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NYS AAP (District II)

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PHYSICIAN AND SCIENTIST
NETWORK ADDRESSING
PLASTICS AND HEALTH



Alliance of Nurses for
Healthy Environments



National
Association of
Neonatal
Nurses



To the members of the New York Legislature,

We, the undersigned nursing and health organizations, write to share our support for legislation which would remove and reduce patient exposure to Di-(2-ethylhexyl) phthalate (DEHP), polyvinyl chloride (PVC), and other regrettable substitutes. Each year over 90% of U.S. hospital patients¹ receive intravenous (IV) therapy or infusions, with IVs providing a delivery route for medicine, fluids and nutrition. Most of these IV bags and tubes are made with PVC plastic which requires a plasticizer like Di(2-ethylhexyl) phthalate (DEHP)² to make the plastic soft and flexible. A particularly troubling route of exposure to DEHP is through intravenous bags and tubing. In a study reviewing 72 single-use medical products, DEHP was found in 99% of samples tested for leaching.³ PVC, throughout its life cycle from production through disposal, exposes communities and workers to vinyl chloride which has been linked to cancer, liver damage, and both developmental and neurological effects.⁴ In fact, PVC cannot be produced, used and disposed of without using (and releasing) some of the most harmful, persistent, bioaccumulative, or toxic chemicals substances into the environment.⁵

¹ Puolitaival, A., Savola, M., Tuomainen, P., Asseburg, C., Lundström, T., & Soini, E. (2022). Advantages in management and remote monitoring of intravenous therapy: Exploratory survey and economic evaluation of gravity-based infusions in Finland. *Advances in therapy*, 39(5):2096-2108. <https://doi.org/10.1007/s12325-022-02093-6>

² Breast Cancer Prevention Partners. (2024). *Toxic free IV: Getting harmful chemicals out of IV bags and tubing*. https://www.bcpp.org/wp-content/uploads/2024/08/BCPP_Toxic-Free-IV-Report_August-2024.pdf

³ Wang, Y., & Qian, H. (2021). Phthalates and their impacts on human health. *Healthcare (Basel, Switzerland)*, 9(5), 603. <https://doi.org/10.3390/healthcare9050603>

⁴ Agency for Toxic Substances and Disease Registry (ATSDR). (Last reviewed: January 19, 2024). *ToxFAQs™ for vinyl chloride*. <https://wwwn.cdc.gov/TSP/ToxFAQs/ToxFAQsDetails.aspx?faqid=281&toxid=51>

⁵ Toxic Free Future. (2019) Connecting the dots between plastic, mercury, asbestos and pfas. <https://toxicfreefuture.org/blog/connecting-the-dots-between-plastic-mercury-asbestos-and-pfas-a-new-report-confirms-pvcs-toxic-life-cycle/#:~:text=A%20new%20catalog%20of%20the,per%2D%20and%20polyfluoroalkyl%20substances>

There is nearly 50 years of research demonstrating that exposure to phthalates, such as DEHP, are linked to many adverse health effects. Di(2-ethylhexyl) phthalate is a potent [endocrine disruptor](#)⁶ for which there is [no safe level of exposure](#).⁷ Health effects from DEHP exposure include [breast and other cancers](#),⁸ [developmental and reproductive effects](#)⁹ including lowered male fertility, [metabolic disorders](#)¹⁰ such as [obesity](#)¹¹ and [type 2 diabetes](#),¹² and negative impacts on [brain development](#)¹³ including attention deficit hyperactivity disorder (ADHD).

Susceptible populations, including neonates, young children, those who are pregnant, and patients receiving cancer treatments, may face the most significant risks from DEHP exposure. Research also shows that elevated in utero exposure to phthalate mixtures is associated with poorer infant executive function and motor reflexes and autism spectrum behaviors.¹⁴ The [continued use of DEHP is particularly concerning for newborns](#) in neonatal intensive care units (NICUs) due to the daily intensive medical interventions they receive, their reduced ability to remove these contaminants from their bodies, and their higher sensitivity to endocrine disruptors from medical devices and plasticizers used in the NICU.¹⁵ Exposure to DEHP is [linked to adverse health effects in infants](#) including early and chronic complications of prematurity, negative effects on neonatal and postnatal growth, and neurodevelopmental concerns including inattention and hyperactivity.¹⁶

⁶ European Chemicals Agency (December 11, 2014). *Bis(2-ethylhexyl) phthalate (DEHP)*. <https://echa.europa.eu/documents/10162/fa429d23-21e7-4764-b223-6c8c98f8a01c#:~:text=DEHP%20has%20been%20shown%20to,in%20the%20steroidogenic%20biosynthesis%20pathway>.

