeting in October 2006 to discuss the new kinds of nanotechnology materials being developed for use in products it regulates, including drugs, foods, cosmetics and medical devices.<sup>83</sup>

In September 2006, the Organisation for Economic Cooperation and Development (OECD) established a Working Party on Manufactured Nanomaterials to “address the health and environmental safety implications of manufactured nanomaterials”.<sup>84</sup>

## FDA Petitioned

Even as cosmetics and personal care companies are investing in the use of nanotechnology, consumer pressure may drive regulatory changes. In May 2006, a coalition of consumer and environmental groups, including Greenpeace, Friends of the Earth, and the International Center for Technology Assessment petitioned the FDA to regulate nanoparticle - containing sunscreens and recall some products. The report was issued at the same time as a Friends of the Earth report identifying at least 116 personal products with nanoingredients currently on the market.



diethylhexyl phthalate (DEHP) and dibutyl phthalate (DBP), both of which are used in cosmetics.<sup>72</sup>

“Scientific bodies are beginning to develop an understanding of the serious risks that may be associated with nanomaterials,” said Joseph Mendelson, legal director of the Washington-based International Center for Technology Assessment, which spearheaded the FDA filing. “Every day, consumers are being asked to be a test market for some of those risks.”<sup>85</sup>

## Preservatives

Preservatives<sup>97</sup> are widely used in cosmetics and other personal care products to extend shelf life by preventing bacterial contamination.<sup>98</sup> Contamination is a problem because many ingredients used in cosmetics are a very good medium for growth of microorganisms, which are attracted to the water, oil, peptides, and carbohydrates that are found in most cosmetic products. Contamination often occurs through regular use—for example, after an applicator touches human skin it is returned to the container, transferring any microorganisms back to the product.<sup>99</sup>

### That Elusive “Fragrance”

The generic term “fragrance” is a very common ingredient in personal care products, appearing in almost 6,500 unique products.<sup>86</sup> DEP, DEHP and other phthalates are among the most common fragrance ingredients in perfumes and cosmetics.<sup>87</sup>

However, phthalates are rarely listed on product ingredient labels when they are part of a fragrance formula. A 2002 investigation by the Environmental Working Group, Coming Clean and Health Care Without Harm identified phthalates in almost 75% of 72 common personal care products tested by an independent lab.<sup>88</sup> Yet none of these 72 products listed phthalates as an ingredient on the label, because fragrance formulas are protected as proprietary information and are therefore exempt from disclosure under federal labeling requirements.<sup>76</sup> Ironically, even products labeled “fragrance-free” may, in fact, contain fragrance. According to FDA Consumer, the term “fragrance-free” implies that a cosmetic product has no detectable odor, but it may contain fragrance used to mask a bad-smelling raw material. However, if chemicals are used to mask odors, the manufacturer is required to indicate “fragrance” in the listing of ingredients on the label.<sup>90</sup>

Most fragrances are synthesized, primarily from petroleum products.<sup>91</sup> About 3,000 chemicals are used in the fragrance industry, but very few of these have been tested for their

cancer-causing potential or other health effects. A single fragrance usually contains multiple chemicals – as few as 10 chemicals or as many as several hundred. Many chemicals used in the fragrance industry are known irritants. For example, the commonly used citrus scent, d-limonene, can cause skin and eye irritation, difficulty breathing and bronchial irritation.<sup>92</sup> It can also react with ozone in indoor air to form tiny particles that aggravate lung and heart disease.<sup>93</sup>

Like the cosmetic and personal care product industry, the fragrance industry is largely self-regulated. The International Fragrance Association (IFRA), which receives funding from the fragrance industry, provides guidelines for its members on the use and safety of fragrances.<sup>94</sup> IFRA guidelines are based on research conducted by the Research Institute for Fragrance Materials (RIFM), another industry-funded organization that tests raw materials used in the fragrance industry.<sup>95</sup>

While the FDA has jurisdiction over perfumes and other fragrance ingredients, no pre-market testing of products or ingredients is required, despite the fact that nearly 25 percent of respondents questioned in a 1994 FDA study responded “yes” to having suffered an allergic reaction to personal care products. If the FDA decides to ban a product for health or safety reasons, the burden of proof lies with the FDA to show that the product is harmful.<sup>96</sup>



Although it is important to keep cosmetics preserved, there are many dangers of using certain preservatives. For example, formaldehyde—a preservative used to preserve medical specimens in a variety of settings from high school biology to autopsies—may also be found in shampoos, mouthwash and nail hardeners.<sup>100</sup> However, in addition to its preservative qualities, formaldehyde often causes inhalant fume reactions and is reasonably anticipated to be a human carcinogen, according to the U.S. National Toxicology Program.<sup>101</sup>

The most widely used group of chemicals used for preservation is parabens. Most skin care products use one or more of the paraben type of preservatives, which are claimed to be the safest and least-irritating for the skin.<sup>102</sup> Although parabens are effective preservatives, a link has been found between some parabens and breast tumors.<sup>103</sup> Animal and laboratory studies have shown that parabens can mimic the actions of the hormone estrogen, which is known to fuel breast cancer.<sup>104</sup> Some studies raised particular concerns regarding underarm products, such as antiperspirant and deodorants, which are applied topically and absorbed through the skin. A study conducted by Philippa D. Darbre, an expert in oncology, found that four of twenty breast tumors had total paraben concentration more than twice the average level.<sup>105</sup>

The Cosmetic, Toiletry and Fragrance Association defends the use and safety of parabens. They assert that, “the FDA regulates cosmetics to assure their safety” and that there is “no evidence of harm from the use of deodorants or antiperspirants.”<sup>106</sup>

## Impurities

Harmful impurities may contaminate many cosmetic products.<sup>107</sup> Impurities can result from an ingredient being contaminated with an unwanted substance or result from two ingredients interacting to create a toxic by-product, or impurity. An Environmental Working Group analysis shows that at least 146 cosmetic ingredients may contain harmful impurities which may be linked to cancer, neurotoxicity, and reproductive problems.<sup>108</sup> The EWG study also identified three common impurities

in personal care products that are linked to mammary tumors in animal studies—ethylene oxide, poly-aromatic hydrocarbons (PAHs), and 1,3-butadiene. At least one of these ingredients is found in one quarter of the personal care products on the market.

Two common impurities are 1,4 dioxane and nitrosamines.<sup>109</sup> The EPA considers these chemicals probable human carcinogens.<sup>110</sup> The FDA has urged cosmetics companies to voluntarily remove any ingredient that may combine with others to form nitrosamines, like N-nitrosoethanolamine.<sup>111</sup> In fact, it may be possible to remove harmful impurities without materially increasing costs. For example, the Environmental Working Group claims that 1,4 dioxane can be removed by means of “vacuum stripping at the end of the polymerization process without an unreasonable increase in material cost.”<sup>112</sup> But the performance of this process is strictly voluntary.

Because impurities are not regulated by federal law, product purity may become a business decision. According to critics such as the Environmental Working Group, companies weigh the costs of creating pure products with the potential liability of selling products that may contain carcinogenic impurities. It is possible that management may perceive carcinogenic liabilities to be low, since cancer usually has a long latency period and a doctor can rarely trace the disease back to its source.

The Cosmetic Ingredient Review Panel does not test final products, only various constituent ingredients, so its process does not ensure that that impurities will not be present in products.<sup>113</sup>

To be sure, the FDA has taken some action against use of impurities in cosmetics—recently banning the use of cow brains and other cattle parts that could carry mad cow disease for use in cosmetics and dietary supplements.<sup>114</sup> However, even the ban against potential mad cow tissue is incomplete—the use of tallow, a processed fat made from cattle, will still be allowed in cosmetics provided it carries less than 0.15% impurities.

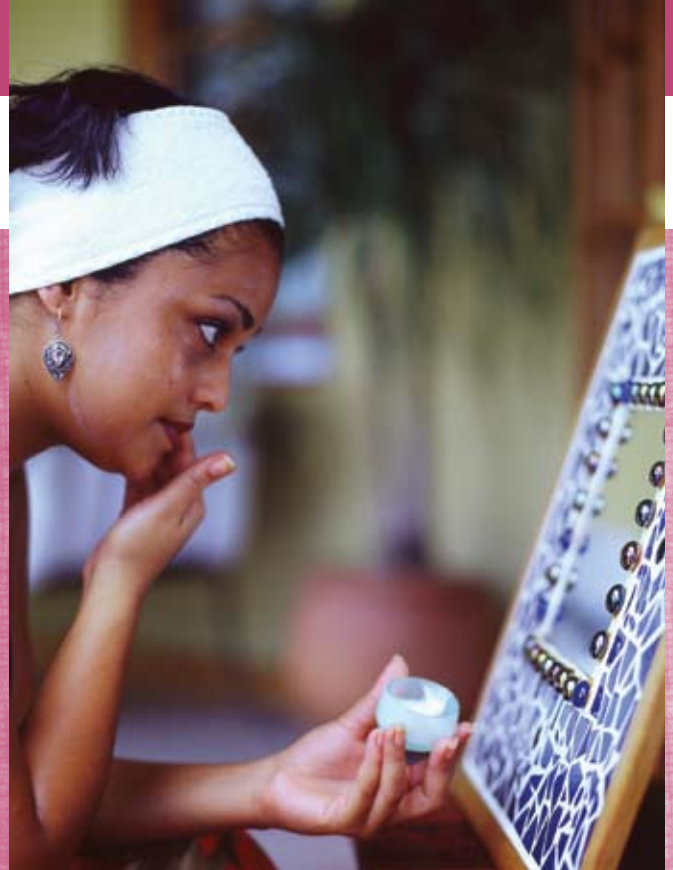


## Growing Public Concern Leads to Market Risks

One way to quantify the growing level of public concern about health problems that may be associated with cosmetics and personal care products is the sharp increase in media coverage of cosmetics and health safety. Major news outlets such as the New York Times, Los Angeles Times, and National Public Radio all ran stories in the past year with headlines like *Should You Worry About the Chemicals in Your Makeup?*,<sup>115</sup> *Labels Can Hide the Presence of Phthalates*,<sup>116</sup> *Legislature Targets Toxic Risks in Products*<sup>117</sup> and *Europe's Rules Forcing U.S. Firms to Clean Up*.<sup>118</sup> In fact, over the last four years, there has been a tremendous growth in media coverage of cosmetics-related health issues. A Lexis-Nexis search of major newspapers and wire stories for coverage of phthalates in cosmetics during the period 1995–2005 showed an increase from a single news story during the five year period prior to 2000 to 165 stories in the four years since 2001. And the trend is increasing—there were 75 news and wire stories about phthalates in cosmetics in 2005 alone.<sup>119</sup>

