Thank you for the opportunity to provide testimony today on this critical topic. My name is Pete Myers and I am the founder, Board Chair and Chief Scientist of Environmental Health Sciences, a 501(c3) that promotes public understanding of key issues in how environmental factors affect human and wildlife health. I am also Adjunct Professor of Chemistry at Carnegie Mellon University and a Founder and Board Member of Sudoc.com.

You have invited me to address the issue of plastic additives and human health. Over the last 30 years a huge scientific literature has arisen that explores this wide and deep issue. There are many dimensions to it. I will cover highlights and point to sources that go deeper. But let me begin by reporting that I have read Judith Enck’s testimony and strongly endorse each point she makes. Fixing the plastics issue is a wicked problem that requires federal and international leadership. Too many decisions about plastic safety were made in ignorance. And now we live and suffer with the consequences.

Here are two overarching realities of plastic:

- There is no single “plastic”… there are virtually an unlimited number of plastics that vary in composition because of:
  - choice of monomer (the basic building block of the polymer chain),
  - choice of additives (thousands of ingredients that can be added to change the material characteristics of the plastic into something a chemical engineer can use to make a product, and
  - “non-intentionally added substances” or NIAS, which are there because of impurities in ingredients that are intentionally added, because of reactions between the chemicals, because of air pollution in the facilities where the plastic is being made, etc.

- Each of these three choices can introduce toxicities into plastics. Therefore, I am going to broaden your request to me to consider all three, not just additives.

Plastic is not inert. Biologically it can be very active. How active depends upon the choice of monomer, the additives and the NIAS. It also depends upon the wear and tear of the plastic, for example, because worn plastic can leach ingredients more rapidly.

The combined effect of these two realities is that plastic cannot be considered “safe” until it is thoroughly tested. And no plastic has ever been thoroughly tested using the tools of modern, 21st century medical science. The closest to a thorough test has been Bisphenol A (BPA) in the US NIEHS/FDA/NTP $30M
experiment called CLARITY-BPA. This research revealed many toxic attributes, which the FDA chose to ignore by invoking a thoroughly falsified 16th Century assumption.¹ [See attachment 1.]

Endocrine disruption is an essential piece of the story of plastic toxicity (See Infographics 1 and 2). Many of the ingredients of plastics disrupt hormone action. They are called endocrine disrupting compounds (EDCs).

Hormones are chemical signals that govern vital physiological and genetic processes in our bodies. They guide development of the fetus to adulthood, controlling how our nervous system is wired, how our reproductive tract grows, how our organs form and mature, whether our immune system works. When those chemical signals get hacked by chemical agents, the effects can be ruinous.

- I began working on endocrine disruption in 1989, when it didn’t have a name.
- In 1991 I coined the term ‘endocrine disruption’ at a scientific meeting in Wisconsin.
- In 1996 I co-authored a book, Our Stolen Future, the first book for the general public on endocrine disruption. It included passages about the effect of plastic ingredients on human health.
- That year, Congressman John Porter, Republican of Illinois and then Chairman of the House Subcommittee on Health Appropriations invited me to attend hearings on the NIH Budget. Dr. Harold Varmus, Director of the NIH, was testifying. In the middle of the hearing Porter held up Our Stolen Future, pointed at it, and said “Dr. Varmus, you need to read this book.”

Now, almost 25 years later,

- Over a billion dollars have been invested around the world in scientific research on endocrine disruption.
- 10s of thousands of papers have been published about it in the peer-reviewed literature.
- Our understanding of how EDCs work has been vastly deepened.
- A lot of this research has been on plastics and what is in them

The bottom line is that it is much worse than we realized 25 years ago. It’s on a scale of bad somewhere near, if not equal to, climate change. And some of its worst impacts may strike well before climate change’s worst consequences unfold.

