Chronic Hazard Advisory Panel on Phthalates
July 26, 2010
Statement by Daniel Penchina on behalf of the Breast Cancer Fund

Thank you for the opportunity to speak today. My name is Daniel Penchina and I am here representing the Breast Cancer Fund, the only national organization focused on preventing breast cancer by identifying, and advocating for the elimination of, the environmental and other preventable causes of the disease. The Breast Cancer Fund was a strong supporter of the phthalate provision within the Consumer Product Safety Improvement Act (CPSIA). We are pleased that you have begun your work reviewing the science on the health impacts of phthalates, and we are grateful for the opportunity to present these comments.

As you know, phthalates are used in a wide variety of consumer products in addition to toys and children's products, including food packaging; personal care products such as soap, shampoo, deodorant, hand lotion, nail polish, cosmetics, and perfume; home vinyl siding; flooring; furniture; car interiors; detergent; solvents; lubricants; glue; paint and medical equipment, including IV bags. Biomonitoring has confirmed that phthalates migrate into the air, into food and ultimately into people, including babies *in utero*. Phthalates have been found in indoor air and dust, and in human urine, blood and breast milk. Levels are highest in children ages 6 to 11 and in women, and African Americans have higher levels of phthalates than Caucasians.

Phthalates are known endocrine disruptors and can affect normal hormonal processes. Phthalate exposure has been linked to reduced testosterone levels, lowered sperm counts in adult men, genital defects in baby boys, and early puberty in girls. Moreover, several studies in humans have shown some of these toxic effects of phthalates at levels similar to what the average American is currently exposed to.

As an organization working to prevent breast cancer, we are extremely concerned about the endocrine disrupting qualities of these chemicals. Much of the research on phthalates has focused on endocrine disrupting effects in males. However, more recent studies link phthalate exposure to early puberty in girls and suggest that females are affected in ways that may increase the risk of breast cancer.

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The Breast Cancer Fund publishes a report entitled *State of the Evidence, The Connection Between Breast Cancer and the Environment*. In this document, which is updated every two years, we review the peer-reviewed scientific studies that show links between environmental toxicants and breast cancer. On the subject of phthalates, SOE notes that some phthalates including butyl benzyl phthalate (BBP) and di-n-butyl phthalate (DBP) act as weak estrogens in cell culture systems. They can bind to estrogen receptors (ER), act like estrogen and act additively with the body's own estradiol to alter these systems. BBP, DBP and another common phthalate, di-(2-ethylhexyl) phthalate (DEHP) significantly increased breast cancer cell proliferation and inhibited the anti-tumor action of breast cancer treatment drug tamoxifen.

A new study found that neonatal/prepubertal exposure to BBP induced changes in gene expression in the rat mammary gland. This exposure also increased proliferation in terminal end buds and in lobules. Researchers noted that terminal end buds are the most susceptible structures to breast cancer.
These studies represent just a few in a large and growing body of scientific studies. Despite the growing evidence, we know that scientific certainty is rare and often policy questions need to be answered before the science is clear. As you review the available evidence on the health impacts of phthalates, we urge you not to require absolute certainty before recommending action be taken to reduce human exposure to these chemicals.

In the Consumer Product Safety Improvement Act (CPSIA), Congress wisely tasked you considering a number of factors before making a safety determination on phthalates. Traditional toxicology methods – one chemical at a time from a single source on an adult, assuming a linear dose-response relationship – are outdated and do not provide an adequate, or frequently even accurate, description of how a particular chemical impacts human health.

We were therefore pleased that Congress explicitly listed several specific elements to guide your safety assessment in the statute, including reviewing all health endpoints, combinations of phthalates, impact of the timing of exposure, cumulative impact of all sources and routes of exposure, all of the relevant peer-reviewed studies, and the impact on vulnerable populations including children, pregnant women and other vulnerable populations. Congress also called for the safety review to "consider the level at which there is a reasonable certainty of no harm" to those vulnerable populations, "using sufficient safety factors to account for uncertainties regarding exposure and susceptibility of children, pregnant women, and other potentially susceptible individuals." As advocates, we were heartened to see that Congress placed the burden of proof on manufacturers of phthalates and phthalate-containing products to show that phthalates are safe – not on the government to prove harm.

In our work on *State of the Evidence*, we found a number of themes in the data which are particularly important in assessing endocrine disrupting chemicals and reflect the concerns expressed by Congress in the phthalate provision of the CPSIA.

Timing of exposures matters. We learned decades ago from the tragic legacy of DES exposures to hundreds of thousands of pregnant women and their developing fetuses in the 1950s, that *in utero* exposure to synthetic estrogens increases the incidence of reproductive abnormalities and breast cancer in the children and grandchildren of the women who took the drug. Similar data from animal models continue to show that prenatal exposures to other synthetic estrogen mimics alter mammary tissue development in ways that predispose the animals to increased risk for mammary tumors later in life and that these effects may be passed on to subsequent generations through epigenetic mechanisms.

Early-life exposure to phthalates holds the greatest risk for harm and prenatal exposure to very low doses can have irreversible, lifelong effects. Therefore, it is essential to protect children and women of childbearing age from exposure to phthalates. Other times of high susceptibility to environmental exposures include adolescence (specifically puberty) and early adulthood, prior to first pregnancy and lactation.