Additionally, several NGOs have published reports on the prevalence of chemicals in everyday consumer products,<sup>120</sup> including cosmetics and personal care products, and the increasing “body burden” of these chemicals.<sup>121</sup> These reports are also cited in mainstream media as evidence of controversy around the issue.<sup>122</sup> In addition to the news coverage, health advocacy organizations such as the Campaign for Safe Cosmetics have sponsored full page ads in the New York Times and USA Today.<sup>123</sup> The Campaign for Safe Cosmetics also sponsored a billboard at the 2005 Cannes Film Festival, which was mentioned in press coverage of the festival by *Women's Wear Daily*, a widely-read industry journal.

Media reports often draw attention to the fact that the cosmetics industry is under-regulated, forecasting the potential for increased levels of regulatory scrutiny—a direction likely to increase research, testing, monitoring and compliance costs. One measure of the behind the scenes, but clearly growing industry concerns are the increased levels at which cosmetic and chemical industry publications are also covering product safety issues,



primarily in terms of new regulations in the European Union and the impact on U.S. manufacturers.<sup>124</sup>

In summary, the growing media coverage about the health impacts of various ingredients used in cosmetics and other personal care products can impact profitability, market share and competitive position in two ways:

- Negative consumer perceptions may reduce sales.
- Heightened public concern may create pressure for increased regulation.

Both of these impacts have the potential to affect the bottom line. So far, industry has responded to most of this bad press by discounting the science and dismissing the results, characterizing organizations that raise questions as radical fear mongers, and maintaining the position that all cosmetic ingredients are safe as used.<sup>125</sup> However, trying to shoot the messenger—while an understandable reaction—does not kill the underlying facts that are driving the negative stories. By only reacting defensively to published criticism, the U.S. cosmetics and personal care industry may simply be playing the ostrich—closing their eyes and ears while exposing their assets.



## Out of Step With the Global Markets' Movement Towards Sustainability?

The controversy swirling around the safety of cosmetics and personal care products, and the related implications for value and competitive posture in an extremely brand-sensitive consumer product industry is playing out against a backdrop of growing international recognition of the long-term financial value of environmental sustainability. For example, Goldman Sachs, Citigroup, JPMorgan Chase and Bank of America have all recently published comprehensive environmental policies. Evidence abounds of this sea change in how both corporate leaders and investors view sustainability. For example, a recently released report from the Economist Intelligence Unit of The Economist, states that 84% of corporate leaders now view firm engagement in socially responsible business practices as contributing to company financial performance.<sup>126</sup> Over the last decade, more than 100 published academic, business and NGO studies collectively point to a robust role for environmental performance as a corporate value driver.<sup>127</sup> These studies lend credence to the idea that sustainability issues matter to corporate—and therefore—investment management performance. But the most telling evidence may be the actions and statements of major business leaders themselves. Already, more than 600 companies internationally are measuring and reporting environmental performance indicators through the Global Reporting Initiative (with many more in the process of developing GRI reports).

Regardless of whether one views it as an important driver of the sustainability groundswell, or one of its early fruits, there is no denying the role of the Precautionary Principle as a bellwether for investors and corporate management alike in the cosmetics and personal care products industry. The Precautionary Principle is essentially a “better safe than sorry” approach to uncertainty about health impacts that embodies expanded screening and testing and restricting or banning existing chemicals even when scientific data are suggestive but not conclusive about effects. In practice, a precautionary approach requires extensive pre-market testing to ensure that chemicals and

products are safe before going into widespread use. The precautionary concept is embodied in the European Union’s new cosmetics directive which restricts the use of more than 1,000 carcinogenic, mutagenic or toxic cosmetics ingredients marketed or sold in the 25 member European Union—potentially excluding any company which refuses to reformulate from a market of 457 million people.

The growing sway of the precautionary concept exerts twin influences on the U.S. cosmetics and personal care industry. First, any U.S. companies that want to compete in lucrative European markets must integrate the precautionary principle into their manufacturing, product and supply chains. Second, just as U.S. companies are starting to follow European leads in responding to climate change, it is reasonable to project the possibility that the precautionary approach towards protecting human health from toxic exposures may also gain increased traction in the U.S.<sup>128</sup> Either way, a cosmetics company that explores less toxic reformulations, embraces a greater degree of pre-market testing for health impacts, and expands its positioning in the use of natural ingredients stands to gain.



# Recommendations

## General Recommendations for the Cosmetics and Personal Care Industry

Since a general trend towards some degree of greater regulation and restriction of ingredients seems inevitable, companies that integrate safer ingredients may stand to gain competitive advantage, maintaining and possibly increasing their brand trust, market opportunities and value. Companies that enhance their competitive positioning in this way will also likely avoid potential liability by removing ingredients that may be found to be toxic in the future, as well as position themselves to avoid future regulatory costs. They may also maintain a competitive edge in global markets.

The primary step that most cosmetics and personal care companies can take is to make formula changes as soon as possible to reduce or eliminate unhealthy or questionable ingredients. In addition to avoiding liability, regulatory and marketplace risks, a company that acts quickly regarding consumer concerns may gain positive consumer perception as a more forward looking and health conscious company. Consumers want the companies whose products they buy to care about their health; in fact, several cosmetics companies support health charities or causes, such as the Avon Walk for Breast Cancer. Even the appearance of a cavalier attitude towards health could seriously hurt a company's bottom line. Given the importance of image in the industry and the fact that there are few things less associated with beauty and fashion than illness, any implication of unhealthiness could taint a company's reputation and its products—leading to consumer distrust and undercutting hard-earned brand loyalty.

Reformulation happens frequently in the cosmetics industry, and a reformulated product is often marketed under the “new and improved” banner. Consistent with this existing marketing philosophy, there may be considerable advertising buzz in being able to trumpet “now with the safest ingredients available” or “phthalate-free formula.” In a climate of rising consumer concern, such

health-oriented marketing could draw positive attention to a company, including free advertising in the form of news coverage. The companies that lead the way in this area would receive the most media attention.

When a company reformulates its products before any negative health effects are firmly proven, it avoids or at least significantly reduces liability associated with torts and other lawsuits which may occur after the weight of such evidence grows. This could potentially save a company millions of dollars, given the high volume of sales and number of customers. In contrast, product liability suits may damage brand value, which translates into lost sales.





## Specific Recommendations for Investors

### 1) Compare and Benchmark Cosmetics and Personal Care Companies on their Performance on These Issues

Benchmarking of company performance and demand for better disclosure should help investors to anticipate the coming changes in regulation and markets that may affect the financial performance of firms within this sector. Investors should take advantage of new benchmarking tools for investors and senior corporate executives, such as the one created in 2005 by Richard Liroff of the Investor Environmental Health Network. The tool is designed for use by senior corporate management teams—EHS (Environment, Health, and Safety) and sustainability vice-presidents, strategy and corporate planning staff, business unit heads, and even boards of directors—to assess the overall toxicity of their product chains. Investors and investment analysts can use this tool to screen investments, assess “best in class” environmental performance and manage portfolio risk.<sup>129</sup>

### 2) Demand Greater Disclosure

Investors should recognize that the current culture of the cosmetics and personal care industry is not oriented towards transparency and disclosure. Therefore, they should act to protect their investment by demanding more disclosure around opportunities for reformulation and launching natural ingredient product lines to compete in the growing natural lifestyles market.

Investors should also closely monitor the growing wave of shareholder resolutions on the specific topic of cosmetics, as well as the general field of product toxicity and safety. These resolutions provide investors with a valuable opportunity to push their portfolio companies away from expensive liabilities and toward realizing long-term financial value. For the 2006 proxy season, 11 resolutions had been filed raising environmental health risk and product health safety issues.<sup>130</sup> As of January 2007, for the 2007 proxy season at least 13 resolutions had been filed

raising environmental health and product health and safety issues. Several specifically target issues related to cosmetics and personal care products, including those at CVS. They generally seek reports on options for reducing the use of toxic chemicals in consumer products and industrial processes. In doing so, they draw attention to the financial liabilities that toxic chemicals present to these companies, as well as to opportunities for developing alternatives.

### 3) Monitor the Emerging Scientific Data

Investors should monitor the mounting adverse health data related to some very common cosmetic ingredients—especially the emerging data around phthalates. Arguments by the cosmetics and personal care industry that the publication of the data is being driven by NGO special interest advocates miss the point. The real issue is not the messenger’s motivation, which in many cases may clearly be rooted in health-based, rather than financial concerns. The key question for investors: Is the message accurate? The weight of the evidence, combined with the sweeping response to the same information by E.U. regulators, suggest that the health concerns are very real. Since adverse health impacts could lead to significant financial liabilities as well as market and regulatory changes, investors need to pay attention.

