Phthalates 20/20:

The need for clarity in assessing safety

Advocacy groups and media are fear-conditioning us through the promotion of unsound science

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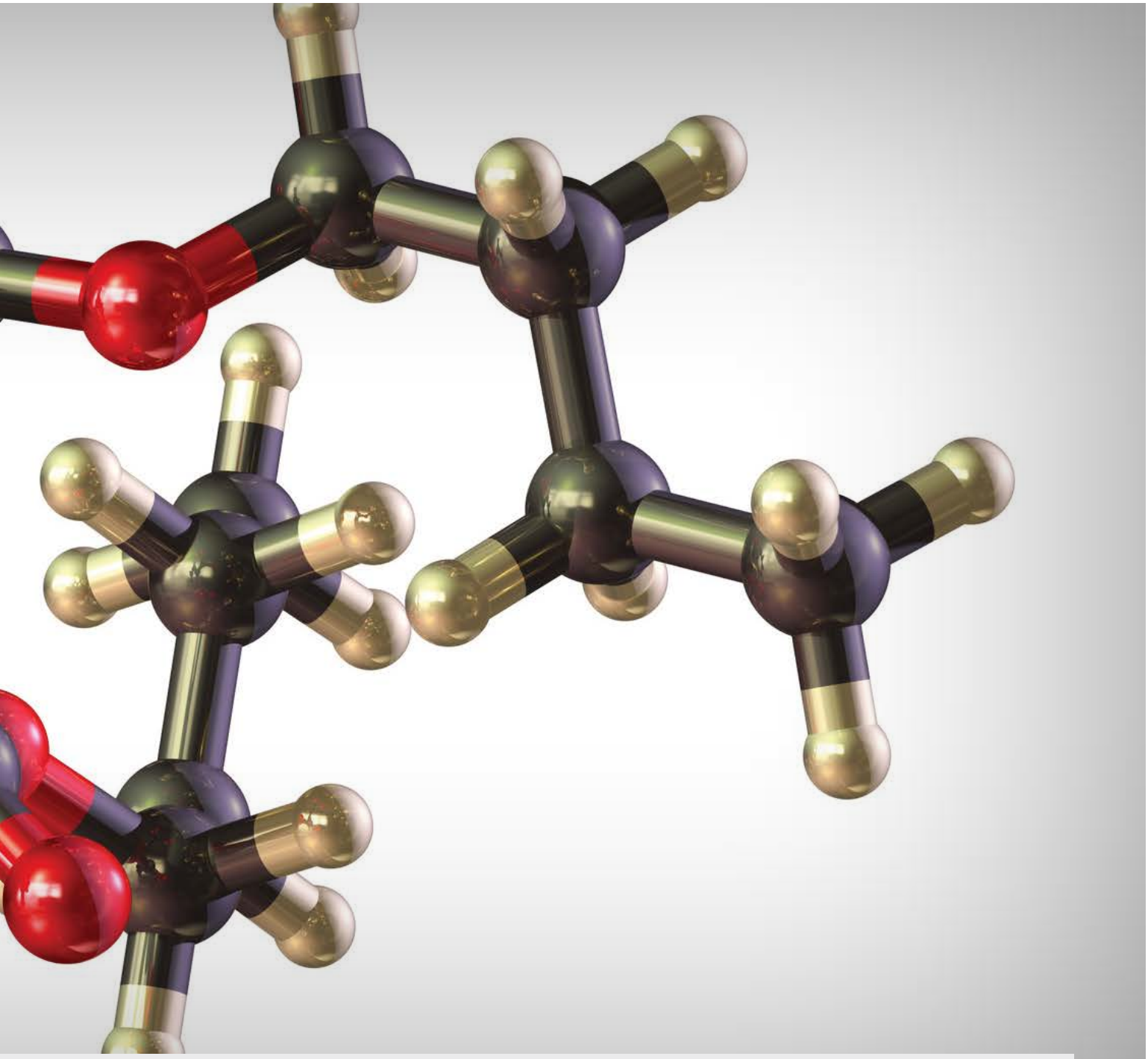
Phthalates, a common family of chemicals used to soften hundreds of vinyl products, have been safely used in consumer and commercial products for more than 40 years to enhance the durability, flexibility and performance of specialized products and consumer staples. During that same timeframe, phthalates have been scrutinized and otherwise maligned by activists as vectors that cause acute and long-term harm to human health.

