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Testimony of David Brookstein, Sc.D. Dean and Professor School of Engineering & Textiles Philadelphia University Before the United States Senate Committee on Commerce, Science and Transportation Subcommittee on Consumer Protection, Product Safety and Insurance

"Use of Formaldehyde and other Toxic Materials in Textiles and Apparel" April 28, 2009

Thank you Chairman Pryor and members of the Committee for this opportunity to provide testimony to the Senate Subcommittee on Consumer Protection, Product Safety and Insurance. I would also like to express my appreciation to Senator Robert P. Casey, Jr. who is at the vanguard of protecting our nation's citizens from potentially toxic materials in consumer products. My testimony is based on over 35 years of experience as a textile engineering professor and researcher including co-founding the Institute for Textile and Apparel Product Safety at Philadelphia University.

In the summer of 2007 reports surfaced about high levels of lead in toys and other consumer goods and there were hundreds of thousands of items recalled. One area that initially escaped scrutiny at that time was textile and apparel product safety. Years before, the federal government recognized the lethal toxicity of asbestos fibers and TRIS flame retardant in children's sleepwear and acted appropriately to ban their use in consumer products. Today, once again, the question of safety is front and center and researchers are looking for answers regarding the safety of textiles and apparel. By researching the prevalence of other potentially toxic chemicals, such as formaldehyde, dyes and finishes, used every day in clothing, we will be able to determine just what chemicals and at what levels could pose risks to all of us, especially our children — and possibly lead to medical conditions ranging from contact dermatitis to neurotoxicity, endocrine disruption and possibly cancer.

Many clothing items are in direct contact with the skin. During contact there can be perspiration which involves moisture transport between the skin and the dyed and chemically treated clothing items. Dyes are used to enhance the appearance of textiles and chemical treatments affect the performance of textile products. While modern dyes and chemical treatments are chemically bound to the fibers in the clothing, there is the possibility that residual dye (dye bleed) and finishes (treatment chemicals) are released in direct contact with the skin. Textile materials are a capillary and porous material with different pore sizes, and can be saturated with both liquid and gaseous water during wear. The transportation of perspiration through this material at different temperatures is a very complex process, which can involve convection, capillary flow, penetration, molecular diffusion, evaporation, and solidification.

On Aug 14, 2008 Public Law 110-314 (Consumer Product Safety Improvement Act) was enacted. The purpose of the law was to establish consumer product safety standards and other safety requirements for children's products and to reauthorize and modernize the Consumer Product Safety Commission.

Formaldehyde is a commonly used chemical treatment for apparel items and has long been recognized as toxic. Accordingly, Senators Casey, Brown, Clinton and Landrieu offered an Amendment to study the use of formaldehyde in manufacturing textile and apparel articles. The Amendment, agreed to unanimously, calls for a study by the GAO in consultation with the Commission, on the use of formaldehyde in the manufacture of textile and apparel articles, or in any component of such articles, to identify any risks to consumers caused by the use of formaldehyde in the manufacturing of such articles, or components of such articles. The law calls for the study to be completed by August 2010 but, to our knowledge, the GAO has not yet begun the study.

Formaldehyde treatment of cellulosic fibers such as cotton was first taught in an invention by the British inventors Foulds, Marsh and Wood in US Patent 1,734,516 in 1929. The inventors claimed that "one of the greatest defects of a fabric composed entirely of cotton has been the ease with which such fabric is creased or crumpled when crushed or folded under pressure in the hand." The invention was to use a mixture of chemicals including formaldehyde to cause a chemical reaction with the cellulose that would cause cross-linking and thus render the fabric wrinkle free.

Substantial commercial interest developed as inherently wrinkle-free synthetic fibers were commercialized and by the 1950's family fabric caretakers (mostly women) were delighted by the potential of wrinkle-free fabrics that would add to other labor-saving chores that were being introduced to the public. As more and more women joined the workforce the entire family became interested in easy care clothing.