### 4) Anticipate Tighter Regulation and Changing Markets

The regulatory changes underway in the E.U. and Canada, and new legislation in California, potentially create pressure for tighter U.S. oversight regarding the cosmetics and personal care industry. The California Safe Cosmetics Act of 2005 includes provisions that require reporting of all cosmetic ingredients “identified as causing cancer or reproductive toxicity,” and also requires the submission of health effects data and the investigation of safety substantiation claims.<sup>131</sup> Another development in California is the proposed listing of four phthalates, including Di-n-butyl phthalate (DBP), which is commonly used in cosmetics, on the state’s Proposition 65 list of chemicals known to the state to cause cancer or



reproductive toxicity.<sup>132</sup> A number of other chemicals used in cosmetics already appear on the list. Although California is only one of 50 states, as the 6th largest economy in the world California has market clout; these California laws have the potential to affect the entire cosmetics industry.

Companies have a choice of investing now in orienting their product lines towards safer or “greener” products, or waiting until regulators force their hand. Investors need to consider which strategy is more likely to drive long-term corporate value—proactive and nimble movement ahead of the regulatory curve, or a retreat into the bunker of denial of global trends?



Investors should monitor the FDA for signs that the agency’s long-dormant approach to regulating cosmetics and personal care products may become more robust. In December 2004, in response to a petition from the Environmental Working Group, the agency announced

its list of 2005 Program Priorities. Although the FDA officially dismissed the petition, these new priorities include the consideration of a voluntary recall, court-ordered injunction or seizure for cosmetics containing ingredients that have not been proven safe through scientific testing that do not bear appropriate warnings,<sup>133</sup> and also include clarification of the requirements for adequate substantiation of product safety.<sup>134</sup> Consistent with its new priority, the FDA wrote a letter to the Cosmetic, Toiletry and Fragrance Association, alerting them of the agency’s intent to “consider taking compliance action, where appropriate, regarding cosmetic products that contain ingredients that we determine have not been shown to be safe ... but that are not currently labeled with the warning statement ... required [by law],” which is stated above.<sup>135</sup> The FDA also informed the CTFA that it would be developing guidelines for industry to use when making the determination that the warning statement was necessary.<sup>136</sup> FDA has also been studying phthalates and the agency found that in 48 cosmetic products tested, most contained at least one phthalate.<sup>137</sup>

Finally, it cannot be emphasized enough that the cosmetics and personal care market is uniquely vulnerable to destabilizing consumer concerns as health issues quickly make their way into the awareness of the buying public. From the new nanotechnologies, to pervasive materials such as phthalates, the internet and other communications technologies are making it possible for information on risks to reach consumers and affect their buying patterns on an accelerated basis. Maintaining customer trust and loyalty through precautionary approaches to chemicals of concern may prove a better way of growing and stabilizing a customer base than continuing to bet that consumers will remain unaware of the concerns emerging among public health experts.



# Appendix A

## Summary of Common Cosmetic Ingredients with Identified Health Impacts<sup>138</sup>

INGREDIENT	WHERE USED/HOW	HEALTH IMPACTS OR IMPLICATIONS
Phthalates	Found in many personal care products, such as lotions and moisturizers (used to soften skin); gives nail polish flexibility; they also help dissolve ingredients	Potential hormone disruptor that causes birth defects and deformities in reproductive organs of lab animals; associated with similar reproductive effects in one human study; may be carcinogenic
Preservatives <sup>139</sup>	Used in almost every personal care product and cosmetic to extend shelf life and prevent bacteria growth	Preservatives are the second leading cause of allergic reactions and irritations caused by cosmetics
<i>Parabens , (methyl-, ethyl-, butyl-, isobutyl-, propyl-)</i>	Most common preservative; found in shampoos, foundations, facial masks, hair-grooming aids, nail creams, and permanent wave products	Potential hormone disruptors; have been linked to breast tumors
<i>Formaldehyde</i>	Preservative in shampoos, mouthwash and nail hardeners	“Reasonably anticipated to be a human carcinogen,” according to the National Toxicology Program’s Ninth Report on Carcinogens; classified as probable human carcinogen by EPA
<i>DMDM hydantoin Diazolidinyl urea Imidazolidinyl urea Quaternium-15</i>	Ingredients that contain formaldehyde	See formaldehyde, above. Also, imidazolidinyl urea can trigger contact dermatitis in some people
<i>Bronopol (2- bromo 2nitropropane-1, 3-diol)</i>	Preservative	It can contribute to formation of nitrosamines (see impurities, below); can break down to create formaldehyde (see above)
<i>Mercury</i>	Used as a preservative in eye area cosmetics, restricted to very small amount	Potent neurotoxin that accumulates in the body
Coal-tar <sup>140</sup>	Used in hair dyes, most often in darker shades	Linked to bladder cancer, and non-Hodgkin’s lymphoma
Fragrances	Fragrances are also used in almost all personal care products and cosmetics; fragrance formulas are “secret” and can be made up of a few, or hundreds, of chemicals; phthalates are commonly used in fragrance formulas	Fragrances are the number one leading cause of allergic reactions and irritations caused by cosmetics; see also phthalates
Diethanolamine (DEA); derivative includes triethanolamine (TEA)	Sudsing agent, or surfactant, in shampoos	Suspected human carcinogen; can be contaminated with nitrosamines (see below), which likelihood is increased if product also contains bronopol
Impurities	Impurities can result from an ingredient being contaminated with an unwanted substance or as a result of two ingredients interacting; can be found in a wide range of personal care products or cosmetics	
<i>1,4 dioxane</i>	Can contaminate other ingredients in cosmetics and personal care products	1,4 dioxane is toxic to the liver, according to National Cancer Institute studies
<i>Nitrosamines</i>	Compounds that result from the interaction between two other ingredients in a product or they can contaminate an ingredient.	Cause cancer in lab animals
Phenylenediamine (PPD)	Found in hair dyes	Linked with skin irritation, respiratory problems and cancer; banned in Europe
Polyethylene and polyethelene glycol (PEG ingredients)	Found in hair straighteners, antiperspirants, baby-care products	These ingredients are safe by themselves, but can be contaminated with 1,4 dioxane
Polysorbate compounds 60 and 80	Found in lotions and creams	Can be contaminated with 1,4 dioxane
Polyvinylpyrrolidone	Found in hair-care products	Contributed to tumor development in rats; it can stay in the body for months
Talc	Ingredient in baby and body powders, feminine powders, eye shadow	Use of feminine powders in the genital area has been associated with increased risk of ovarian cancer; also a respiratory irritant
Toluene	Still found in at least two brands of nail polishes and treatments	Linked to cancer and reproductive toxicity; respiratory irritant. International Fragrance Association lists it as an unsafe ingredient.





# Appendix B

## Selected Companies

### AVON

Avon Products, which advertises itself as “the company for women”, is a global beauty company with over \$8 billion in annual revenue.<sup>141</sup> It markets to women in over 100 countries, mainly through over 5,000,000 independent Avon sales representatives. Its product line includes cosmetics, fragrances, skin care products, fashion jewelry and apparel.

Avon’s global product safety standard states that it complies fully with legal requirements in all the countries where it does business, underpinned by a “global product safety standard” requiring the substantiation of the safety of every product prior to sale. The company states, “We will remove any ingredient from our cosmetic products should new evidence emerge that would no longer support its safe use.”<sup>142</sup>

In response to investor initiatives, Avon announced just prior to its 2004 annual meeting that it planned to remove dibutyl phthalate (DBP) from products in Europe to comply with EU requirements and would study the feasibility of reformulating all products without DBP. In response to a shareholder resolution filed for its 2005 meeting requesting that the company reformulate all its products globally to meet the requirements of the EU cosmetics directive, the company stated that except for DBP, the company does not use any of the EU Cosmetics Directive’s most worrisome substances anywhere else in the world. The company further insisted that it imposes its own restrictions on the use of particular ingredients since it’s able to respond more quickly to new safety data than are regulatory agencies. The company also detailed its efforts to remove DBP from markets outside Europe and reported elimination of DBP in nail product brands in the United States and progress elsewhere in the world.<sup>143</sup> Avon’s reliance on contract manufacturers throughout the world using different product formulas may make it harder for Avon to have one global product formulation as compared to cosmetics companies doing all their own manufacturing to one global standard.

Investors filed yet another resolution on cosmetics safety for Avon’s 2006 shareholder meeting. Reflecting continuing wariness of Avon’s assurances about its cosmetics safety practices, the resolution asked Avon to prepare a report “analyzing and articulating Avon’s policy on using safer substitutes for chemicals that are known or suspected carcinogens, mutagens, and reproductive toxicants, as well as chemicals that affect the endocrine system, accumulate in the body, or persist in the environment.” In a statement supporting the resolution, the investors contended that “by disclosing how it systematically reviews suspect chemicals and encourages safer substitutes, Avon can enhance its reputation among its health- and safety-conscious customers.” The 2006 resolution received support from 4% of the shares voted.