To date, phthalates remain some of the most tested substances in commerce. While their use is regulated by multiple government agencies in the United States, Europe, Canada and Australia, all have concluded that phthalates, for their intended uses, present a low risk for any human health indications. In fact, a March 2018 analytical report on the types of plasticizers used in common food-contact materials by U.S. Food and Drug Administration researchers noted that: "There have been no studies to date which show any connection between human dietary exposure to phthalates and adverse health effects."



Source: Investigation of the primary plasticizers present in polyvinyl chloride (PVC) products currently authorized as food contact materials. Article in "Food Additives and Contaminants" Part A: March 2018.

Assessing common risks

In spite of this record, phthalates continue to be called out in speculative health studies. However, such studies do not meet typical "peer-reviewed" scientific standards and are consequently fueling safety misperceptions. Phthalates are not alone in this regard – consider the "newsworthy" debates around acrylamides in coffee, artificial sweeteners, MMR vaccines, cell phone radiation, and concerns with salts, sugars and preservatives in food. What are the real risks we face? And, are phthalates part of that risk equation?

The answer is yes, and no. Because, lost in all of this is the basic concept of risk. Consider that there are measurable amounts of arsenic in your table wine; 0.1 percent of your body bulk is toxic cadmium; and, 61 percent of any human is oxygen (mostly bound with hydrogen to form water). Any of these chemicals alone, in excess, is fatal, including water at high doses. Therefore, the presence of "harmful" chemicals is not the issue, but the concentration of them. Ultimately, this is the essence of risk: hazard-coupled with exposure. While activists mount campaigns to eliminate PVC in hospitals, there are 99,000 deaths from hospital acquired

infections in the U.S. every year. The cost to treat these infections is $45 billion per year, according to the Centers for Disease Control. The risk, in this case, is uncontrolled infectious agents – and the critical lack of R&D for next generation antibiotics – not the phthalate content of the blood or saline infusion bags.

What makes a "good" study?

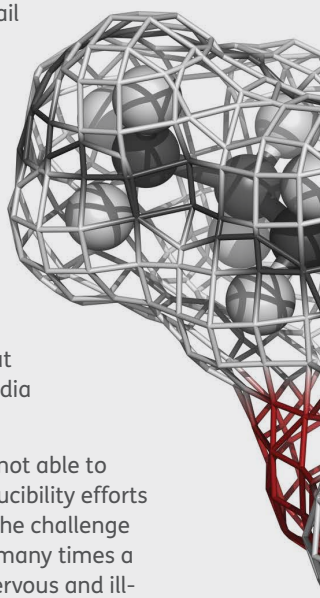
When it comes to commercial chemicals, sensationalist science commonly drives misperceptions around risk. The most frequently cited studies attacking phthalates don't account for cause and effect, real risk, or exposure. The trustworthiness of any given study, whether it be around phthalates or any other plastic additive is steeped in an accepted hierarchy of legitimate scientific studies, which are:

- An observational study, which may be interesting but is not trustworthy;
- An epidemiological study: trustworthy if large and well done;
- A meta-analysis study or review study: trustworthy;
- A randomized controlled trial: the gold standard.

Source: Wrong: Why Experts Keep Failing Us – and How to Know When Not to Trust Them: David H. Freedman 2010: Little, Brown, and Company.

Unfortunately, the breathless reports often seen in the health sections of newspapers, on television news and countless websites are often based on studies that fall into Category 1 as observational.

Coming into play in the "Observational Study" arena are confirmation bias and confounding variables. Know these terms. Confirmation bias is when a researcher takes the hypothesis that he or she starts out with - for example, phthalates cause obesity - and shapes the study methodology or the analysis of the data in a way that confirms the original premise, whether or not it's actually justified. As a corollary, often to prove the worthiness of their studies, investigators cite other studies to back up their claims. This is the dog chasing its tail syndrome.



On the other hand, confounding variables are, indeed, confounding. For example, there are studies that point to phthalates as disruptors of sperm quality and production – a malady in search of a cause. However, lifestyles, diets, prescription medicines, ambient air quality, Vitamin D deficiencies and even tight underwear could also be the cause. But, somehow, it's the chemicals that take the rap – and the bloggers and the media pounce.

Moreover, much reported research is often not able to be reproduced by other scientists. If reproducibility efforts are made, and the study is proven flawed, the challenge often goes un-reported. So, the consumer, many times a concerned parent, is essentially left both nervous and ill-

informed. For an accurate, if irreverent, assessment of "bad science" see HBO's John Oliver's take on the issue here: www.statnews.com/2016/05/09/john-oliver-bad-science

Conclusion: Recognize poor science and its reporting

Science remains under threat in the public eye, due to fear-conditioning advocacy groups which promote unsound science.

