Congress of the United States
House of Representatives
Washington, DC 20515–0545

February 18, 2021

Janet Woodcock, M.D
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Acting Commissioner Woodcock:

We write to you today about the well-established harms of certain toxic chemicals. We call on the Food and Drug Administration (FDA) to prioritize reviewing and updating the agency's 2002 guidelines on the use of phthalates and other endocrine-disrupting chemicals (EDCs) in IV containers and other medical devices.[1] American patients receiving care in hospitals and other settings are overly exposed to dangerous levels of phthalates, a family of toxic chemicals including diethylhexyl phthalate (DEHP) and other EDCs.[2] This critical patient safety issue has been the subject of extensive research over the last few decades, but thus far the guidance to protect patients from these harmful chemicals has done very little to actually reduce the use of the chemicals' use in health care settings. Nearly 20 years after the FDA's first guidance was issued on this subject, the time has come to take aggressive and necessary steps forward to protect patients' lives.

DEHP belongs to a family of chemicals called phthalates, which are added to certain plastic products to increase their flexibility. There is no question that the use of DEHP in IV bags and other medical devices harms patients: The evidence of patient exposure to DEHP and other toxins during the course of clinical care is well established, and science continues to demonstrate the need to reduce patient risk from such exposure.[3] The European Union has determined that DEHP is a reproductive toxicant and endocrine disruptor, and in 2017 adopted regulations requiring a benefit-risk assessment before certain phthalates (including DEHP) can be used in medical devices.[4] The State of California has determined that DEHP is a reproductive and developmental toxicant and a carcinogen, and advises patients to request devices that do not contain DEHP when undergoing medical treatment.[5] In 2002, based on the agency's 2001 safety assessment of DEHP, FDA recommended that health care providers "consider" alternatives to DEHP

[1] Food and Drug Administration [Docket No. 02D–0325] Medical Devices; Draft Guidance; Medical Devices Made With Polyvinylchloride Using the Plasticizer di-(2–Ethylhexyl)phthalate; Availability, Food and Drug Administration, Retrieved at: https://www.govinfo.gov/content/pkg/FR-2002-09-06/pdf/02-22687.pdf
[2] Polyvinyl chloride in health care, A rationale for choosing alternatives, Health Care Without Harm, Retrieved at: https://noharm-uscanada.org/sites/default/files/documents-files/6222/Polyvinyl%20chloride%20in%20health%20care%20-%20A%20rationale%20for%20choosing%20alternatives%20-%201-31-2020.pdf
[3] NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Di(2-Ethylhexyl) Phthalate (DEHP), National Toxicology Program, Department of Health and Human Services, Retrieved at: https://ntp.niehs.nih.gov/ntp/ohat/phthalates/dehp/dehp-monograph.pdf
[4] Guidelines on Phthalates in Medical Devices, European Commission, Retrieved at: https://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scheer_consultation_08_en
[5] Di(2-ethylhexyl)phthalate (DEHP), State of California, Retrieved at: https://www.p65warnings.ca.gov/fact-sheets/di2-ethylhexylphthalate-dehp

when conducting procedures on high risk patients.[6] This was followed by repeated echoes from the medical community to do the same: The American Academy of Pediatrics warned about pediatric exposure and potential toxicity of phthalates in a technical report;[7] the American Medical Association passed an organizational resolution for members encouraging alternatives to DEHP products;[8] and the American Public Health Association issued a policy statement discouraging the use of DEHP and other phthalates in facilities that serve vulnerable populations.[9]

Despite these findings and the growing body of evidence that has confirmed earlier research and identified additional risks of adverse health effects on vulnerable patients, there has been minimal progress in the US over the last 20 years in reducing the use of DEHP in medical devices.[10,11,12] Even though DEHP-free IV containers have been available in the marketplace for over 40 years and are manufactured by multiple suppliers, it is estimated that over 60 percent of the more than 400 million IV bags used in the US each year are made from DEHP.[13] The infusions that occur with these IV bags, which can contain up to 40 percent DEHP by weight, can result in the leaching of high dosages of DEHP to individual patients.[14]

Patients should not be exposed to phthalates and EDCs when they seek medical treatment. It's also not something that parents should worry about when their infant is receiving critical treatment in the neonatal intensive care unit (NICU). We agree with the sentiment of researchers at the University of Illinois, as expressed in a recently published article: "It is time for a reckoning in the healthcare community to address our role in exposing patients to potentially harmful chemicals and to devise a path forward to address the ethical and clinical implications of this poorly understood iatrogenic risk."[15]

To address these concerns, we are requesting that you establish an FDA senior level working group to:

1) Review and update FDA guidelines on the use of phthalates and other EDCs in IV containers and other medical devices;

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[6] Safety Assessment of Di(2-ethylhexyl)phthalate (DEHP) Released from PVC Medical Devices, Food and Drug Administration, Retrieved at: https://www.fda.gov/media/114001/download

[7] Pediatric Exposure and Potential Toxicity of Phthalate Plasticizers, American Academy of Pediatrics, Retrieved at: https://pediatrics.aappublications.org/content/pediatrics/111/6/1467.full.pdf

[8] Encouraging Alternatives to PVC/DEHP Products in Health H-135.945, American Medical Association, Retrieved at: https://policysearch.ama-assn.org/policyfinder/detail/pvc?uri=%2FAMADoc%2FHOD.xml-0-316.xml

[9] Reducing PVC in Facilities With Vulnerable Populations, American Public Health Association, Retrieved at: https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2014/07/08/15/13/reducing-pvc-in-facilities-with-vulnerable-populations

[10] Impact of Di-2-Ethylhexyl Phthalate Metabolites on Male Reproductive Function: a Systematic Review of Human Evidence, Curr Environ Health Rep, Retrieved at: https://pubmed.ncbi.nlm.nih.gov/29468520/

[11] Phthalate exposure and childrens neurodevelopment: A systematic review, Environ Res., Retrieved at: https://pubmed.ncbi.nlm.nih.gov/26101203/

[12] Systematic reviews and meta-analyses of human and animal evidence of prenatal diethylhexyl phthalate exposure and changes in male anogenital distance, J Toxicol Environ Health B Crit Rev, Retrieved at: https://pubmed.ncbi.nlm.nih.gov/30199328/

[13] Saline Shortages – Many Causes, No Simple Solution, NEJM, Retrieved at: https://www.nejm.org/doi/full/10.1056/NEJMp1800347 and Analysis of Global Healthcare Exchange (GHX) data (GHX is a global healthcare and data automation company)

[14] Health risks posed by use of Di-2-ethylhexyl phthalate (DEHP) in PVC medical devices: A critical review, American Journal of Industrial Medicine, Retrieved at: http://www.sustainableproduction.org/downloads/DEHP%20Full%20Text.pdf

[15] Unwitting Accomplices: Endocrine Disruptors Confounding Clinical Care, Journal of Clinical Endocrinology & Metabolism, Retrieved at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7442273/

2) Identify and recommend additional regulatory actions needed to reduce patient exposure to harmful toxins, including but not limited to the labeling of medical devices containing phthalates and EDCs; and
3) Establish an education program to build clinician awareness of the risks of using medical devices that contain harmful toxins.

The time for action on this health risk to patients is long overdue. We implore you to take the steps necessary to protect Americans from harmful exposure to toxins in medical devices, and thank you for your attention.

Very Truly Yours,

KATIE PORTER
Member of Congress

SUSAN WILD
Member of Congress

JACKIE SPEIER
Member of Congress

JAN SCHAKOWSKY
Member of Congress

LUCILLE ROYBAL-ALLARD
Member of Congress

ANNA ESHOO
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