Avon remains particularly vulnerable to concerns about the safety of its cosmetics ingredients, because of the company’s substantial investment in breast cancer cause-related marketing. In September 2005, The Campaign for Safe Cosmetics ran a full page advertisement in USA Today, just prior to a cosmetics industry expo, urging Avon (and also L’Oreal and Procter & Gamble) to join the approximately 200 (now 500) cosmetics companies that have signed the Compact for Safe Cosmetics, a pledge to remove dangerous and untested chemicals from their products.<sup>144</sup>





## THE BODY SHOP

The Body Shop International PLC has, through the years, carefully cultivated a reputation for reliance on natural ingredients and for sensitivity to social and environmental concerns. The company has more than 2,000 stores world-wide. The Wall Street Journal, in a recent report on L’Oreal SA’s proposed \$1.1 billion bid to acquire The Body Shop, noted that the company “gained popularity during the 1980s when it became one of the first to sell skin-care products made of natural ingredients in recycled packaging.” However, according to the Journal, “It has lost cachet more recently ... as other stores—especially in the U.S.—have introduced earth-friendly products.”<sup>145</sup>

The Body Shop published a detailed list of policies on chemicals in its 2004 Environmental Report. According to the report, they apply the precautionary principle if there are “legitimate concerns about the safety credentials of materials.”<sup>146</sup> There are currently a number of chemicals used in cosmetics and toiletries that are of concern due to their reported and perceived negative impacts on human health and the environment. The following are chemicals for which The Body Shop has taken action to eliminate or restrict their use in its products: Alkylphenols and derivatives, Brominated Flame Retardants, Organic Tin Compounds, PVC (Polyvinylchloride) and Triclosan. The following chemicals are currently used in products, but prioritized for phase-out or limited use: Bisphenol A, Musks, Phthalates. The following chemicals are being used until better alternatives become available: Aluminium Chlorohydrate, Parabens, PEGs (Polyethylene Glycol derivatives), Propylene Glycol, Silicones, Sodium Laureth Sulfate (SLES), and Triethanolamine.<sup>147</sup>

The Body Shop has signed the Compact for Safe Cosmetics and perhaps is the largest cosmetics company employing a proactive precautionary approach to managing their use of synthetic chemicals in cosmetics and product packaging.

## CVS

CVS Corporation is the second largest retail pharmacy chain in the United States, behind Walgreens. According to CVS’ 10-K statement for 2004, it is number one or number two in prescription market share in 73% of the markets in which its pharmacies operate.<sup>148</sup> CVS’ strategy is to “provide a broad assortment of quality merchandise at competitive prices using a retail format that emphasizes service, innovation and convenience (easy-to-access, clean, well-lit and well stocked).”<sup>149</sup> In 2004, CVS filled approximately 14% of prescriptions in the U.S. retail pharmacy market and its sales totaled \$30.6 billion.

In addition to selling popular brand name cosmetics from major cosmetics companies, CVS sells a range of beauty and skin care preparations and accessories under the CVS label. Such products listed on its website include, e.g., cleansing skin cream, cleansing and make-up remover towelettes, nail polish remover, and hair regrowth treatment.

For CVS’s 2006 shareholder meeting, investors submitted a resolution requesting that the company prepare a report on the feasibility of CVS a) reformulating its private label products to meet the standards of the EU Cosmetics Directive, b) complying with a broader evaluation of cosmetics ingredients as requested by the Campaign for Safe Cosmetics in its Safe Cosmetics Pledge, and c) encouraging or requiring manufacturers or distributors of other cosmetics products sold in CVS to ensure their products comply with the same reformulation and other actions that the company is taking.

CVS aggressively opposed the shareholder resolution in a filing at the Securities and Exchange Commission, but was unsuccessful in its challenge. The resolution was supported by 8.7% of the shares voted.

## ESTEE LAUDER

According to its fiscal year 2005 10-K report to the SEC, Estee Lauder Companies Inc. is a “pioneer in the cosmetics industry” and a “leader in the industry due to the global recognition of our brand names, our leadership in product innovation, our strong market position in key geographic markets and the consistently high quality of our products.”<sup>150</sup> Net sales in 2005 exceeded \$6.3 billion. In 2005, skin care products accounted for approximately 37% of net sales, makeup products accounted for approximately 38%, fragrance products accounted for approximately 20%, and hair care products accounted for approximately 4%.

Estee Lauder’s corporate website aggressively pushes back against environmental health activists’ concerns about the safety of cosmetics. Estee Lauder’s approach stands in sharp contrast to The Body Shop’s explicit embrace of precaution and listing on its web site of chemicals it has phased out or plans to. Estee Lauder asserts that “statements that cosmetics contain ingredients that may be harmful to your health are both inaccurate and misleading” and that all its own products “meet or exceed stringent global regulatory requirements.”<sup>151</sup> The company states that they are in compliance with EU regulations banning two phthalates, and in meetings with investors concerned about cosmetics safety, have indicated they comply globally with the EU regulations because they manufacture 95% of their own products to one safety standard.

The company has declined to sign the Compact for Safe Cosmetics, contending that this would give “activist groups—who often do not rely on sound, peer-reviewed science in their reports—the authority to define ‘safe’.”<sup>152</sup> It states that “The Estée Lauder Companies has been producing safe products for more than 55 years. All of our formulas are continuously reviewed and measured against the most current peer-reviewed and scientifically sound body of knowledge.” The company further observes that it “does not need a compact to ensure that consumers are receiving the safest, most up-to-date products based on the latest peer review, scientific knowledge.”

Moreover, when the potential link of some Estee Lauder product ingredients to breast cancer is discussed, the company asserts “To suggest that we would knowingly

sell products that cause any serious health problems is offensive. Moreover, to date there have been no scientifically sound peer reviewed studies which indicate any harm when cosmetics are used as intended.”

With other cosmetics companies, most notably Procter & Gamble, and the cosmetics industry trade association, Estee Lauder lobbied against enactment of California’s new safer cosmetics law. The company states that “bills that have been opposed by the Cosmetics Industry have not been carefully drafted and would not make good law.”

## PROCTER & GAMBLE

The Procter & Gamble Company’s 10-K for fiscal year 2005 states that the company’s business is focused on “providing branded products of superior quality and value to improve the lives of the world’s consumers.”<sup>153</sup> The Company is organized into three Global Business Units: P&G Beauty (hair care, skin care, feminine care, cosmetics, fragrances and personal cleansing) P&G Family Health; and P&G Household Care. One key customer is Wal-Mart, representing approximately 16% of 2005 total revenue. No other customer represents more than 10% of net sales.



Sales for 2005 were \$56.8 billion. In 2005, P&G Beauty accounted for 34% of sales, Family Health for 34%, and Household Care for 32%.<sup>153</sup>

On its website, [www.psbeautyscience.com](http://www.psbeautyscience.com), Procter & Gamble goes to great lengths to defend the safety of its products, chemical ingredients, and products. The company devotes two pages to phthalate safety. P&G eliminated DBP (dibutyl phthalate) from all of its products globally, to comply with new European regulations, but “not because of safety concerns.” They continue to use DEP and DMP “at trace levels” in some products.<sup>155</sup> P&G praises the CIR as an “independent” scientific panel, and discusses why the company has not signed the Safe Cosmetics Compact.<sup>156</sup> The company maintains that parabens are safe, and speaks out against the European REACH legislation that may restrict the use of some substances in P&G products sold in Europe.<sup>157</sup> The company has argued against hazardous-based chemicals management under proposed REACH legislation, preferring an approach based on risk assessment, and lobbied against California’s safe cosmetics legislation.

## WALGREENS

Walgreen Company’s 2005 annual report is titled “We Take Care of People.”<sup>158</sup> Walgreens operates nearly 5,000 retail stores in 45 states and Puerto Rico. With 2005 sales of \$42 billion, Walgreens fills 15 percent of the prescriptions in the United States. In recent years prescriptions have constituted over 60 percent of the company’s sales, nonprescription drugs approximately 11 percent, and general merchandise between 25 and 30 percent.

In July 2006, investors in Walgreens filed a shareholder resolution requesting that the company publish a report characterizing the extent to which Walgreens’ private label cosmetics and personal care products contain suspected carcinogens, mutagens, reproductive toxicants and other chemicals of concern, and describing options for new Walgreens policies that would proactively seek safer alternatives for these chemicals within the company’s private label cosmetics lines.

## WAL-MART

Wal-Mart Stores Inc.’s 10-K report for fiscal year 2005 states that the company “provides a broad assortment of quality merchandise and services at everyday low prices (EDLP) while fostering a culture that rewards and embraces mutual respect, integrity and diversity.”<sup>159</sup> Wal-Mart strives to keep prices low and to create customer expectations that they will remain low. Wal-Mart is the world’s largest retailer; sales for 2005 were approximately \$300 billion. In 2005, the Wal-Mart Stores division accounted for 67.3% of sales, Sam’s Club 13%, and International 19.7%. Health and beauty aids made up 7% of sales in Discount Stores and Supercenters in 2005.<sup>160</sup> Wal-Mart sells hair spray, skin creams, shampoos, nail polish remover, and other beauty products under its private label “Equate” and “Simply Basic” brands.

In October 2005, Wal-Mart’s CEO established three core environmental goals for Wal-Mart—to be supplied 100 percent by renewable energy, to create zero waste, and to sell products that sustain our resources and environment.<sup>161</sup> As part of this multi-pronged initiative, Wal-Mart’s website speaks of “Smart Products”—“we see real promise in our ability to bring cleaner, more environmentally preferable products within the reach of everyday people around the world.”<sup>162</sup> Wal-Mart states, “We are working on sustainable packaging, cotton, wood, fish, product electronics *and the elimination of substances of concern* in all merchandise.” (emphasis added) Wal-Mart indicates it is encouraging smart choices by “developing incentive plans and common-sense scorecards for our merchandise buyers that encourage innovation and more environmentally preferable products.”

Assuming Wal-Mart includes cosmetics and beauty products within its Smart Products initiative, this could bode well for elimination of worrisome chemicals from cosmetics in supply chains well beyond Wal-Mart’s, because Wal-Mart’s size gives it substantial influence over its suppliers’ product formulation decisions.

# Appendix C

## Suggestions for More Information

### Campaign for Safe Cosmetics

The Campaign for Safe Cosmetics is a coalition of public health, educational, labor, religious, women's, environmental and consumer groups with the stated goal of protecting the health of consumers and workers by requiring the health and beauty industry to phase out the use of chemicals linked to cancer, birth defects and other health problems and replace them with safer alternatives. The Campaign for Safe Cosmetics primary initiative has been the Compact for Safe Cosmetics, an industry pledge promising to phase out hazardous materials in cosmetics and personal care products within three years, and to meet the new tough European Union cosmetics ingredients standards worldwide. To date, over 400 manufacturers, distributors and retailers have signed the pledge.