For its part, industry is committed to ensuring that good product development and sound and safe manufacturing practices are employed to find the right chemistry for the right application. As new scientific experimentation is completed through reliable peer-reviewed processes, additional details continue to guide manufacturers on safe production and product-use practices, including the use of phthalates.

For the scientific rigor part, understanding the importance of detailed knowledge about these chemicals is paramount to their safe use and to the publication of study results.

At the end of the day, it is incumbent on us, the consumer and the manufacturer, to assess if a study is legitimate and what the real implications are. If it is not good science, call it out – write, call or comment, using your own resources and/or that of your trade association. In the end, all we ask is that science, good science, be a partner in this endeavor, as well as those who report on it. 20/20 vision around the safety of chemicals is paramount to us all and our well-being.

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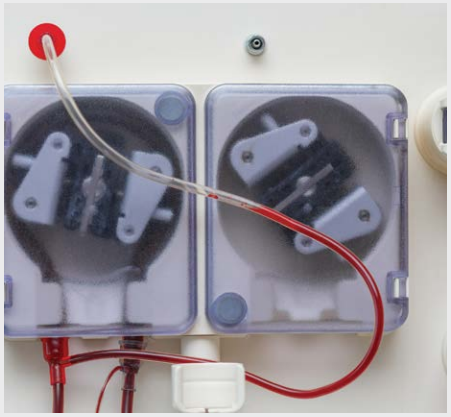

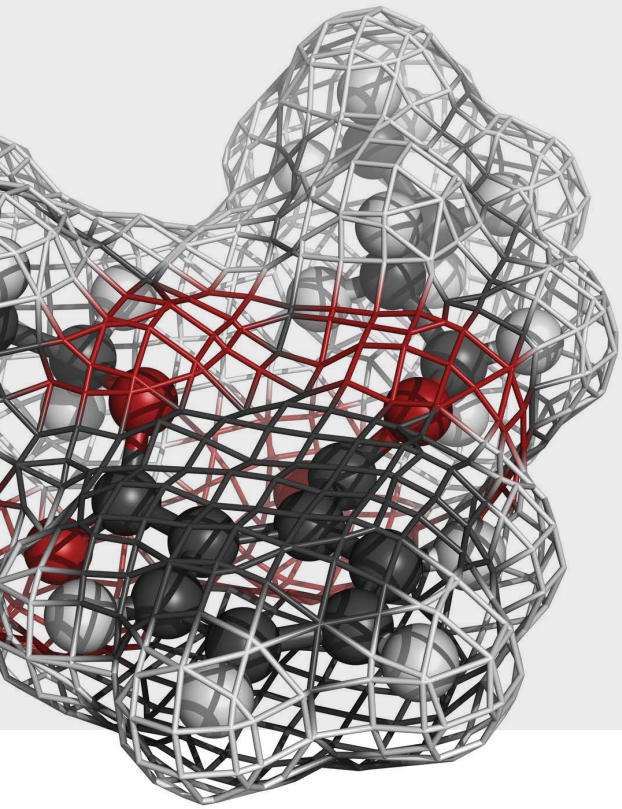

Phthalates: Essential to a diverse array of products

Phthalates are a common family of chemicals used to soften hundreds of vinyl products used in everyday life. While the spelling of "phthalates" is confusing (even tracing its etymology is difficult) uses for phthalates are not.

Applications employing phthalate "plasticizers" in flexible PVC (polyvinyl chloride) plastic products are diverse, noteworthy and essential:

- Automotive dashboards and interiors
- Commercial wallcoverings
- Blood bags and dialysis equipment
- Conveyor belts
- Roofing membranes
- Graphic inks
- Tool grips
- Marine upholstery
- Computer cables
- Building electrical wiring systems (including Google's server farms – remember, wireless isn't wireless)

All these employ flexible PVC and plasticizers to an exacting degree to enhance performance, utility and longevity. And, to ensure performance to exacting specifications, including consumer safety, different phthalates have different uses.

Phthalate chemistry in vinyl

When deployed in commercial products, phthalates are held in the structure of the component. The bond strength is measurable. Various chemical-physical attractive forces hold the phthalate within the vinyl matrix, so that migration occurs at a very low rate under extreme conditions or if at all during normal use. Therefore, retention in the polymer matrix is one of the main factors in considering which phthalate-ester to use. Together with their low vapor pressure, phthalates are beneficial to long service life to keep products flexible, and in service for many years.