⁷ Agency for Toxic Substances and Disease Registry. (2022, January). *Toxicological profile for Di(2-Ethylhexyl)Phthalate (DEHP)*. <https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=684&tid=65>

⁸ Yang, L., Liu, X., Peng, Z., Liu, Z., Song, P., Zhou, J., Ma, K., Yu, Y., & Dong, Q. (2024). Exposure to di-2-ethylhexyl phthalate (DEHP) increases the risk of cancer. *BMC Public Health*, 24(1):430. <https://doi.org/10.1186/s12889-024-17801-w>

⁹ Swan, S.H. (2008). Environmental phthalate exposure in relation to reproductive outcomes and other health endpoints in humans. *Environmental Research*, 108(2), 177-184. <https://doi.org/10.1016/j.envres.2008.08.007>

¹⁰ Stahlhut, R.W., van Wijngaarden, E., Dye, T.D., Cook, S. & Swan, S. H. (2007). Concentrations of urinary phthalate metabolites are associated with increased waist circumference and insulin resistance in adult U.S. males. *Environmental Health Perspectives*, 115(6), 876-882. <https://doi.org/10.1289/ehp.9882>

¹¹ Kim, S.H. & Park, M.J. (2014). Phthalate exposure and childhood obesity. *Annals of Pediatric Endocrinology & Metabolism*, 19(2):69-75. <https://doi.org/10.6065/apem.2014.19.2.69>

¹² See citation 7 [Stahlhut et al. 2007]

¹³ Engel, S.M., Patisaul, H.B., Brody, C., Hauser, R., Zota, A.R., Bennet, D.H., Swanson, M., & Whyatt, R.M. (2021). Neurotoxicity of Ortho-Phthalates: Recommendations for Critical Policy Reforms to Protect Brain Development in Children. *American Journal of Public Health*, 111(4):687-695. <https://doi.org/10.2105/AJPH.2020.306014>

¹⁴ Stroustrup, A., Bragg, J.B., Andra, S.S., Curtin, P.C., Spear, E.A., Sison, D.B., Just, A.C., Arora, M., & Gennings, C. (2018). Neonatal intensive care unit phthalate exposure and preterm infant neurobehavioral performance, *PLOS One*. <https://doi.org/10.1371/journal.pone.0193835>

¹⁵ Bernard, L., Masse, M., Boeuf, B., Chennell, P., Decaudin, B., Durand, N., Genay, S., Lambert, C., Le Basle, Y., Moreau, E., Pinguet, J., Ponsonnaille, V., Richard, D., Saturnin, N., Storme, L., Sautou, V., & the ARMED study group (2023). Medical devices used in NICU: The main source of plasticisers' exposure of newborns, *Science of The Total Environment*, 858(3), 159994. <https://doi.org/10.1016/j.scitotenv.2022.159994>

¹⁶ Green, R., Hauser, R., Calafat, A.M., Weuve, J., Schettler, T., Ringer, S., Huttner, K. & Hu, H. (2005). Use of di(2-ethylhexyl) phthalate-containing medical products and urinary levels of mono(2-ethylhexyl) phthalate in neonatal intensive care unit infants. *Environmental Health Perspectives*, 113(9), 1222-1225. <https://doi.org/10.1289/ehp.7932>

Di(2-ethylhexyl) phthalate exposures in neonatal intensive care units are much higher than what is considered a safe level of exposure. In fact, the daily intake of DEHP for critically ill preterm infants can reach 16 mg/kg per day, which is on the order of [4,000 and 160,000 times higher](#) than levels shown to avoid reproductive and hepatic toxicities.¹⁷ Patients with cancer also face higher risks from DEHP exposure. Recently published research shows that DEHP not only [promotes drug resistance and inhibits the effectiveness](#) of breast cancer drugs like tamoxifen but it also [interferes with the ability of chemotherapies](#) to fight breast cancer.¹⁸ Exposure to DEHP can undermine the immune system, so children or adults battling cancer or other severe illnesses in hospitals are at particular risk of getting even sicker.