The Endocrine Society, the world’s largest professional association of doctors and scientists specializing in hormone related diseases, has identified endocrine disruption as its top public policy issue, because its membership is on the front lines of witnessing, and treating, a wave of non-communicable endocrine-related epidemics that research has revealed are at least in part caused by endocrine disruption.²

All that research has made it very clear that common chemical exposure levels... levels that people encounter every day... can have severe effects (Infographic 3).

Hundreds of epidemiological studies published in the last 20 years support that assessment, as do thousands of laboratory studies with animals, cells and cellular machinery.

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¹ Data integration, analysis and interpretation of eight academic CLARITY-BPA studies. doi: 10.1016/j.reprotox.2020.05.014
ENDOCRINE DISRUPTING CHEMICALS (EDCs) ➤ What Policymakers Need to Know

What are EDCs?
Endocrine Disrupting Chemicals (EDCs) are chemicals that mimic, block, or interfere with hormones in the body's endocrine system.

To Understand EDCs, We Must Understand Hormones
Hormones are tiny molecules that are the body's chemical messenger system: they tell different parts of the body what to do. Hormones are produced and released by the body's endocrine organs, such as the thyroid, ovary, and pancreas. Hormones travel through the blood to affect the activity of distant cells.
Hormones influence every system in the human body, from reproduction to energy expenditure, and also guide development and growth in early life.
There are more than 50 hormones, such as estrogen, testosterone, insulin, and adrenaline.
Hormones interact with proteins called hormone receptors. Cells respond to a hormone only if they have the receptors for that hormone.

How do EDCs Work?
Endocrine disruptors do just that: disrupt hormones. Scientists have identified key ways that EDCs can affect the body.
EDCs can, for example:
- bind with (activate) hormone receptors
- block (inhibit) hormone receptors
- alter the production of hormones
Some EDCs act on a single hormone, while some can interfere with several hormone systems at once.

If EDCs cause biological effects, are the effects necessarily harmful?
Since we don't know all the long-term consequences of hormonal disruptions caused by EDCs, any exposure could be "adverse" in the long run. What we now know is much worse than what we knew in 1990.

What EDCs are Not
Some argue that even a chocolate bar is an EDC because it increases levels of the hormone insulin.
This is not the case, since eating any food results in increased insulin production.
Rather, an EDC would be a chemical that interferes with the amount of insulin produced after eating, or the ability of insulin to maintain blood glucose control.

Why are EDCs Important?
- We are all exposed to hundreds of EDCs throughout our lives.
- Like hormones, EDCs have health effects at tiny levels—at levels to which people are commonly exposed. Unless you test for EDC characteristics, you don't know if a chemical is safe.
- Exposure to EDCs during development can have lifelong, permanent health effects. But EDCs can cause adverse effects throughout life.

Understanding what EDCs are and their effects will help guide smart policy.

For sources, resources, and to keep up to date on endocrine disruptor science, visit EESciences.org.
Environmental Health Sciences is a nonpartisan U.S. 501(c)(3) corporation permanently dedicated to public benefit and education.

Infographic 1.
Do plastic additives harm human health? Yes.

Many plastic additives disrupt hormone signaling. That makes them endocrine disrupting chemicals (EDCs), which links them to many of today’s epidemics of non-communicable diseases, like breast cancer, testicular cancer, infertility, immune disorders, and brain impediments, including ADHD, autism and degenerative neurological disorders.

Sometimes the toxicity stems from additives which are mixed with the pure plastic. Additives alter the material characteristics of the basic plastic so that engineers can make products, like converting a hard plastic into a soft one.

But plastic additives are not the only source of harm from plastics. Sometimes it’s caused by the monomers, the backbone of plastic chains. Sometimes it’s impurities in the ingredients that interact chemically with the additives or other impurities. Very often we don’t even know their identity, but we do know they are there.

Most chemicals in plastics have never been tested for safety. A few, like BPA, phthalates, perfluorinated compounds (PFAS, the “forever chemicals”), are notoriously hazardous. Studies from Europe demonstrate that even there chemicals “of very high concern” are regularly used in plastics. Even bio-based plastics can have toxic characteristics.