In 1985, The US National Institute for Occupational Safety and Health (NIOSH) completed its first research study of formaldehyde. The study examined death certificates among 256 deceased workers from three plants which made shirts from formaldehyde treated cloth. Formaldehyde was used at these plants to help make shirts more crease resistant. The 1985 study found a significantly increased risk of cancer of the buccal cavity (cancer of the inside of the mouth) and for multiple myeloma (cancer of the bone marrow). In 1988, NIOSH completed its second study of formaldehyde exposure. This study looked at employment records from 11,030 workers who had been employed at any one of three plants. Two of the three plants were the same as in the previous study. As in the 1985 study, the 1988 study found a significantly increased risk for cancer of the buccal cavity. Excess risks were also seen for multiple myeloma and leukemia.

In 2004, NIOSH conducted a substantially large study of cause of death among clothing workers exposed to formaldehyde and found that:

- 1. The death rates from all causes combined and for all cancers combined among the 11,039 workers in the updated study were lower than expected, based on the U.S. population rates.
- 2. There were no deaths from cancers of the nasopharynx (nose). The death rate for cancer of the buccal cavity (inside of the mouth) was only slightly elevated.
- 3. The overall risk for myeloid leukemia was almost $1\frac{1}{2}$ times what was expected.
- 4. For workers who were employed at the plants for 10 or more years and were first exposed 20 years earlier, the risk for myeloid leukemia was increased over 2 times what was expected.
- 5. The increase in myeloid leukemia was also seen among those workers who were first exposed prior to 1963, when formaldehyde exposures were likely higher.

NIOSH reported that the overall average concentration of formaldehyde measured by NIOSH at the three plants during the early 1980's was 0.15 parts per million (ppm). This was below the permissible level at that time, which was 3.0 ppm over an 8-hour work day. Exposures were similar across departments and plants. In 1987 the permissible level of formaldehyde exposure was reduced to 1.0 ppm and in 1992 was further reduced to 0.75 ppm. OSHA regulation 29 CFR 1910-1048 regulates the exposure limit for workers in the US textile and apparel industry to 1 part formaldehyde per

million parts of air as an 8-h time-weighted average. The NIOSH study was based on a group of scientific research papers published from 1985-2004.^{i,ii,iii}

While the NIOSH studies and subsequent regulations were directed at American workers, the same concerns obtain for American consumers.

In 2004, the World Health Organization International Agency for Research on Cancer (IARC) categorized formaldehyde as a known cancer-causing agent in humans.

The United States apparel manufacturing industry has declined precipitously and today it has been estimated that approximately 90% of consumer apparel sold in the United States is not manufactured in the United States. Accordingly, today the safety hazards associated with formaldehyde to US apparel workers is negligible, if any. Yet while there are essentially no occupational hazards associated with formaldehyde processing of apparel to US workers there could be hazards to those overseas workers who produce clothing and textiles for the US marketplace. Additionally, American workers can be exposed to potential toxic off-gassing from textile products when imported items are received in US distribution centers.

However, humans can be exposed to formaldehyde associated with textiles and clothing in an additional manner than that from manufacturing. For instance, in the clothes treated with formaldehyde can come into direct contact with the skin. In 1959, Marcussen (Denmark) reported that during a period between 1934-1958 there were 26 cases (11% of studied cases) of garment formaldehyde dermatitis.^{iv} Marcussen also reported results of a study conducted from1934-1955 a study in which 1-3% of 36,000 eczematous patients showed formaldehyde sensitivity.^v In 1965, US dermatology researchers O'Quinn and Kennedy reported contact dermatitis caused by formaldehyde in clothing.^{vi} Hatch published a complete review of references to clothing based formaldehyde sensitivity in 1984.^{vii} The medical literature is replete with many studies showing the adverse dermatological effects of formaldehyde. An excellent current review of this subject has been written by Fowler "Formaldehyde as a Textile Allergen" in 2003. ^{viii}

On the next page is a table which shows common formaldehyde resins used in textiles and apparel.

