

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

NATURAL RESOURCES DEFENSE)	
COUNCIL, INC., and PUBLIC CITIZEN,)	
INC.,)	
)	
Plaintiffs,)	
v.)	08 Civ. 10507 (PGG)
)	
U.S. CONSUMER PRODUCT)	
SAFETY COMMISSION,)	
)	
Defendant.)	

DECLARATION OF SARAH JANSSEN, M.D., Ph.D, M.P.H.

Sarah Janssen, M.D., Ph.D., M.P.H., declares as follows:

Introduction and Qualifications

1. I am a Medical Doctor. I received my M.D. in 2001 from the University of Illinois at Urbana-Champaign (UIUC). I did my internship in General Surgery (2001) and a Fellowship in Occupational and Environmental Medicine (2004-06) at the University of California at San Francisco (UCSF). Since 2006 I have been certified by the American Board of Preventive Medicine, with a specialty in Occupational and Environmental Medicine. I have been licensed to practice medicine in the State of California since 2003.

2. I received an M.S. (1993) and Ph.D. (2001) in Molecular and Integrative Physiology from the UIUC. My doctoral research focused on male reproductive physiology, with particular emphasis on chemicals that interfere with reproduction and fertility.

3. I earned a Masters Degree in Public Health from the University of California, Berkeley (2005).
4. I have written scholarly articles and book chapters on the subject of endocrine-disrupting chemicals and their impacts on human reproduction and fertility. I am familiar with the existing scientific literature on this subject.
5. I was hired in 2006 by plaintiff Natural Resources Defense Council (NRDC) as a Science Fellow. My work at NRDC has centered on the effects of endocrine-disrupting chemicals, including phthalates.
6. I testified before the San Francisco Board of Supervisors and the California Legislature when the City and County of San Francisco and State of California, respectively, considered and adopted bans on the six phthalates at issue in this case.
7. When Congress considered the Consumer Product Safety Improvement Act of 2008 (CPSIA), I provided an oral report via telephone to staff for the House Committee on Energy and Commerce, Subcommittee on Commerce, Trade, and Consumer Protection. I presented oral testimony to that Subcommittee in July 2008.
8. In addition to my work at NRDC, I am an Assistant Clinical Professor at UCSF, in the Division of Occupational and Environmental Medicine, where I teach medical residents and students of medicine and nursing. I am also a pool physician for Kaiser Permanente of Northern California, where I evaluate and treat injured workers.
9. A more complete description of my educational and work experience, as well as a complete list of my publications, is appended as Exhibit A to this declaration.
10. By virtue of my medical, doctoral, and public health training, my clinical work, my research, and my knowledge of the pertinent scientific literature, I consider

myself an expert on the effects of endocrine-disrupting chemicals, including phthalates, on human health, including human reproduction and fertility.

Effects of Phthalates on Human Health

11. Phthalates are a class of chemicals used to soften plastics in children's toys and other products. They are commonly found in articles made of polyvinyl chloride, including bath toys and books, teething rings, bibs, dolls, balls, plastic figures, and a variety of other plastic toys.

12. Phthalates leach steadily from plastics, including vinyl, and other materials to which they are added. Studies of population-wide exposure in the United States show that essentially all children over the age of six years and adults have measurable levels of phthalate metabolites in their bodies. Children ages 6-11 have the highest levels of the phthalates DEHP, DBP, and BBP. Infants appear to be highly exposed as well. With the exception of infants, there is not very much information available on exposures in children under the age of six; however, it is likely that young children are just as highly exposed as older children because they are in frequent contact with products containing phthalates.

13. In the CPSIA, Congress banned the manufacture, sale, distribution, and import of all child care products and children's toys containing more than 0.1 percent of any of three different phthalates: di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), and benzyl butyl phthalate (BBP). Subject to further study and rulemaking, the CPSIA also banned children's toys that contain more than 0.1 percent of three additional phthalates: diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), and di-n-octyl phthalate (DnOP).

14. There is epidemiological evidence that certain phthalates (DEHP, DBP, DINP, and BBP) are associated with abnormalities in human reproductive outcomes. These human abnormalities are similar to the harm that has been demonstrated with phthalate exposure in laboratory animal studies. Phthalates are endocrine disruptors that interfere with the production of the steroid sex hormones. Because development of the reproductive system is hormonally driven, it is particularly sensitive to interference with normal hormone action during infancy and childhood. Endocrine disruptors can interfere with natural hormone levels and with hormonally-driven development of reproductive organs.

15. Scientific studies indicate that some phthalates, including DBP, DEHP, and BBP, interfere with production of the male sex hormone testosterone. This effect has been well documented in laboratory animal studies and now in a human study that found abnormalities in reproductive hormone profiles of infant males exposed to phthalates via breast milk. Interference with reproductive hormones in males, particularly during susceptible windows of development, has been associated with alterations in the onset of puberty, and, later in life, with poor sperm quality, infertility, and testicular cancer.

16. The effects of DINP, DIDP, and DnOP are not as well studied, although in animal studies DINP has been shown to lower testosterone levels and cause reproductive harm similar to the effects seen after DBP, DEHP, and BBP exposure. DIDP has been linked to musculoskeletal harm.