[www.safecosmetics.org](http://www.safecosmetics.org)

### Cosmetic Ingredient Review Panel

The toxicity of product ingredients is scrutinized almost exclusively by a self policing industry safety committee, the Cosmetic Ingredient Review (CIR) panel. The CIR Expert Panel voting members include scientists who have been publicly nominated by consumer, scientific, and medical government agencies and industry. Based on voluntary testing, the panel classifies ingredients as either safe (as currently used or with qualifications); unsafe, or insufficient information for a determination. Testing by the CIR is voluntary; so many ingredients in cosmetics products are not tested at all. The CIR and the review process are funded by the Cosmetic, Toiletry and Fragrance Association. The industry uses the CIR's findings, but is not bound specifically to follow them.

[www.cir-safety.org](http://www.cir-safety.org)

### Cosmetic, Toiletries and Fragrance Association

The Cosmetic, Toiletries and Fragrance Association (CTFA) is an industry trade association that provides a complete range of services that support the personal care products industry's needs and interests in the scientific, legal, regulatory, legislative, and international fields. CTFA strives to ensure that the personal care products industry has the freedom to pursue creative product development and compete in a fair and responsible marketplace. CTFA represents the industry's interests at the local, state, national, and international levels, promoting voluntary industry self-regulation and reasonable governmental requirements that support the health and safety of consumers. CTFA has approximately 600 member companies. Active members are manufacturers and distributors of finished products. Associate members are suppliers of ingredients, raw materials, packaging, and other services used in the production and marketing of finished products, as well as consumer and trade publications.

[www.ctfa.org](http://www.ctfa.org)

### Environmental Working Group

The Environmental Working Group (EWG), a public interest research and advocacy organization based in Washington DC, has released a series of detailed and influential reports exploring the safety of ingredients in personal care products. EWG has published a series of influential studies on the health effects of various ingredients in cosmetics and personal care products, including "Not Too Pretty," "Pretty Nasty," and "Skin Deep," as well as a searchable database with safety ratings for over 14,000 cosmetic and personal care products.

[www.ewg.org](http://www.ewg.org)





## International Fragrance Association

The International Fragrance Association (IFRA) was founded in 1973 to represent “the collective interests of the fragrance industry worldwide.” This organization seeks to preserve the self-regulatory practices of the fragrance industry. It explains that “self regulation is second to none in working towards an objective of global, worldwide rules.” IFRA also believes that “the adaptation of industry rules worldwide to new scientific findings can occur more quickly through self-regulation than a change in legislation in different countries on different continents.” Registration with this association seems to be voluntary as well. The main thrust of IFRA’s activities includes developing, communicating and implementing a Code of Practice for the fragrance industry. This code provides voluntary standards of operating practice and product safety, and has been utilized by companies since 1973.

[www.ifraorg.org](http://www.ifraorg.org)



## Additional Resources

National Toxicology Program—Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR, 2003a). NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Butyl Benzyl Phthalate (BBP). NIH Publication No. 03-4487.

National Toxicology Program—Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR, 2003b). NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Di-n-Butyl Phthalate (DBP). NIH Publication No. 03-4486.

National Toxicology Program—Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR, 2003c). NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Di-n-Hexyl Phthalate (DnHP). NIH Publication No. 03-4489.

National Toxicology Program—Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR, 2003d). NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Di-Isodecyl Phthalate (DIDP). NIH Publication No. 03-4485.

Erickson, Kim, *Drop Dead Gorgeous: Protecting Yourself from the Hidden Dangers of Cosmetics*, (Contemporary Books, 2002)

U.S. FDA/CFSAN: FDA Authority over Cosmetics, May 2005, <http://www.cfsan.fda.gov/~dms/cos-206.html>

## Endnotes

- <sup>1</sup> Environmental Working Group, “Skin Deep” 2005. See [www.ewg.org](http://www.ewg.org).
- <sup>2</sup> *Wall Street Journal*, October 4, 2005, Page A1.
- <sup>3</sup> Dawar & Pillutla, “The Impact of Product-Harm Crisis on Brand Equity: The Moderating Role of Consumer Expectations,” *Journal of Marketing Research*, May, 2000
- <sup>4</sup> Alex Berenson, *San Francisco Chronicle*, December 13, 2005
- <sup>5</sup> Press release issued by New York State Controller’s Office, *Hevesi Sues Merck & Co. Inc. Over New York Pension Fund Losses Related to Vioxx*, November 30, 2004.
- <sup>6</sup> *Id.* Statement by New York State Controller Alan Hevesi.
- <sup>7</sup> Swan, Shanna H., et al., “Decrease in Anogenital Distance among Male Infants with Prenatal Phthalate Exposure,” *Environmental Health Perspectives*, Vol. 113, No. 8, p. 1056 (August 2005); available at: <http://ehp.niehs.nih.gov/members/2005/8100/8100.pdf> and <http://ehp.niehs.nih.gov/docs/2005/8100/abstract.html>.
- <sup>8</sup> Pamela Lundquist, Lexis Nexis search, December 2005.
- <sup>9</sup> See [www.ewg.org](http://www.ewg.org) for detailed studies, including “Not Too Pretty,” “Pretty Nasty,” and “Skin Deep,” as well as a searchable database with safety ratings for over 14,000 cosmetic and personal care products.
- <sup>10</sup> See [www.safecosmetics.org](http://www.safecosmetics.org) for extensive information about the Campaign for Safe Cosmetics and the Compact for Safe Cosmetics. (See also 76/768/EEC Article 14)
- <sup>11</sup> Vesela Veleva, “New EU Rules for the Cosmetics Industry: What do They Mean for U.S. Companies and Stakeholders?” *Corporate Environmental Strategy*, Vol. 12 Issue 3, p. 142 (2005)
- <sup>12</sup> *Id.*, p. 141.
- <sup>13</sup> *Id.*
- <sup>14</sup> See Appendix B of this report for a summary of the several shareholder resolutions introduced at, e.g., Avon Products and CVS Corporation.
- <sup>15</sup> *Supra*, Note 10, p 144.
- <sup>16</sup> *Id.* P 144
- <sup>17</sup> Health Canada, List of Prohibited and Restricted Cosmetic Ingredients (The Cosmetic Ingredient “Hotlist”) May, 2005, available at: [www.hc-sc.gc.ca/cosmetics](http://www.hc-sc.gc.ca/cosmetics).
- <sup>18</sup> *Id.*
- <sup>19</sup> CFSAN webpage “Ingredients Prohibited and Restricted by FDA Regulations,” [www.cfsan.fda.gov/~dms/cos-210.html](http://www.cfsan.fda.gov/~dms/cos-210.html)
- <sup>20</sup> Cosmetic Ingredient Review, [http://www.cir-safety.org/staff\\_files/unsafe.pdf](http://www.cir-safety.org/staff_files/unsafe.pdf)
- <sup>21</sup> Health Canada, “Sections 10 and 30 of the *Cosmetic Regulations* of the *Food and Drugs Act* require that a Cosmetic Notification Form be submitted to Health Canada prior to importation of a cosmetic, or within 10 days of first sale if the product is manufactured in Canada.” available at: [www.hc-sc.gc.ca/cosmetics](http://www.hc-sc.gc.ca/cosmetics).



- <sup>22</sup> Section 30 (2) (d): the notification form must include “a list of the cosmetic’s ingredients and, for each ingredient, its exact concentration or the concentration range that includes its concentration, as set out in the table to this section.”
- <sup>23</sup> Health Canada, Regulations Amending the Cosmetic Regulations, Published in *Canada Gazette*, Part II, Vol. 138, No. 24, December 1, 2004.
- <sup>24</sup> Simon Pitman, “US Cosmetics Industry Reacts to BSE,” *Cosmetics Design*, October 27, 2004; available at: <http://cosmeticsdesign.com/productnews/nws.asp?id=55679>.
- <sup>25</sup> *Supra*, note 21.
- <sup>26</sup> SB 484. [http://www.leginfo.ca.gov/pub/bill/sen/sb\\_0451-0500/sb\\_484\\_bill\\_20051007\\_chaptered.html](http://www.leginfo.ca.gov/pub/bill/sen/sb_0451-0500/sb_484_bill_20051007_chaptered.html)
- <sup>27</sup> The statistics in this paragraph are taken from Kline and Company “Cosmetics and Toiletries USA 2004”, available at <http://www.klinegroup.com/brochures/cia4c/brochure.pdf> (accessed July 17, 2006).
- <sup>28</sup> CVS 2003 Annual Report, p. 3.
- <sup>29</sup> “Natural Personal Care Products Clean Up the Market With 51.9% Growth,” Organic Consumers Association, August 24, 2004, reporting the findings of a report entitled “The US Market for Natural Personal Care Products,” available at [MarketResearch.com](http://MarketResearch.com).
- <sup>30</sup> “US Market for Natural Care Products,” *TNS Media Intelligence/CMR*, as reported in *Cosmetics Design.com*, May 10, 2005.
- <sup>31</sup> [www.cosmeticsdesign-europe](http://www.cosmeticsdesign-europe) May 10, 2005
- <sup>32</sup> 21 USCA § 321(i)
- <sup>33</sup> 21 USCA § 321 (g)(1)
- <sup>34</sup> <http://www.cfsan.fda.gov/~dms/cos-206.html>
- <sup>35</sup> See generally, Bryan A. Liang and Kurt M. Hartman, It’s Only Skin Deep: FDA Regulation of Skin Care Cosmetics Claims, 8 *Cornell J of Law and Pub Policy*, 249 Winter 1999 (describing several cases where the court determined that a product was really a drug based on the manufacturer’s marketing and labeling claims); and Laura A. Heymann, The Cosmetic/Drug Dilemma: FDA Regulation of Alpha-Hydroxy Acids, and p. 355-56] *Food and Drug Law J* (1997).
- <sup>36</sup> *Id.*
- <sup>37</sup> *Id.*
- <sup>38</sup> 21 C.F.R. 740.10 (a).
- <sup>39</sup> See Environmental Working Group (EWG), Citizen Petition to Cease Unlawful Sale of Misbranded & Adulterated Cosmetics. Petition from EWG to the Food and Drug Administration. June 14, 2004. Available online at [www.ewg.org/petition/petition.php](http://www.ewg.org/petition/petition.php).
- <sup>40</sup> WEST-FDADM § 3854 (Part 7. “Business Regulation”- Chapter 41B. “Food and Drug Administration”) (21 U.S.C. 361, section 601)
- <sup>41</sup> 42 AMJUR POF 2d 97
- <sup>42</sup> The Environmental Working Group, [www.ewg.org](http://www.ewg.org). The Environmental Working Group is the author of several studies examining potential health threats from cosmetics, including, “Pretty Nasty,” and “Beauty Secrets.” Cosmetics Industry Review panel: <http://www.cir-safety.org>
- <sup>43</sup> <http://www.cir-safety.org/findings.shtml>
- <sup>44</sup> The CIR’s practices are described at <http://www.cir-safety.org/info.shtml>.
- <sup>45</sup> See <http://www.ewg.org/reports/skindeep2/newsrelease.php>.
- <sup>46</sup> See <http://www.ewg.org/reports/skindeep/petition/petition.php>
- <sup>47</sup> 51 Food & Drug L.J. 243
- <sup>48</sup> WEST-FDADM § 3854: FDA Authority Over Cosmetics, 3/2005: <http://www.cfsan.fda.gov/~dms/cos-206.html>
- <sup>49</sup> FDA Authority Over Cosmetics, 3/2005: <http://www.cfsan.fda.gov/~dms/cos-206.html>
- <sup>50</sup> [www.ewg.org](http://www.ewg.org).