Resin Type	Relative Formaldehyde Release*
Urea formaldehyde/DMU	High
Melamine formaldehyde	High
DMDHEU (Fixapret CPN)	Low
DMDHEU blended or reacted with glycols (modified) (Fixapret ECO)	Very low
Dimethoxymethyl dihydroxyethylene urea (methylated DMDHEU)	Very low
Dimethyl dihydroxyethylene urea (Fixapret NF)	None

*High signifies a formal dehyde release of > 1,000 ppm; low, a release of < 100 ppm; and very low, a release of < 30 ppm. ix

At a recent workshop held at Philadelphia University attended by personnel from the Consumer Product Safety Commission, Dr. Susan Nederost of University Hospitals of Cleveland/Case Western Reserve University reported that patients with allergic contact dermatitis, such as that caused by allergic response to formaldehyde exposure, results in substantial amount of days missed from employment.

Another exposure route is from off-gassing of stored or closeted clothing with relatively high levels of formaldehyde. As early as 1960 researchers reported on release of formaldehyde vapors on storage of wrinkle-resistant cotton fabrics.^x The exposure route from off-gassing of formaldehyde could soon be recognized as a significant health risk to United States consumers as a result of recent testimony to the US House of Representatives which reports the relatively high levels of formaldehyde in house and office blackout shades and other drapery items.^{xi} Using the AATCC Test Method #112 free formaldehyde values of between 1000 ppm and 3000 ppm were found in a relatively large group of imported items available in the United States marketplace.

As of yet, there are no formaldehyde restrictions or standards for clothing and other textile items that are distributed and sold in the United States. However more and more nations are adopting standards for formaldehyde in clothing and textiles. In Japan, textile fabrics are required by law to contain less than 75 ppm free formaldehyde, as measured by the method described in Japan Law 112. And no formaldehyde is tolerated for infant clothing. The Hong Kong Standards and Testing Center produced the table below which shows the status of formaldehyde regulations in countries that are currently addressing this situation.^{xii} From the table, the Committee can easily see how

other industrialized countries are dealing with this important issue that affects the health of their citizenry.

Country	Regulations / Requirements	Objection Limit / Limit
Germany	Gefahrstoffverordnung (Hazardous Substances Ordinance) Annex III, No. 9, 26.10.1993	Textiles that normally come into contact with the skin and release more than 1500 mg/kg formaldehyde must bear the label "Contains formaldehyde. Washing this garment is recommended prior to first time use in order to avoid irritation of the skin."
France	Official Gazette of the French Republic, Notification 97/0141/F	The regulations apply to products that are intended to come into contact with human skin, including textiles, leather, shoes, etc. Textiles for babies: 20 mg/kg Textiles in direct skin contact: 100 mg/kg Textiles not in direct skin contact: 400 mg/kg
Netherlands	The Dutch (Commodities Act) Regulations on Formaldehyde in Textiles (July 2000)	Textiles in direct skin contact must be labeled "Wash before first use" if they contain more than 120 mg/kg formaldehyde and the product must not contain more than 120 mg/kg formaldehyde after wash.
Austria	Formaldehydverordnung, BGBL Nr. 194/1990	Textiles that contains 1500 mg/kg or above must be labeled.
Finland	Decree on Maximum Amounts of Formaldehyde in Certain Textiles Products (Decree 210/1988)	Textiles for babies under 2-year-old: 30 mg/kg Textiles in direct skin contact: 100 mg/kg Textiles not in direct skin contact: 300 mg/kg
Norway	Regulations Governing the Use of a Number of Chemicals in Textiles (April 1999)	Textiles for babies under 2-year-old: 30 mg/kg Textiles in direct skin contact: 100 mg/kg Textiles not in direct skin contact: 300 mg/kg
China	Limits of Formaldehyde Content in Textiles GB18401-2001	Textiles for infants and babies: ≤20 mg/kg Textiles in direct skin contact: ≤75 mg/kg Textiles not in direct skin contact: ≤300 mg/kg
Japan	Japanese Law 112	Textiles for Infants: not detectable Textiles in direct skin contact: 75 ppm

In addition Poland, Russia, Lithuania and South Korea now regulate formaldehyde in textiles and apparel.