You can’t assume plastics are safe. If you don’t test using tools from 21st century science, you don’t know. Most chemicals in plastics were grandfathered into commerce as “safe,” before we understood how endocrine disrupting chemicals cause damage. We have a lot of catching up to do.

And, unfortunately, most of the readily available substitutes for hazardous chemicals were designed using the same flawed design criteria as the chemical they are replacing. This has led to endless cycles of replacement with what turn out to be regrettable substitutes.

If you don’t test, you don’t know.

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ENDOCRINE DISRUPTING CHEMICALS (EDCs) ▶ What Policymakers Need to Know

Do EDCs Affect Health at Low Doses? Yes.

*Hormones work at very low doses* — parts per billion and below. They are chemical signals that control when genes are turned on and off. This process is crucial to all of life, including how fetal humans become adults, whether our immune system works properly, how are brains are wired, whether we are fertile, and much more.

**EDCs hack hormone signaling.** Very low doses of EDCs can interfere with hormone signaling and have severe health effects. Typically, EDCs do not kill directly. They are not poisons. But by hacking hormones they can dramatically undermine our health.

**But “low doses” doesn’t mean “little exposure.”** Toxicologists traditionally consider a part per billion to be a low dose. But how many molecules of BPA are in one drop of water in which the dose is one part per billion? There are approximately 2.65 trillion molecules of BPA in that one drop.

**A core business of the endocrine system is to amplify hormonal signals so they cause important physiological and developmental effects.** A single hormone molecule’s effect can be amplified more than a million-fold. The same is true for EDCs. Only a few molecules can be amplified in ways that cause serious adverse effects. When you have 2.65 trillion molecules in each drop, that creates the possibility for significant harm.

**Serious scientific research indicates that EDCs are associated with a wide array of today’s non-communicable disease and disability pandemics:**

- Breast cancer
- Prostate cancer
- Interference with chemotherapy

- Infertility including low sperm count
- Decreased effectiveness of artificial reproductive technology

- Obesity
- Type 2 diabetes
- Mis-wired brains

**Understanding what EDCs are and their effects will help guide smart policy.**

For sources, resources, and to keep up to date on endocrine disruptor science, visit ENSciences.org.

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Infographic 3.
The Endocrine Society periodically assesses the state of EDC science (as well as publishing peer-reviewed journals that carry original EDC research). In the most recent assessment, published in 2015, they state that the evidence is strongest for: “1) obesity and diabetes; 2) female reproduction; 3) male reproduction; 4) hormone-sensitive cancers in females; 5) prostate; 6) thyroid; and 7) neurodevelopment and neuroendocrine systems.”3

The published evidence since then has only become stronger. For example:

Relevant to human reproduction:

- In November 2022, Levine, Swan et al. published strong evidence showing that sperm counts world-wide continue to decline... by over 50% over the period 1973-2018, and that the decline is speeding up.4
- This decline is linked by strong evidence from other research to exposure to chemicals common in plastics, including phthalates, bisphenols and perfluorinated compounds. The crucial exposure is when the baby is in the womb. The impacts manifest later in life.5
- If current trends continue, average sperm counts around the world will approach zero by 2045. Most of today’s infant boys when they mature will be unable to have babies the old-fashioned way. Artificial reproductive technologies will be necessary for most couples.

- Research on PFAS in Italy “found increased levels of PFCs and seminal fluid positively correlate with circulating testosterone and with a reduction of semen quality, testicular volume, penile length and ano-genital distance (a marker of maleness). Experimental evidence supports our observational results and points toward antagonistic action of PFOA on the binding of testosterone to its natural androgen receptor.”
- Moreover, exposure to bisphenols can decrease the success of artificial reproductive technologies.6

Plastic chemicals rewire the developing brain:

- Epidemiological studies link brains exposed during development to plastic chemicals to neurological disorders such as ADHD and autism.7,8,9
- One expert on how chemicals alter thyroid signaling, which plays a powerful role in guiding brain development, has predicted that if the increases in autism in the US continue to grow

Footnotes:


5 Count Down: How our modern world is threatening sperm counts, altering male and female reproductive development, and imperiling the future of the human race. Swan and Colino. Scribner, NY.

