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Introduction

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A lack of care and precaution regarding the exposure of fetuses and children to potentially toxic substances has resulted in serious and at times tragic consequences, including the birth defects caused by thalidomide, cancers from diethylstilbestrol (DES), and the nearly universal lead poisoning of the 1970's and before, when the average child's blood lead level far exceeded the current CDC action level. Over this time, environmental health professionals have gained much greater awareness of the unique susceptibilities of children to environmental toxins. This awareness has been augmented by products of several dedicated research programs for children's environmental health that were funded during the 1990's and this decade.

While children are not universally more susceptible to toxic exposures than adults, several key features of their physiology and behaviors make them particularly vulnerable, especially at certain critical points in their development. Because young children's intake of air, water, and food are relatively larger than an adult's when measured per unit of body weight, they receive a greater dose of air pollution or ingested toxins than adults in the same situation. Children's organs, especially the brain, lungs, and reproductive system, undergo dramatic growth and differentiation, which leaves them more vulnerable to disruption from toxic exposures. Children typically engage in behaviors that put them in greater contact with many harmful substances, whether that means sticking their hands in their mouths, crawling on the floor, exploring dangerous environments without the maturity to recognize those dangers, or simply spending more time running around outdoors. Finally, fetuses and very young children have immature metabolism and excretion systems that can lead to unique susceptibility to certain toxic substances.

The recognition of children's unique susceptibilities, as well as the simple truth that healthy children are the foundation of a healthy and prosperous future, has led to the development of special protections for children's environmental health. President Clinton signed Executive Order 13045 in 1997 to assure that greater attention was paid to the protection of children from toxic environmental agents. Subsequently, Administrator Browner chartered the Children's Health Protection Advisory Committee (CHPAC) in 1998. The CHPAC is a body of university, state government, and industry scientists, pediatricians and nurses, environmental non-governmental organizations, and children's advocates who advise EPA on science and policy issues that affect children, providing recommendations directly to the Administrator in the

form of consensus letters. One of its more unique features is that this consensus is achieved among technical and policy experts from all sectors.

Over the past four years, the CHPAC has made recommendations to the Administrator on a number of science issues regarding the protection of children that have not been followed by the agency. These include recommendations for setting the level of the National Ambient Air Quality Standards (NAAQS) for Particulate Matter (PM) and Ozone, relying on a voluntary program to obtain critical information on children's risks through the Voluntary Children's Chemical Evaluation Program (VCCEP), and implementing EPA's 2005 Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens in an expeditious and health-protective manner. This testimony reviews in more detail the CHPAC recommendations and their scientific basis, and the specific EPA actions that were in conflict with those recommendations. It also highlights examples of lack of care and attention to children's susceptibility to toxic insults demonstrated by recent risk characterizations of specific chemicals.

Setting the PM NAAQS to Protect Children's Health

EPA revised the NAAQS for particulate matter on October 17, 2006. The CHPAC wrote two letters to the Administrator in 2005 and 2006 calling on him to consider the health effects in children and set the standard at a level sufficient to protect them. In addition to breathing more air per pound of body weight than adults, children experience higher levels of particle deposition in their airways, which are smaller than adult airways. Thus, the dose of fine particles to the lung is likely greater in children than adults for a given concentration in the air, particularly as they are more active. The CHPAC letters documented the health effects of particulate matter on children, including exacerbation of asthma, reduced lung function, increased chronic respiratory symptoms, infant mortality, and adverse birth outcomes. These health effects had been observed in a number of studies at exposure levels near and below the proposed standards.