- <sup>51</sup> U.S. FDA Office of Cosmetics and Colors Fact Sheet, “Phthalates and Cosmetic Products,” April 19, 2001; available at: <http://www.cfsan.fda.gov/~dms/cos-phth.html>.
- <sup>52</sup> *Id.*
- <sup>53</sup> CHEC website: phthalates chemical profile at [http://www.chechnet.org/healthhouse/chemicals/chemicals-detail2.asp?Main\\_ID=281](http://www.chechnet.org/healthhouse/chemicals/chemicals-detail2.asp?Main_ID=281) See also: Jane Houlihan, Richard Wiles. “Beauty Secrets: Does a Common Chemical in Nail Polish Pose Risks to Human Health?” (Environmental Working Group, November 2000), p.22-24; See also Phthalate Information Center, [http://www.phthalates.org/resources/health\\_absorption.asp](http://www.phthalates.org/resources/health_absorption.asp).
- <sup>54</sup> Beauty Secrets, p. 23, Table 6. See also FDA Factsheet, “Phthalates and Cosmetics,” *infra*.
- <sup>55</sup> Skin Deep database, Phthalate summary; available at: <http://www.ewg.org/reports/skindeep2/findings/index.php?content=phthalates#begin>.
- <sup>56</sup> *Id.*
- <sup>57</sup> *Id.*
- <sup>58</sup> Phthalate Information Center, [www.phthalates.org](http://www.phthalates.org).
- <sup>59</sup> See CHEC article at [http://www.chechnet.org/healthhouse/education/articles-detail.asp?Main\\_ID=559](http://www.chechnet.org/healthhouse/education/articles-detail.asp?Main_ID=559) (March 31, 2003).
- <sup>60</sup> Consumer Product Safety Review, Vol. 8, No. 1, pp. 3-5, Summer 2003; available at: [http://www.cpsc.gov/cpscpub/pubs/cspr.html/cpsr\\_nws30.pdf](http://www.cpsc.gov/cpscpub/pubs/cspr.html/cpsr_nws30.pdf)
- <sup>61</sup> *Id.*
- <sup>62</sup> Castle, Stephen, “EU Bans Hazardous Chemicals Used in Toys” *The Independent (London)* September 25, 2004, and, Wall Street Journal, “WORLD WATCH: Briefly,” July 6, 2005, *Wednesday, Section A; Page 13, Column 2*.
- <sup>63</sup> Except as otherwise noted, health effects data in this paragraph was supplied by the U.S. Center for Disease Control, *Third National Report on Human Exposure to Environmental Chemicals*, July, 2005, p. 253; available at: <http://www.cdc.gov/exposurereport/>.
- <sup>64</sup> *Supra*. Note 6.
- <sup>65</sup> *Supra* Note 61, p. 253.
- <sup>66</sup> Colón I., et al. “Identification of Phthalate Esters in the Serum of Young Puerto Rican Girls with Premature Breast Development,” *Environmental Health Perspectives*, Vol. 108, No. 9 (September 2000). <http://ehpnet1.niehs.nih.gov/docs/2000/108p895-900colon/abstract.html>
- <sup>67</sup> Blount, et. al. “Levels of Seven Urinary Phthalate Metabolites in a Human Reference Population,” *Environmental Health Perspectives*, Vol. 108, No. 10, October 2000; available at: <http://ehpnet1.niehs.nih.gov/docs/2000/108p972-982blount/blount-full.html>.
- <sup>68</sup> *Id.*
- <sup>69</sup> States News Service, July 21, 2005, “Telebriefing Transcript: Third National Report on Human Exposure to Environmental Chemicals.”
- <sup>70</sup> David Loos and Lauren Morello “Chemicals: CDC Toxics Report Reveals Need for Expanded Testing, *Enviros Say*,” As reported in *Greenwire*, July 22, 2005 (Direct quote is from Tim Cropp, EWG chief scientist);
- <sup>71</sup> US & Europe at odds on phthalates issue, *Cosmetics International*, December 15, 2002
- <sup>72</sup> *Supra*, Note 11, p. 142.
- <sup>73</sup> Linda A. Johnson, “Nano-based products starting to have consumer impact”, Associated Press, November 8, 2004.
- <sup>74</sup> Tatiana Boncompagni, “The appliance of nanoscience: Cosmetic chemists and engineers are working hard to enhance product effectiveness”, *Financial Times of London*, October 16, 2004
- <sup>75</sup> “Nano, Nano, On The Wall... L’Oréal and others are betting big on products with microparticles”, *Business Week*, December 12, 2005.
- <sup>76</sup> Claudia H. Deutsch, “Cosmetics break the skin barrier”, *The New York Times*, January 8, 2005.
- <sup>77</sup> Claudia H. Deutsch, “Cosmetics break the skin barrier”, *The New York Times*, January 8, 2005.







<sup>78</sup> Rick Weiss, "Nanotechnology Precaution Is Urged: Minuscule Particles in Cosmetics May Pose Health Risk, British Scientists Say", *The Washington Post*, July 29, 2004

<sup>79</sup> Press Release issued by Friends of the Earth Australia and Friends of the Earth U.S., *Nanomaterials, sunscreens and cosmetics: small materials, big risks*, May 2006.

<sup>80</sup> Press Release issued by Friends of the Earth Australia and Friends of the Earth U.S., *Nanomaterials, sunscreens and cosmetics: small materials, big risks*, May 2006.

<sup>81</sup> Rick Weiss, "Nanotechnology Precaution Is Urged: Minuscule Particles in Cosmetics May Pose Health Risk, British Scientists Say", *The Washington Post*, July 29, 2004.

<sup>82</sup> Press Release issued by Friends of the Earth Australia and Friends of the Earth U.S., *Nanomaterials, sunscreens and cosmetics: small materials, big risks*, May 2006.

<sup>83</sup> Barnaby J. Feder, "Engineering Food at Level Of Molecules", *The New York Times*, October 10, 2006.

<sup>84</sup> Organisation for Economic Cooperation and Development, "Current Developments/Activities on the Safety of Manufactured Nanomaterials", London, October 26-27, 2006. Available at: [http://appli.oecd.org/olis/2006doc.nsf/linkto/env-jm-mono\(2006\)35](http://appli.oecd.org/olis/2006doc.nsf/linkto/env-jm-mono(2006)35)

<sup>85</sup> Rick Weiss, "FDA Asked to Better Regulate Nanotechnology", *The Washington Post*, May 17, 2006.

<sup>86</sup> For a large volume of detailed information about the prevalence of phthalates in cosmetics, see the Skin Deep searchable database, maintained by the Environmental Working Group, for the ingredient listing "fragrance" at: <http://www.ewg.org/reports/skindeep2/report.php?type=INGREDIENT&id=1004655>

<sup>87</sup> Phthalate Information Center, [www.phthalates.org](http://www.phthalates.org). See also, U.S. FDA Office of Cosmetics and Colors Fact Sheet, "Phthalates and Cosmetic Products," April 19, 2001; available at: <http://www.cfsan.fda.gov/~dms/cos-phth.html>.