Low doses may have profound effects, especially at critical periods of development. The study of endocrine disrupting compounds, many of which have been implicated in increased risk for breast cancer, has taught us that the traditional model of toxicology, that "the dose makes the poison" is outdated and no longer the standard by which we assess the safety of chemicals, particularly endocrine disruptors. We have substantial evidence from wildlife and laboratory studies that exposures to environmentally relevant levels of endocrine disrupting compounds, even when apparently very low in concentration, can alter reproductive development and risk for disease, including breast cancer.

Mixtures matter. The effects of phthalate exposure depend not only on timing, but also on mixtures of phthalates and their interaction with other environmental factors. In our real lives, we are not exposed to one environmental challenge at a time. Rather we live in a world where we daily breathe the air, drink the water, walk the grass, work in the offices, play with toys, use household cleaning products, apply cosmetics and other personal care products, etcetera. We are exposed not only to a number of phthalates, but to a vast mixture of chemicals. Each chemical does not act alone. Growing evidence indicates that many of these common exposures work additively, and sometimes synergistically, both within the family of phthalates and beyond.

All of us are exposed to more than one phthalate as well as multiple other chemicals. A 2008 study reported in *Pediatrics* found measurable levels of seven out of nine phthalates tested in the urine of infants born between 2000 and 2005. Levels were closely correlated with use of infant care products (lotion, powder, shampoo) within 24 hours of urine sample collection, making it clear that what goes on baby also goes into baby.

Interactions matter. Some of the evidence that is the most compelling is the growing literature examining complex interactions between risk factors. These studies are expanding our understanding of the variability of susceptibility to environmental, as well as lifestyle, reproductive and genetic factors. The data are critical for understanding impacts on vulnerable populations and designing community-based studies that examine these important interactions.

All of these factors will be important considerations for the CHAP in getting an accurate and full picture of how phthalates are impacting the health of children, both at the time of exposure and much later in life when some of these impacts may manifest.

In addition to hazard characteristics, the CHAP has been asked to look at exposure data not just from toys, but from the numerous other sources of phthalates. As I mentioned, we know some of these sources, and biomonitoring data gives us part of the picture of exposure. However, it is frustrating to have to point out that we don't know all the products that contain phthalates, much less which phthalate, because our chemical management laws are weak. Not only is safety testing not required before various chemicals, including phthalates, are released into commerce, but frequently our laws don't even require disclosure of ingredients. We know that phthalates are a common component of the fragrance used in numerous products, from cosmetics to household cleaning products; but current law allows industry to hide the component ingredients of "fragrance" as "confidential business information," thereby masking the presence of potentially harmful substances including phthalates. Understanding the full scope and level of exposure to phthalates will be an important challenge for this Panel to meet.

The Breast Cancer Fund and our allies have long focused on the impact of environmental toxicants on the incidence of numerous diseases, including breast cancer, and the need to adopt a precautionary approach to science and policy. As you determine how you will view the existing data on phthalates relative to the risk they pose, we would like to call your attention to two new reports that have informed that discussion. The Endocrine Society and the President's Cancer Panel (PCP) both released reports in the last year with conclusions and recommendations calling for precaution.

The Endocrine Society is an international association, founded in 1916, with 14,000 members representing medicine and a wide variety of scientific disciplines including molecular and cellular biology, biochemistry, physiology, genetics and immunology. Last year, this highly esteemed association released a *Scientific Statement on Endocrine Disrupting Chemicals*, which included a section entitled "Endocrine Disruptors, Mammary Gland Development, and Breast Cancer." This section discusses the impact of exposure to endocrine disrupting chemicals, or EDCs, during certain critical windows of susceptibility and how those exposures can alter the structure of the breast, making the tissue more sensitive to carcinogenic exposures later in life. The scientific evidence led the Endocrine Society to state in a separate Position Statement:

"Until such time as conclusive scientific evidence exists to either prove or disprove harmful effects of substances, a precautionary approach should be taken in the formulation of EDC policy." We encourage the Panel to review and consider this important document.

Another voice calling for a precautionary approach to chemicals is the President's Cancer Panel (PCP). The Panel, established in 1971, is tasked with monitoring the development and execution of the activities of the National Cancer Program. In May of this year, the Panel released a report entitled *Reducing Environmental Cancer Risk, What We Can Do Now.* In developing the report, the Panel did its own research and held four public meetings where over 45 invited experts – representing academia, government, industry, environmental and cancer advocacy communities and the public – contributed testimony on research, policy and programs concerning environmental contributions to cancer.

Finding that the true burden of environmentally induced cancer has been grossly underestimated, the *Reducing Environmental Cancer Risk* report issued a call to action to the President and for our nation – a call to re-evaluate the role of environmental contaminants in the incidence of cancer; to institute the use of precautionary, rather than reactionary, policies regarding chemical management; and to create a true national cancer prevention strategy. The public instinctively knows that the chemicals in our daily lives threaten our health and the President's Cancer Panel's review of the scientific evidence confirmed that belief.

The President's Cancer Panel's report also included several specific recommendations for "What Individuals Can Do." The recommendation related to children reflects the growing concern about EDCs by calling on parents to "avoid exposure to endocrine disrupting chemicals and known or suspected carcinogens prior to a child's conception and throughout pregnancy and early life." Both of these highly regarded institutions found the scientific evidence to be compelling and called for precautionary action.

Answers in science are rarely absolute, and absence of knowledge is not the same as absence of harm. The impact of our inaction in the face substantial evidence of harm is irreversible – in terms of public health as a whole and the devastating impact on people's lives. The Breast Cancer Fund strongly urges you, in your deliberations and conclusions, to adopt a precautionary approach to interpreting the science and to advocate that precaution be the foundation for the CPSC's ultimate regulatory decisions regarding phthalates.