The final standards selected by the Administrator for annual and daily concentrations of fine particulate matter were well above those recommended by the CHPAC, and indeed, above the range recommended by the Clean Air Scientific Advisory Committee (CASAC), the federal committee charged with evaluating EPA's assessment of the science behind the standards. In justifying the selection of these higher standards, the Administrator dismissed the agency's own

quantitative risk assessment as being inappropriate for the setting of a standard. Instead, the Administrator replaced the expert judgment of the CASAC and the agency's own risk assessment with a judgment that was not science-based that the average PM air pollution concentrations in studies where health effects are observed provide the most valid basis for setting a standard. The Federal Register notice discusses in some detail the comments from the medical and public health community that urge the Administrator to set a lower standard on the basis of greater certainty and more robust data on health effects at levels below the current standard, and the opposing comments from the business and industry groups that emphasized the uncertainty inherent in the data. In justifying his decision, the Administrator reiterated the concerns of the business and industry groups, claiming that below the mean of observed concentrations, the dose response was uncertain, without specifying how far below the mean that might occur. The Agency ultimately set standards that do not provide an adequate margin of safety for infants and children.

Setting the Ozone NAAQS to Protect Children's Health

As is the case with PM, children are uniquely vulnerable to the effects of ozone air pollution because they breathe more air per unit of body weight, roughly 80% of their lung development occurs after they are born, and they typically spend much more time outdoors, often engaged in active play. The CHPAC sent two letters to Administrator Johnson that reviewed children's unique susceptibility and reviewed some of the scientific literature that provided a basis for setting a standard that would be protective of children. The letters emphasized the special susceptibility of the nation's six million children with asthma to ozone air pollution, and cited numerous studies documenting adverse effects of ozone on this vulnerable group.

The CHPAC urged the Administrator to set the ozone standard at the bottom of the range (0.060 parts per million) indicated by the CASAC. In addition, the CHPAC noted that a number of child-specific outcomes were omitted from consideration of the benefit of reducing the ozone standard, including school absences, doctor visits, medication use, and decreased resistance to infections. Furthermore, risks to children under age five were not well considered. These effects contribute to the physical and economic burden associated with children's exposure to ozone. The CHPAC asked the Administrator to consider these uncounted benefits of lowering the ozone

standard in his final decision, in order to lend more weight to the need to choose a more protective standard.

Once again, the Administrator set the ozone standard well above the CHPAC's recommended level and above the range recommended by the CASAC. The justification for doing so, published in the Federal Register on March 27, 2008,[1] was again based in part on discounting the epidemiologic evidence of harmful affects in children at levels below the revised standard. The Administrator claimed that his choice of an appropriate level to protect public health differed from the CASAC's because of the latter's overreliance on evidence from a single clinical study and the EPA risk assessment. In fact, the CASAC's letter of October 24, 2006[2] criticized the EPA staff for not paying enough attention to the epidemiologic evidence for serious health effects occurring at low levels of exposure:

"Agency staff's analyses placed most emphasis on spirometric evidence and not enough emphasis on serious morbidity (e.g., hospital admissions) and mortality observed in epidemiology studies."

While the background justification for the standard includes studies demonstrating effects in children, the Administrator, in strong disagreement with his expert advisory panel, discounts their results. He concludes:

"A standard set at a level lower than 0.075 would only result in significant further public health protection if… the reported associations observed in epidemiological studies are, in fact, causally related to O3 at those lower levels." [3]

In other words, the Administrator, going against the recommendations of the leading air quality and public health experts on his advisory committees, concluded that the substantial body of evidence from epidemiologic studies showing ozone effects at levels below 0.075 parts per

[1] Federal Register, Volume 73, Number 60. Final Rule: National Ambient Air Quality Standards for Ozone, Environmental Protection Agency (March 27, 2008), 16435-16514.
[2] Clean Air Scientific Advisory Committee (CASAC). Letter to EPA Administrator Stephen L. Johnson, October 24, 2006. Re: Clean Air Scientific Advisory Committee's Peer Review of the Agency's 2nd Draft Ozone Staff Paper.
[3] Federal Register, Volume 73, Number 60. Final Rule: National Ambient Air Quality Standards for Ozone, Environmental Protection Agency (March 27, 2008), 16435-16514.

million could not be trusted. This results in a standard in which there is no margin of safety to protect children from ozone's damaging effects.