<sup>88</sup> EWG, "Not Too Pretty" (2002)

<sup>89</sup> 21 C.F.R. 720.4 (d) (1), (4), (5). <http://www.cfsan.fda.gov/~lrd/cfr720.html>. See also, Fisher, Brandy E. "Scents and Sensitivity," *Environmental Health Perspectives*, Vol. 106, December 12, 1998 ;, <http://www.ehponline.org/docs/1998/106-12/focus.html>

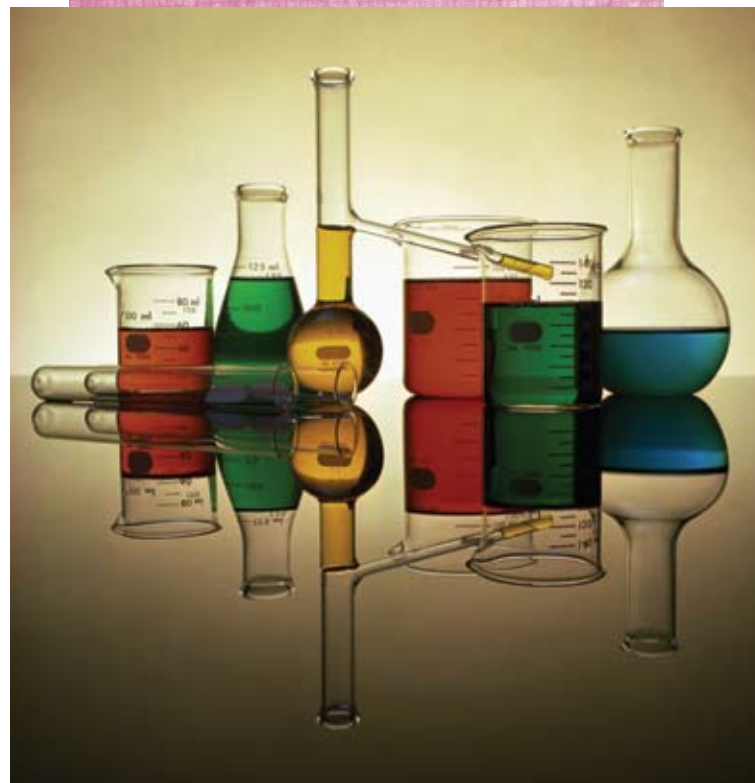
<sup>90</sup> Lewis, Carol. "Clearing Up Cosmetic Confusion," FDA Consumer, updated August 2000: [www.cfsan.fda.gov/~dms/fdconfus.html](http://www.cfsan.fda.gov/~dms/fdconfus.html)

<sup>91</sup> This discussion is informed by the following sources: Fisher, Brandy E. "Scents and Sensitivity," *Environmental Health Perspectives*, Vol. 106, December 12, 1998; Franz, Damon and Holly Prall. "Smelling Good But Feeling Bad," *E Magazine*, Jan/Feb 2000: [www.emagazine.com/january-february\\_2000/0100gl-health.html](http://www.emagazine.com/january-february_2000/0100gl-health.html), Clearing the Air: Asthma and Indoor Air Exposures (2000), National Institute of Medicine, p. 247. <http://books.nap.edu/books/0309064961/html/9.html>

- <sup>92</sup> CHEC, d-limonene Chemical Profile; available at: [http://www.checnet.org/healthhouse/chemicals/chemicals-detail2.asp?Main\\_ID=276](http://www.checnet.org/healthhouse/chemicals/chemicals-detail2.asp?Main_ID=276).
- <sup>93</sup> Raloff, Janet. "Lemon-scented products spawn pollutants," *Science News*, Vol. 158, No. 24, Dec. 9, 2000, p. 375. <http://www.sciencenews.org/20001209/fob7.asp>
- <sup>94</sup> IFRA website, [www.ifraorg.org/AboutIfra.asp](http://www.ifraorg.org/AboutIfra.asp).
- <sup>95</sup> IFRA website and phone interview w/ Glen Roberts, a spokesperson for the RIFM. December 4, 2002, 202/293-5800, and Fisher, supra Note 60. <http://www.ritm.org>
- <sup>96</sup> FDA, Office of Cosmetics and Colors "Cosmetic Labeling Manual," October 1991: [www.cfsan.fda.gov/~dms/cos-lab1.html](http://www.cfsan.fda.gov/~dms/cos-lab1.html) (definition of cosmetics); see also "Prohibited Ingredients and Related Safety Issues," supra, and Lewis, Carol. "Clearing Up Cosmetic Confusion," FDA Consumer, updated August 2000: [www.cfsan.fda.gov/~dms/fdconfus.html](http://www.cfsan.fda.gov/~dms/fdconfus.html)
- <sup>97</sup> The authors are indebted to Erin Neale for the following discussion.
- <sup>98</sup> "The Hazards of Cosmetics" by Carol Barczac. *AEHA Quarterly* Summer 1995
- <sup>99</sup> U.S. FDA, "Cosmetic Safety: More Complex Than at First Blush," *FDA Consumer*, May 1995; available at: <http://www.cfsan.fda.gov/~dms/cos-safe.html>
- <sup>100</sup> [www.ewg.org](http://www.ewg.org)
- <sup>101</sup> [www.environmentalhealth.ca/summer95cosmetic.html](http://www.environmentalhealth.ca/summer95cosmetic.html), U.S. National Toxicology Program's 11<sup>th</sup> Report on Cancer, available at: <http://ntp-server.niehs.nih.gov/ntp/roc/eleventh/profiles/so89form.pdf>
- <sup>102</sup> American Academy of Dermatology Press Release, "Sensitive About Your Skin?" 8/2/02; available at: <http://www.aad.org/public/News/NewsReleases/Press+Release+Archives/General+Skin+Care/Sensitive.htm>
- <sup>103</sup> Gardner, Amanda, "Chemicals Common in Cosmetics Found in Breast Tumors," *HealthDay Reporter*, January 12, 2004, <http://www.danielchapterone.com/danielchapterone/pdfs/chemicals.pdf>
- <sup>104</sup> Gardner, Amanda, "Chemicals Common in Cosmetics Found in Breast Tumors," *HealthDay Reporter*, January 12, 2004 <http://www.danielchapterone.com/danielchapterone/pdfs/chemicals.pdf>
- <sup>105</sup> *Id.* See also Routledge, E.J., J. Parker, et al., "Some Alkyl Hydroxyl Benzoate Preservatives (Parabens) are Estrogenic," *Toxicology and Applied Pharmacology*, 153: 12-19; Pedersen, K.L., et al., "The Preservatives Ethyl-, Propyl-, and Butylparaben are Oestrogenic in an In-Vivo Fish Assay," *Pharmacology Toxicology*, March 2000.
- <sup>106</sup> *Id.* See also <http://www3.interscience.wiley.com/cgi-bin/abstract/108566653/ABSTRACT> Also, please note: CTFA Response to Darbre research at: [http://www.ctfa.org/Content/ContentGroups/News/Latest\\_Statements/CTFA\\_Response\\_Statement\\_-\\_Safety\\_of\\_Parabens.htm](http://www.ctfa.org/Content/ContentGroups/News/Latest_Statements/CTFA_Response_Statement_-_Safety_of_Parabens.htm).
- <sup>107</sup> See <http://www.cfsan.fda.gov/~dms/cos-hdb3.html>. See also [www.ewg.org](http://www.ewg.org) ("Skin Deep" section).



- <sup>108</sup> [http://www.ewg.org/reports/skindeep/petition/petition.php?print\\_version=1](http://www.ewg.org/reports/skindeep/petition/petition.php?print_version=1)
- <sup>109</sup> See <http://www.epa.gov/ttn/atw/hlthef/dioxane.html>
- <sup>110</sup> Id. See also <http://lpi.oregonstate.edu/f-woo/nitrosamine.html>.
- <sup>111</sup> See <http://www.cfsan.fda.gov/~dms/qa-cos25.html>; <http://www.cfsan.fda.gov/~dms/cos-210.html> (in section “Contaminants Raise Concerns”)
- <sup>112</sup> Id. [www.ewg.org/reports/skindeep](http://www.ewg.org/reports/skindeep)
- <sup>113</sup> Id.
- <sup>114</sup> [www.rense.com/general54/dfa.htm](http://www.rense.com/general54/dfa.htm)
- <sup>115</sup> Lauren Naversen Geraghty, *New York Times*, July 7, 2005.
- <sup>116</sup> Natasha Singer, *New York Times*, July 7, 2005.
- <sup>117</sup> Jordan Rau, *Los Angeles Times* May 30, 2005 (The article discussed SB 484 (Sen. Carol Migden, D-San Francisco), the bill requires cosmetic manufacturers to report to the California state Department of Health Services all ingredients in their products that may cause cancer or birth defects.
- <sup>118</sup> Marla Cone, *Los Angeles Times* May 16, 2005.
- <sup>119</sup> Pamela Lundquist, personal research, December 2005
- <sup>120</sup> [www.ewg.org](http://www.ewg.org), [www.chemicalbodyburden.org](http://www.chemicalbodyburden.org), [www.calbbc.org](http://www.calbbc.org), [www.watoxics.org](http://www.watoxics.org)
- <sup>121</sup> Id.
- <sup>122</sup> EWG Report “Body Burden: The Pollution in Newborns”, cited in Rita Savard, “‘Natural’ Doesn’t Always Mean ‘Safe,’ *Lowell Sun*, March 6, 2006.
- <sup>123</sup> *USA Today* ad, September 27, 2005, (Highlights an untested, unregulated cosmetics industry), *New York Times* advertisement, 2002, (After the release of “Not Too Pretty,” report on the presence of phthalates, chemicals linked to birth defects, in products marketed to women.)



- <sup>124</sup> See, e.g.: Kara Sissell, “Personal Care Products Face Increased Regulatory Scrutiny,” *Chemical Week*, May 11, 2005; Glenn Hess, “US FDA Asked to Release Data on Phthalates in Cosmetics,” *Chemical News & Intelligence*, April 7, 2005; “US & Europe at Odds on Phthalates Issue,” *Cosmetics International*, December 15, 2002.
- <sup>125</sup> See Phthalate Information Center [www.phthalates.org](http://www.phthalates.org).
- <sup>126</sup> *Business Ethics*, Spring 2005, page 35.