Formaldehyde is also found in glues and adhesive used to bond materials to each other such as in layers of shoes and fabrics to each other. In particular, para-tertiary butylphenol (PTBP) formaldehyde resin is sometimes used. This type of formaldehyde resin can also cause allergic reactions.^{xiii}

Some have suggested that one way for the consumer to deal with residual formaldehyde on newly purchased clothing is to just wash it prior to wearing it. This is fundamentally problematic since many consumers will not heed this labeling "suggestion" and will just wear newly purchased clothing without taking the time to wash it. Additionally, further scientific evidence needs to be obtained that shows there is no residual formaldehyde on clothing even after its been washed. And finally, there are many items where formaldehyde is used and there is no opportunity for pre-washing. These items include baseball caps and footwear.

While currently there are no US standards or regulations associated with formaldehyde in clothing and textiles the American Apparel and Footwear Association (AAFA) published a 2008 Restricted Substance List (RSL) which was refined in 2009. AAFA requested that its members abide voluntarily to the standards listed. For formaldehyde the RSL suggests no detectable formaldehyde for infant clothing (0-36 months), 75 ppm for clothing in direct contact with skin (>36 months) and 300 ppm for textiles with no direct skin contact (>36 months).

In addition to formaldehyde in textiles and apparel, there are other well documented toxic chemicals that are used in clothing, furniture and other textile-based consumer items. In particular, there are two classes of dyes that are commonly used in consumer textile-based products that are widely recognized as having the potential to cause allergic contact dermatitis and possibly to cause cancer. These two dye classes are azoic (azo) and disperse dyes. There is such a widespread concern associated with the use of azo dyes in textile-based products that many countries have enacted restrictive standards and stringent regulations that limit their use. In 2002 the European Union published a Directive (2002/61/EC) to restrict the marketing and use of certain dangerous substances and preparations (azo colorants) in textile and leather products Thus, in the European Union their use is regulated by law; in the United States, at this time, there exist only voluntary standards by those companies that agree to regulate their use.

In 2006 a series of previously unreported cases of dermatitis appeared in Finland. Rantanen, a Finnish physician, reported that by 2007 "many cases from all over the country" were reported in the internet discussion forum of the Finnish Dermatological Society. After an extensive investigation it was found that the cases were due to exposure to dimethylfumarate (DMF).^{xiv} It was reported by British newspaper accounts that sachets of DMF were put in thousands of Chinese manufactured furniture items to prevent mold while in storage or while being transported.^{xv} Rantenen reported that the patients showed strong positive patch test reactions to upholstery fabric samples and to dimethylfumarate, down to a level of 1 ppm in the most severe case. It was concluded that the cause of the Chinese sofa /chair dermatitis epidemic was likely to be allergy to dimethylfumarate, a novel potent contact sensitizer. Thus, a serious health issue can occur, not from the furniture fabric but from the release of allergenic agents contained in the foam cushioning. As can be seen from the picture of a patient exposed to DMF the condition presents itself in a most devastating manner.



Patient Exposed to Dimethylfumurate in Sofa

The European Union acknowledged the dangers of using dimethylfumurate in consumer products and issued European Directive (2009/251/EC) on March 17, 2009. The directive requires that products containing DMF are not to be placed on the market. The Directive also requires any product containing DMF that has already been placed on the market be withdrawn by May 1, 2009 and that consumers be made aware of the potential risks.

Brominated chemicals, used to make fabrics flame retardant, are another class of toxic substances that is of great concern to researchers. Of particular concern to child safety advocates are flame retardant fabrics used in children's car seats. While flame retardant fabrics play a beneficial role in preventing or minimizing serious injury, the long-term harmful effects to children exposed to this class of toxic chemicals is unknown and should be a matter for further research.