Protecting Children from Toxic Chemicals – the Voluntary Children's Chemical Evaluation Program and Current Chemical Risk Management Practices

The EPA is responsible for protecting the public, including the developing fetus, infants, and children, from exposure to toxic chemicals in the environment. The main regulatory authority for this responsibility comes from the 1970 statute, the Toxic Substances Control Act (TSCA). However, the large number of chemicals already in commerce before 1970 was allowed to stay on the market without any additional review or consideration. And while TSCA gives the EPA the authority to screen all new chemicals before they can be commercially sold, the reality is that this screening is limited, because there is no requirement that companies generate toxicity data before submitting these chemicals to the EPA for approval. The EPA has limited ability to request toxicity data and also has very little ability to collect data on where and how chemicals are used. While this is a problem for the general public, it is a particularly critical situation for protecting children. A number of chemicals can now be routinely found in our bodies and the bodies of children. Lead, brominated flame retardants, fluorotelomers, and bisphenol-A are well known examples. Children's health problems like autism, attention-deficit disorder, obesity, asthma, and certain cancers have risen over the past few decades, and while specific chemicals have been linked to some of these problems, there is still great uncertainty as to just what children are exposed to and what those exposures may be doing to children's health.

The CHPAC has been urging the EPA since its inception to improve the understanding and management of chemical exposures in children. The committee wrote a letter to the Administrator recommending that the Agency begin to gather the needed data to determine whether exposures to these chemicals are harming America's children, starting with prioritizing the inventory of chemicals under TSCA. While the agency has begun to analyze data collected through the High Production Volume (HPV) Chemical Challenge program and the Inventory Update Rule (IUR) to improve understanding of risks posed by existing chemicals on the market, these data are very limited in their ability to assess children's risks, and the use and interpretation of these data by the agency to date has been highly questionable. For example, under the IUR, the chemical manufacturers only need to report "readily obtainable" information on potential

exposures of children or adults to their chemicals. Manufacturers may simply state that the data were not readily obtainable, and they have no further obligations. Moreover, the Agency only asks manufacturers whether products made from their chemicals are intended for use by children. The CHPAC notes in its letter that the IUR will not provide information about early life exposures, because infants and fetuses are more likely to be exposed inadvertently through their parents' use or through the ambient environment. Information on movement of chemicals from products into the environment is also needed to improve our understanding of both exposure potential and risk. The letter notes that EPA's existing exposure screening tools are not predictive of child-specific pathways, and recommends that the Agency adapt exposure tools to encompass child-specific exposure routes and pathways (e.g., mother's milk, mouthing of objects, household dust).

Under the HPV program, manufacturers volunteered to provide a minimum base set of hazard data on chemicals produced in quantities over one million pounds. Shortcomings of the information generated include the fact that industry was allowed to group chemicals into categories and provide estimated values of hazard indicators by extrapolating from tests done on other chemicals within the category. With respect to toxicity to children, data were limited to fairly basic tests of reproductive and developmental toxicity, which are far from adequate to determine the potential for many types of effects on children and their development. EPA's new Chemical Assessment and Management Program (ChAMP) is starting to produce screening risk characterizations and prioritizations, specifically including risks to children, using the data obtained from the IUR and the HPV program. The purpose of such efforts is to prioritize the thousands of chemicals on the market for more thorough scrutiny, testing and assessment. With any screening process, to be protective of public health, it is important to avoid mislabeling a situation as safe when in fact it is not, as this stops the process of determining more definitively whether or just how harmful the situation (in this case, the chemical exposure) actually is. In particular, it is critical that any decision to place chemicals into low-priority categories be based on solid information, and that chemicals for which there is poor information upon which to base a decision be maintained as higher priority until such information can be reliably obtained. These basic scientific and public health principles are being violated by the Agency in their initial risk characterizations and prioritizations under the ChAMP.