Repetto & D. Austin, "Coming Clean: Corporate Disclosure of Financially Significant Environmental Risks" (World Resources Institute 2000); Repetto, "Silence is Golden, Leaden and Copper" (2004); Michelle Chan-Fishel, "After Enron: How Accounting and SEC Reform Can Promote Corporate Accountability While Restoring Public Confidence," 32 ELR 10965, August 2002; Goodman & Little, "The Gap in GAAP: An Examination of Environmental Accounting Loopholes" (2003); and Lewis & Little, "Fooling Investors and Fooling Themselves: How Aggressive Corporate Accounting and Asset Management Techniques Can Lead to Environmental Accounting Fraud" (2004).

<sup>128</sup> In fact, this already seems to be occurring. For example, the California Safe Cosmetics Act of 2005 (SB 484) requires reporting of any identified carcinogenic properties or reproductive toxicity in cosmetics ingredients, as well as health effects data.

<sup>129</sup> A condensed version of the tool is available under the title "Benchmarking Corporate Management of Safer Chemicals in Consumer Products—A Tool for Investors and Senior Executives," in *Corporate Environmental Strategy: International Journal for Sustainable Business*, Vol. 12, Issue 1 (January/February 2005). Accessible at [www.rosefdn.org/cesreport.pdf](http://www.rosefdn.org/cesreport.pdf). For a full version, see: <http://www.rosefdn.org/liroffpr.html>

<sup>130</sup> In addition to the resolutions mentioned in the text, a resolution filed at Johnson & Johnson was withdrawn when the company agreed to meet with stakeholders to discuss cosmetics safety issues.

<sup>131</sup> See the California Safe Cosmetics Act of 2005 (SB 484) [http://www.leginfo.ca.gov/pub/bill/sen/sb\\_0451-0500/sb\\_484\\_bill\\_20051007\\_history.html](http://www.leginfo.ca.gov/pub/bill/sen/sb_0451-0500/sb_484_bill_20051007_history.html). and the Safe Drinking Water and Toxic Enforcement Act of 1986, commonly known as Prop 65.

<sup>132</sup> See California's Safe Drinking Water and Toxic Enforcement Act of 1986, commonly known as Prop 65.

<sup>133</sup> CFSAN 2005 Program Priorities, 3.2.3a., available at <http://www.cfsan.fda.gov/~dms/cfsando4.html>

<sup>127</sup> See, for example, numerous studies by U.S. EPA, PriceWaterhouse Coopers, World Resources Institute, CERES, Innovest, Tellus Institute, Friends of the Earth, the Rose Foundation and many other sources. A number of these reports are available at [www.rosefdn.org](http://www.rosefdn.org) or [www.foundationpartnership.org](http://www.foundationpartnership.org). On performance impacts, see Office of Cooperative Environmental Management, U.S. EPA, "Green Dividends? The Relationship Between Firms' Environmental Performance and Financial Performance" (2000); Ralph Earle III, "The Emerging Relationship Between Environmental Performance and Shareholder Wealth" (2000); Stephen Garone, "The Link Between Corporate Citizenship and Financial Performance" (1999); Don Reed, CFA, "Green Shareholder Value, Hype or Hit?" (World Resources Institute 1998). A few bibliographical websites have also been created to house academic research on this topic, including: <http://www.figsnet.org>, <http://www.sristudies.org>, and <http://web.mit.edu/doncram/www/environmental/envir-fi>. On environmental risk, disclosure and materiality see, Cynthia Williams, "The Securities and Exchange Commission and Corporate Social Transparency," 112 Harv. L. Rev. 1258 (1999); Robert



- <sup>134</sup> *Id.*
- <sup>135</sup> [http://www.ewg.org/issues\\_content/cosmetics/FDA\\_Warning/FDA2CTFA\\_letter.pdf](http://www.ewg.org/issues_content/cosmetics/FDA_Warning/FDA2CTFA_letter.pdf)
- <sup>136</sup> *Id.*
- <sup>137</sup> <http://www.cfsan.fda.gov/~frf/forum05/I-15.htm>
- <sup>138</sup> Sources for chart: Diane Dicostanzo and Pamela Lundquist, “Shopping Guide: The Good, The Bad, & The Ugly,” *The Green Guide* #94, Jan/Feb 2003, p. 5. See also “Skin Deep: Top Ingredients of Concern,” updated Oct. 2005, available at: [http://www.ewg.org/reports/skindeep2/findings/index.php?content=findings\\_ingreds\\_of\\_concern#begin](http://www.ewg.org/reports/skindeep2/findings/index.php?content=findings_ingreds_of_concern#begin) (see Coal Tar and Phthalates) CHEC HealthHouse website, search by ingredient at: [www.checnet.org/healthhouse](http://www.checnet.org/healthhouse)
- <sup>139</sup> Some of this section contains information from “Cosmetic Safety: More Complex than at First Blush,” *FDA Consumer*, (Revised May, 1995): <http://www.cfsan.fda.gov/~dms/cos-safe.html>
- <sup>140</sup> “Are Hair Dyes Safe?” FDA, available at: <http://www.cfsan.fda.gov/~dms/qa-cos17.html>; also EWG Skin Deep website: “Coal tar, Hair dyes, Bladder Cancer, and Non-Hodgkin’s Lymphoma,” at: [http://www.ewg.org/reports/skindeep2/findings/index.php?content=coal\\_tar\\_hair\\_dye#begin](http://www.ewg.org/reports/skindeep2/findings/index.php?content=coal_tar_hair_dye#begin)
- <sup>141</sup> <http://www.avoncompany.com/investor/>
- <sup>142</sup> <http://www.avoncompany.com/responsibility/safety.html>
- <sup>143</sup> Avon statement of opposition to Proposal 6—Resolution Requesting Global Reformulation of Avon Products to EU Standards, 2005 Avon Annual Meeting Proxy Statement, page 39.
- <sup>144</sup> Campaign for Safe Cosmetics Press Release, September 27, 2005, available at [www.safecosmetics.org/newsroom/press.cfm?pressReleaseID=12](http://www.safecosmetics.org/newsroom/press.cfm?pressReleaseID=12).
- <sup>145</sup> “L’Oreal Makes \$1.1 Billion Bid to Acquire Retailer Body Shop,” *Wall Street Journal*, March 18, 2006, page A7. (available at [www.wsj.com](http://www.wsj.com))
- <sup>146</sup> [http://www.thebodyshopinternational.com/web/tbsgl/images/Environment\\_ISA\\_2004.pdf](http://www.thebodyshopinternational.com/web/tbsgl/images/Environment_ISA_2004.pdf)
- <sup>147</sup> [http://www.thebodyshopinternational.com/web/tbsgl/images/Environment\\_ISA\\_2004.pdf](http://www.thebodyshopinternational.com/web/tbsgl/images/Environment_ISA_2004.pdf)
- <sup>148</sup> CVS 10-K For fiscal year ended Jan. 1, 2005
- <sup>149</sup> CVS 10-K For fiscal year ended Jan. 1, 2005
- <sup>150</sup> Estee Lauder 10-K—For the fiscal year ended June 30, 2005
- <sup>151</sup> “Cosmetics are Safe” page on Estee Lauder corporate citizenship website, [http://www.elcompanies.com/citizenship/product\\_safety\\_testing/cosmetics\\_are\\_safe.asp](http://www.elcompanies.com/citizenship/product_safety_testing/cosmetics_are_safe.asp)
- <sup>152</sup> “Product Safety FAQs” page at Estee Lauder corporate citizenship website, [http://www.elcompanies.com/citizenship/product\\_safety\\_testing/product\\_safety\\_faqs.asp](http://www.elcompanies.com/citizenship/product_safety_testing/product_safety_faqs.asp)
- <sup>153</sup> Procter and Gamble 10-K For the Fiscal Year Ended June 30, 2005
- <sup>154</sup> Procter and Gamble 10-K For the Fiscal Year Ended June 30, 2005
- <sup>155</sup> [http://www.pgbeautyscience.com/en\\_UK/programs/phthalates\\_safety\\_en.html](http://www.pgbeautyscience.com/en_UK/programs/phthalates_safety_en.html)
- <sup>156</sup> [http://www.pgbeautyscience.com/en\\_UK/programs/product\\_safety\\_substantiation\\_en.html](http://www.pgbeautyscience.com/en_UK/programs/product_safety_substantiation_en.html)
- <sup>157</sup> [http://www.pgbeautyscience.com/en\\_UK/programs/commonquestionsandanswers\\_en.html?#three](http://www.pgbeautyscience.com/en_UK/programs/commonquestionsandanswers_en.html?#three)
- <sup>158</sup> Financial data in this paragraph are based on Walgreens 2005 annual report, “We Take Care of People” accessible at <http://investor.walgreens.com/downloads/ar2005.pdf>
- <sup>159</sup> Wal-Mart 10-K—for period ending January 31, 2005
- <sup>160</sup> Wal-Mart 10-K—for period ending January 31, 2005
- <sup>161</sup> “Twenty First Century Leadership” Remarks of Lee Scott, October 21, 2005, <http://www.walmartstores.com/Files/21st%20Century%20Leadership.pdf>
- <sup>162</sup> <http://walmartstores.com/GlobalWMStoresWeb/navigate.do?catg=355>

Investor Environmental Health Network  
1901 North Moore Street, Suite 509  
Arlington, Virginia 22209  
(703) 243-0085  
info@iehn.org  
www.iehn.org

Rose Foundation for Communities and the Environment  
6008 College Ave., Ste. 10  
Oakland, CA 94618  
(510) 658-0702  
rosefdn@earthlink.net  
www.rosefdn.org  
(February 2007)

Design by Kesler Creative Communications  
www.keslercommunications.com