17. Exposure to phthalates during early childhood prompts particular concern because infants and children are more susceptible to the toxic effects of chemical exposures. On a pound for pound basis, children are exposed to higher levels of

chemicals and, because of their natural tendency to explore their world by mouthing objects, children are more likely to place inanimate objects, including toys, into their mouths. Infants have immature detoxification systems that place them at greater risk of harm from exposures to chemicals. Children also experience more rapid growth and development than do adults, sometimes in concentrated spurts. Endocrine disruptor interference with natural hormonally driven development can cause long term and irreversible reproductive and other damage. Exposures early in life may result in adult disease such as infertility and cancer.

18. Based on numerous animal studies, scientists understand the mechanisms through which phthalates act. These studies have examined effects on large numbers of subjects and have been replicated by independent researchers, making their conclusions reproducible and reliable. Federal agencies, such as the National Toxicology Program, have reviewed this science and expressed concerns about early life exposures to some phthalates. More recent research has found evidence of harm in humans exposed to phthalates, with outcomes similar to those observed in animal studies. Together, this body of research provides strong evidence that some phthalates harm human health, in particular the development and function of reproductive organs.

19. Animal studies indicate that *in utero* exposure to some phthalates can cause birth defects to genitalia, including cryptorchidism (undescended or incompletely descended testicles) and hypospadias (a birth defect of the penis in which the opening of the urethra is not at the tip but on the underside of the penis). *In utero* phthalate exposure has also been associated with the development of testicular cancer later in life. This

reinforces concern about phthalates' effects on the overall development and health of the male reproductive system.

20. Although phthalates' effects on women and girls are not as well documented, animal studies link fetal exposure to DBP with alterations in female sex hormones and pregnancy loss. Phthalates have also been linked to earlier puberty in girls and endometriosis (an abnormal growth of uterine lining outside of the uterus) in adult women. While less comprehensive than the literature describing effects of phthalates on males, this research suggests that phthalates affect female as well as male reproductive development and fertility through similar, endocrine-disrupting mechanisms.

21. Other studies link DEHP to growth of human breast cancer cells and BBP to gene expression changes and proliferation of mammary tissue in rodents. Although human epidemiological studies examining this link have not yet been conducted, these preliminary data raise legitimate and serious human health concerns.

Additive Exposure to Phthalates

22. Given the widespread exposure to phthalates measured in American infants and children, it is particularly important to reduce childhood exposures to these toxins.

23. Scientists have identified several pathways through which children may be exposed to phthalates. Children who mouth or chew on toys may swallow phthalates that leach from the toys, or they may absorb phthalates directly through the oral mucosa. Absorption is also available through direct dermal contact. Finally, phthalates have been shown to leach from products and bind to dust particles that can be inhaled or ingested.

24. Studies in laboratory animals have shown that some phthalates are able to act together in an additive manner to cause injury. Therefore, exposure to a mixture of

phthalates at low doses can cause the same harm as one phthalate at a high dose of exposure. Small exposures to individual phthalates from multiples sources of exposure increase the risk for an exposed person to suffer adverse health effects caused by the total exposure to all toxic phthalates. In children, small exposures from toys and other childcare articles contribute to their total body burden and may be both significant and harmful. This additive function is particularly important given that people of all ages are exposed to phthalates from a variety of sources on a regular basis, intensifying concern about each incremental exposure.

25. Scientists have not determined the fraction that individual sources contribute to children's total exposure for either discrete phthalates or phthalates as a whole. This highlights the importance of eliminating known sources that are identifiable and for which substitute materials are available. Toys and children's products fall within this category. Because of the additive nature of phthalates' effects on human health, each incremental reduction in avoidable exposure reduces the risk of harm to human health and development.

Summary and Conclusion

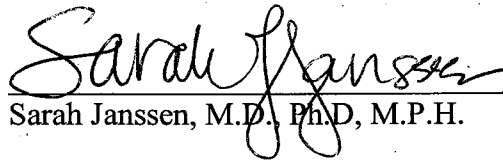
26. I am the mother of a 16-month old girl. Informed by my scientific and medical knowledge, I want to eliminate my child's exposure to the phthalates Congress has banned in the CPSIA. With substantial and substantiated medical reason, I fear that such exposure may cause her irrevocable biological harm. I would advise any patient I see, or group I talk to, to eliminate every avoidable exposure their child may have to these toxic chemicals. The best available science indicates that such exposures, especially at a critical developmental age, may cause severe and permanent damage.

27. There is no effective labeling that informs a consumer whether a toy or child care product contains phthalates, or, if it does, in what concentration. As a result, unless sale of all products containing more than 0.1 percent of the six banned phthalates is prohibited after the effective date of the Congressional ban, consumers will have no way of knowing whether products they purchase after that date contain phthalates exceeding the statutory threshold. They will be helpless to protect themselves and their children from harm.

28. In my scientific opinion, postponing implementation of the Congressional ban on the sale of phthalates in children's toys and child care products will generate and prolong exposures that may cause irretrievable medical injury to those exposed.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Dated: December 9, 2008
San Francisco, California


Sarah Janssen, M.D., Ph.D., M.P.H.