Environmental Defense Fund (EDF) has carefully reviewed the first eight such risk documents made available by EPA. As noted above, the IUR is a problematic source of exposure data for these characterizations, especially for children, because of its voluntary nature and the limited scope of information relevant to children's exposures. Some examples of poor protection of children based on limitations of the data include the following:

- For n-butyric acid, the EPA notes that "*n*-Butyric acid is used as an intermediate, food additive, and ingredient in varnish, cosmetics and detergents." However, the company(ies) providing data under the IUR apparently stated that all production was used solely as a chemical intermediate. On the basis of this, the EPA concludes, "The IUR-based ranking for children is low due to the assumption that these chemicals will not be present in products intended for use by children." Thus, *despite clear recognition that this chemical is used as a food additive and consumer product ingredient, the EPA dismisses the possibility of exposure based on one year's worth of production and use data.*
- In its characterization of a group of dibasic esters, the EPA notes that publicly available sources state that one of the compounds is used as a food additive and all of the group are components of paint strippers, polishes, and lacquer thinners. Nonetheless, the agency concludes: "Based on IUR data, the likelihood that DMS, DMA and DMG will be used in products intended for use by children is low. Therefore, the IUR-based ranking for exposure to children is low." *EPA ignores the food additive use altogether and dismisses the paint stripper use with one sentence*: "The paint stripping consumer use described above is not likely to involve children." This claim fails to recognize that children will be exposed to chemicals in paint strippers and other products even if they do not directly use them.

These two examples highlight not only the statutory limitations restricting EPA's ability to gather necessary information, but also the insufficient rigor in EPA's efforts to protect children's health. Instead of addressing these concerns, as raised by the CHPAC, EPA has pointed to a very blunt tool, the IUR, as a sufficient way to address children's exposures. EPA must more transparently acknowledge the inadequacies in the data supplied by the IUR on children's exposures and commit to using all available sources of data in its characterizations. The agency

is also not exercising its existing authority under TSCA Section 8 reporting rules to gather the necessary data to assess children's exposures and risks more thoroughly.

In a separate effort to collect and assess the scientific information needed to protect children's health, the EPA initiated the Voluntary Children's Chemical Evaluation Program, starting with a pilot project in 2000. Its stated goal is to ensure that there are adequate publicly available data to assess risks from environmental exposures to chemicals known to be of concern to children, and the pilot project was intended to quickly pave the way for a more comprehensive review program. Eight years after the pilot program's initiation, progress is meager at best. Of the 23 chemicals nominated for the pilot because of clear demonstration of children's exposure:

- 3 were never sponsored by industry;
- 5 never had data submitted by industry;
- 3 had data submitted by industry, but no decision on data needs has yet been made by EPA;
- 12 have completed at least the first tier of the program.

There is still no user-friendly source of VCCEP information that the general public can access to find out about potential risks to children. The public may download reports one chemical at a time and read them, or travel to Washington, DC to read these documents in the EPA's Reading Room. At this rate of 1.5 chemicals per year making it through just the first tier of three within the program, the EPA does not appear to be placing adequate priority on assembling the scientific data needed to determine and then act upon chemical risks to children. This is underscored by the fact that the program appears to have ground to a complete halt at present. A mandatory review of the pilot took place in the Fall of 2006, with a summary of the (largely critical) comments received published in March of 2007. Since then, over a year later, there still is no indication of EPA's plans to revise, resume, or replace this inadequate program. The CHPAC's comments on the weaknesses of this program have not been addressed by EPA.

EPA's Supplemental Guidance for Assessing Susceptibility from Early-Life Exposures to Carcinogens

The rapid turnover and differentiation of their cells make children more susceptible to developing certain types of cancer. It can also enhance the effect of cancer-causing chemicals, making them relatively more potent in children than in adults. Thus, exposures to cancer-causing chemicals during childhood may sow the seeds for the development of cancer later in life. A growing body of scientific evidence documenting this window of greater susceptibility in children led EPA scientists to recommend adjustments to the way risk assessments are performed for cancer-causing chemicals that account for this enhanced potency. But a subsequent EPA document providing more specific guidance on the conduct of cancer risk assessments has ensured that vanishingly few cancer-causing chemicals will ever meet the criteria to be treated as more potent in children. By using the narrowest possible definition of one particular mechanism of causing cancer, the agency has strayed from usual risk assessment practices and backed off from providing greater protection for children in accordance with their greater susceptibility. The following paragraphs tell this story in greater detail.