6 Urinary bisphenol A concentrations and early reproductive health outcomes among women undergoing IVF. https://doi.org/10.1093/humrep/des328

7 Prenatal phthalates, maternal thyroid function, and risk of Attention Deficit Hyperactivity Disorder in the Norwegian Mother and Child Cohort. https://doi.org/10.1289/EHP2358

8 Gestational exposures to phthalates and folic acid, and autistic traits in Canadian Children. https://doi.org/10.1289/EHP5621

9 Bisphenol A exposure in children with autism spectrum disorders. DOI: 10.1002/aur.1444
exponentially, as they have since the 1970s, by 2045 one in two US children will be on the autism spectrum.  

Plastic chemicals contribute to obesity and type 2 diabetes:

- Animal experiments exposing fetuses in the womb to EDC chemicals common in plastic cause morbid obesity in adulthood.  
- Elegant cell and animal experiments show that very low doses of BPA induce insulin resistance and type 2 diabetes.  
- These studies are consistent with multiple human epidemiological findings.  

Plastic chemicals may be driving the increases in obstructed bladder syndrome (OBS), where men have difficulty urinating. Think about your experience in a public restroom. How often do guys have problems urinating? In the developed world, OBS can be managed pharmaceutically and sometimes via surgery. In the developing world without advanced health care, OBS is a death sentence because it leads to kidney failure. For people in the US without sufficient health insurance to cover the intensive treatments required, OBS is also a death sentence.  

- The only animal model that manifests obstructed bladder syndrome is caused by BPA exposure in the womb, coupled with natural hormonal changes that occur as men age. It can also be induced by an adult exposure to BPA when fetal exposure had preceded adult exposure. This “second-hit” pattern is common in EDC studies. Fetal exposure sets it up. A second exposure later in life seals the deal.  
- A 6-year prospective epidemiological study found that BPA is a predictor of chronic kidney disease and high blood pressure in men.  

Plastic-related EDCs are strongly implicated in causation of cardiovascular disease, the leading cause of death for men and women and people in most racial and ethnic groups in the US. A now famous prospective study reported that levels of BPA measured in adult men was a strong predictor of heart disease victims a decade later. Phthalates are also associated with cardiovascular diseases.

Perhaps the biggest surprise in EDC research over the past 30 years has been the discovery and repeated reporting of “transgenerational epigenetic inheritance,” including with plastic-related chemicals such as organotins, bisphenols and plastics. Fetal exposure during crucial windows of development cause effects not only after birth, but those same (and related) effects are carried on to subsequent generations, with no changes in DNA sequence. What changes are the control mechanisms (epigenetic) for how hormones

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11 Obesity II: Establishing causal links between chemical exposures and obesity. doi: 10.1016/j.bcp.2022.115015  
12 Endocrine disruptors in the etiology of type 2 diabetes mellitus. doi:10.1038/nrendo.2011.56  
13 Interactive effects of perinatal BPA or DES and adult testosterone and estradiol exposure on adult urethral obstruction and bladder, kidney and prostate pathology in male mice. doi: 10.3390/jmzs21113902  
14 Serum bisphenol A as a predictor of chronic kidney disease progression in primary hypertension: a 6-year prospective study. DOI:10.1097/HJH.0000000000000780  
16 Urinary bisphenol A concentration and risk of future coronary artery disease in apparently health men and women. DOI: 10.1161/CIRCULATIONAHA.111.069153  
17 Phthalates implications in the cardiovascular system. https://doi.org/10.3390/jcdd7030026
turn genes on and off. The details of the mechanisms are still under study but the phenomenon, however it is caused, is real.\textsuperscript{18} This phenomenon is especially troubling for safety testing of chemicals because sometimes adverse effects do not appear until the second generation after fetal exposure to the first generation.