Unfortunately, a recent study conducted at Philadelphia University using an X-Ray Fluorescence analyzer showed a range of bromine readings from about 0.43% to 0.86%. It is widely recognized by the research community that levels in excess of 0.1% are considered toxic. Consequently, this standard has been adopted by the European Union in the Restriction of Hazardous Substances (RoHS) standards. The RoHS Directive is an EU Legal Directive for environmental regulations concerning the Restriction of Use of Hazardous Substances. The Directive requires the removal of five hazardous substances from electric and electronic equipment (Pb, Cd, Cr, Hg, Br compounds). While these toxic compounds are restricted in electric and electronic equipment, we were concerned that the same chemical compounds might be used in children's car seats. Accordingly, an extensive chemical analysis of the fabric was conducted to determine the bromine compounds that were present in car seat fabric with relatively high levels of bromine. Two specific brominated compounds were found: Hexabromocyclododecane (HBCD) – 0.425% and Tetrabromobisphenol A (TBBPA) – 1.185%.

HBCDs are included on the OSPAR^{xvi} list of chemicals for priority action. HBCDs have been identified by the U.K. Chemical Stakeholders Forum as persistent, bioaccumulative and toxic.^{xvii} While currently no specific regulatory actions are being taken in the United States, HBCDs have been identified for risk assessment in Canada Australia and Japan. Further regulatory/assessment activities in these countries will take place over the next few years.^{xviii}

Studies suggest that HBCD affects thyroid hormone levels, causes learning and memory defects in neonatal laboratory animals, and has been detected in breast milk.^{xix} There are indications that oral exposure to HBCDs induces drug-metabolizing enzymes in rats, such as hepatic cytochrome P450 (CYP),^{xx} and that HBCDs may induce cancer by a nonmutagenic mechanism.^{xxi, xxii} There are reports that HBCDs can disrupt the thyroid hormone system^{xxiii} and affect the thyroid hormone receptor-mediated gene expression.^{xxiv} Following neonatal exposure experiments in rats, developmental neurotoxic effects can be induced, such as aberrations in spontaneous behavior, learning, and memory function.^{xxv} HBCDs can also alter the normal uptake of neurotransmitters in rat brains.^{xxvi}

TBBPAs are included on the OSPAR list of chemicals for priority action. TBBPA is known to off-gas to the environment, though the amount of off gassing varies depending how the TBBPA was combined with other materials.^{xxvii} Lab tests have suggested that it may disrupt thyroid function.^{xxviii} Studies also suggest that it may adversely affect hormone levels and the immune system.^{xxix} Histological findings showed that the slight enlargement of the hepatocytes, inflammatory cell infiltrations and focal necrosis of hepatocytes were more marked in liver of treated groups (from 350 mg/kg Body Weight) than in control group. The present data suggest the possibility of inducing hepatic lesions by TBBPA.^{xxx}

In view of my testimony and the wide body of knowledge associated with the use of toxic chemicals in textiles and apparel I believe that now is the time to look again at the issue of formaldehyde and other potential toxic dyes and finishes in textiles and apparel. It is recommended that future legislation dealing with consumer product safety should include a study on the use of formaldehyde and other known toxic dyes, finishes, and preservatives in the manufacture of textile and apparel articles, that consumer product safety standards be implemented based on the findings of these studies, and a reasonable testing program be established for textile and apparel items including components of such articles in which formaldehyde and other known toxic chemicals were used in their manufacture.

The suggested study of the use of toxic chemicals in textiles and apparel products will provide Congress the needed information to consider whether new laws and /or regulations are necessary to protect the health and welfare of American citizens.

In conclusion, I would like to again express my appreciation to the Committee and to Senator Casey for this opportunity to provide testimony on this important issue that affects the health of our citizenry. I stand ready to serve the Committee in any way in the future.

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