In March 2005, EPA issued new guidelines for assessing the risk of cancer from exposure to chemicals in the environment. The guidelines were accompanied by a supplement describing the assessment of cancer risk when exposure occurs during infancy and childhood. The agency was not talking strictly about childhood cancers, but rather the risk of developing cancer over a lifetime due to exposures that occur early in life. The EPA staff scientists thoroughly analyzed the available information on the effects of cancer-causing chemicals given to immature animals versus mature animals. They also looked at the available evidence in humans. Their analysis indicated that many cancer-causing chemicals produced worse results – that is, higher tumor incidence – when the exposures happened before the animals matured. Standard cancer risk assessment practices are based on toxicological studies that only expose animals after maturity.

Chemicals can cause cancer a number of ways: by directly damaging DNA, by causing DNA damage indirectly, or by changing the expression of DNA. The EPA report noted that cancer-causing chemicals were most potent in early life if they acted by causing DNA damage in the form of mutations, although there was uncertainty about whether other types of carcinogens would also be more potent in children. The Agency decided that exposures occurring in infancy and childhood should be considered more dangerous only when there was evidence for mutations and declined to consider the chemicals that caused cancer by other means. This decision leaves out chemicals like DES, which acts via hormonal mechanisms but clearly still displays increased

potency with early life exposures. For DNA damaging chemicals, the guidelines require the risk assessor to apply a potency factor of 10 for exposures occurring between birth and 2 years of age, and a 3 fold increase in potency between 2 and 15 years of age. The CHPAC closely followed and made recommendations on the development of the SG in 2004 and 2005.

The Agency subsequently wrote a document to guide their staff in implementing the SG by more precisely defining the mutagenic "mode of action" (MOA) for cancer. Unfortunately, this framework greatly restricts the implementation of child-specific potency factors. The Agency asserts that data showing the chemical is mutagenic is not sufficient to use the child protective factors. Rather, the Agency proposal requires very detailed information on how a chemical reacts with the DNA and where in the process of tumor formation this interaction occurs. These data are almost never available. In fact, these data are not available for most of the chemicals that the staff scientists used as examples to document increased potency in early life. Thus, the Framework greatly restricts the application of the extra potency factors for early life exposures. This has the effect of not taking into account children's unique susceptibility to carcinogens in regulatory pollution limits that affect air, water and soil.

The CHPAC wrote a letter to the Administrator recommending that the Agency not further delay implementation of the 2005 SG for children and re-draft this framework in a manner that is more consistent with standard risk assessment practice and with the underlying science. EPA's sent their guidance to a Peer Review panel, which met on April 4, 2008. This panel had similar concerns to those expressed by CHPAC. In the meeting, the panel stated that the Agency should use the children's potency factors with all carcinogens until the data are available showing the factors are unnecessary. The EPA has not adequately addressed the CHPAC concerns and still appears to intend to create a high burden of proof to apply the potency factors. This not only is inadequate to protect public health, but it also creates a strong disincentive for industry to do key testing on children's vulnerabilities.

Conclusion

Taken as individual phenomena, none of these examples might stand out as remarkable, but when considered as a whole, a picture emerges of an agency whose senior leadership has repeatedly chosen to stray from the clear and science-based recommendations of expert advisory

panels, public health organizations and advocates, and in some cases even its own career staff scientists, in order to make policies and decisions that fall short of adequately protecting children as well as the general public. In some cases, these policies and decisions are justified on the basis of arguments that run counter to established scientific principles and the judgments of the most prominent experts in the country. In other cases, these policies and decisions are made with little justification whatsoever. I applaud this committee for its effort to shine a light on the misuse of science within the EPA. Greater transparency in agency decision-making and greater adherence to the recommendations of the agency's scientific experts will help bolster public trust in the agency and lead to greater protection of the public's health.