Recent studies demonstrate that plastics in medical equipment can undermine chemotherapy for breast cancer, including increasing the risk of relapse and death.\textsuperscript{19}

**Recommendations:**

As I stated early in this testimony, the plastic problem is wicked. There are no silver bullets. But there are important steps to take beginning now that can reduce the threat that plastics represent for our health and environment.

**Re-think:** Many applications of single use plastics are not essential. Packaging can be reduced and eliminated. Re-use and re-fill systems can be implemented that dramatically reduce the need for single use packaging. Serious efforts should be made to identify the essential uses of plastics vs. non-essential. Decisions on what is essential should be made by parties with no conflicts of interest.

**Reform:** The regulatory system needs to be reformed by (1) incorporating 21st century biomedical science in its assessments of safety and (2) eliminating conflicts of interest that currently pervade the system. See Attachment 1 and Infographic 4 (next page).

**Redesign:** There are essential uses of plastic, especially in medicine. But chemists should be given the challenge of creating safer materials to use when the services of the material are required. We know enough now from all the research that’s been conducted on endocrine disruption to help chemists avoid EDC characteristics in the design of new materials.\textsuperscript{20}

The US should study the approach upon which the European Union is now embarked: The Chemical Strategy for Sustainability.\textsuperscript{21} It embraces modern biomedical science, based upon endocrinological principles to avoid EDC hazards. It is structured around the issue of essential use. And its implementation will involve major commitments to funding sustainable chemistry.

\textsuperscript{18} Molecular mechanisms of transgenerational epigenetic inheritance. https://www.nature.com/articles/s41576-021-00438-5
\textsuperscript{20} Designing endocrine disruption out of the next generation of chemicals. https://pubs.rsc.org/en/content/articlelanding/2013/gc/c2gc35055f#divAbstract
ENDOCRINE DISRUPTING CHEMICALS (EDCs) ➤ What Policymakers Need to Know

Five Fatal Flaws of today’s chemical testing for safety

Most regulatory toxicology tests used to evaluate endocrine disruption are inadequate to the task.

1. Most tests ignore today’s diseases
   - Most tests are based on decades-old methods, and look for effects on things like organ weight, but not for effects relevant to today’s common diseases or disabilities.
   - Most tests only look for short-term, not long-term health effects.
   - Most tests do not evaluate endocrine disruption, these tests require endocrinological expertise, which most traditional toxicologists do not have.

2. Most chemicals are only tested at high doses, not low doses
   - Endocrine disrupting chemicals (EDCs) affect different genes at different doses, which can lead to specific effects at low doses, but different effects at high doses.
   - This doesn’t mean that high doses are safe; other adverse effects occur at high doses.
   - Because regulators only test at high doses, they never detect the low dose effects.
   - Testing only high doses cannot predict all the health effects of our current exposures.

3. Chemicals are tested one at a time, not in mixtures
   - What’s the first question your doctor asks when she prescribes a new medicine? “What medicines are you already taking?”
   - That’s because chemicals mixed in our bodies interact, and those interactions can alter the effects of exposure.
   - We are all exposed to mixtures of chemicals, all the time, and these mixtures have not been tested for safety.

4. Chemicals are not tested for transgenerational effects
   - Exposures during development can lead to permanent health effects in later generations without changes in DNA sequence or gene mutations.
   - Sometimes the exposure causes no detectable effect on the fetus; effects only begin to appear in the second generation.

5. Regulators ignore independent research
   - Regulators discard studies done by independent university researchers, which are of much higher quality than standard regulatory testing.
   - The criteria used to discard university research are arbitrary and biased.
   - University-based research is conducted by the world’s best scientists, peer-reviewed, and funded by governmental institutes of health. Yet it is still ignored by regulators.

Understanding what EDCs are and their effects will help guide smart policy.

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