The good news is that it is both possible and cost-comparative to make IV bags and tubing without DEHP, with three out of four of the nation's major IV bag manufacturers already having a large portfolio of Food and Drug Administration (FDA) approved DEHP-free IV bags.¹⁹

Many health care systems and hospitals have already adopted policies against using DEHP containing IV medical devices, including California's Loma Linda and City of Hope hospitals, Pennsylvania's St. Luke's University Health Network who have eliminated DEHP and PVC in IV solution containers²⁰ and national systems like Kaiser Permanente. When Kaiser made the switch to PVC/DEHP-free IVs in 2012, it estimated its savings to be \$5 million annually²¹, ultimately saving lives by preventing patients from getting sicker.

In 2002, the [U.S. Department of Health & Human Services highlighted the risks](#) of DEHP in medical devices²² and the [American Academy of Pediatrics](#),²³ the [American Medical Association](#),²⁴ and the [American Public Health Association](#)²⁵ all discourage the clinical use of IV bags made with DEHP. Although there is substantial research on the

¹⁷ Mallow, E. & Fox, M. (2014). Phthalates and critically ill neonates: device-related exposures and non-endocrine toxic risks. *Journal of Perinatology*, 34, 892–897. <https://doi.org/10.1038/jp.2014.157>

¹⁸ Hsieh, T., Hsu, C., Yang, P., Chiu, C., Liang, S., Ou-Yang, F., Kan, J., Hou, M., Wang, T., & Tsai, E. (2022). DEHP mediates drug resistance by directly targeting AhR in human breast cancer, *Biomedicine & Pharmacotherapy*, 145, 112400. <https://doi.org/10.1016/j.biopha.2021.112400>

¹⁹ See citation 2 [BCPP, 2024]

²⁰ Senator Lisa Boscola. (April 2, 2024). Boscola to introduce legislation phasing out toxic additives in IV bags & medical equipment and requiring medical facilities to notify patients of their use. <https://senatorboscola.com/boscola-to-introduce-legislation-phasing-out-toxic-additives-in-iv-bags-medical-equipment-and-requiring-medical-facilities-to-notify-patients-of-their-use/>

²¹ See citation 2 [BCPP, 2024]

²² U.S. Department of Health and Human Services. (July 12, 2002). *Public health notification: PVC devices containing the plasticizer DEHP*. <http://accessmedicausa.com/pdf/fda-dehp-letter.pdf>

²³ American Academy of Pediatrics. (June 1, 2003). Pediatric exposure and potential toxicity of phthalate plasticizers. Shea, K.M. Committee on Environmental Health. *Pediatrics*, 111(6), 1467–1474. <https://doi.org/10.1542/peds.111.6.1467>

²⁴ AMA Policyfinder. (2023). Environmental health: Encouraging alternatives to PVC/phthalate products in health H-135.945 <https://policysearch.ama-assn.org/policyfinder/detail/pvc?uri=%2FAMADoc%2FHOD.xml-0-316.xml>

²⁵ American Public Health Association. (November 11, 2011). *Reducing PVC in facilities with vulnerable populations*. <https://www.apha.org/policy-and-advocacy/public-health-policy-briefs/policy-database/2014/07/08/15/13/reducing-pvc-in-facilities-with-vulnerable-populations>

health effects of DEHP, many patients, nurses, and health care providers do not know about these significant health risks. Because nurses are led by our professional obligations which make addressing health, environment, and safety a professional focus, we must address DEHP exposure as a serious health concern.

In 2021, [Congressional lawmakers urged the U.S. Food and Drug Administration \(FDA\)](#)²⁶ to take regulatory action on DEHP containing medical devices, particularly IV bags. In the absence of federal regulations, in 2024 California banned the use of DEHP in IV bags and tubing manufactured, sold, or used in the state and will require IV bags to be DEHP-free by 2030 and tubing by 2035.²⁷ Action by your state is critically necessary given both the overwhelming scientific evidence demonstrating harm from DEHP exposure and how prevalent DEHP exposure remains in our health care systems.

Globally, the market is moving away from DEHP with [France banning DEHP in tubing materials and medical devices](#) for hospitals' maternity, pediatric, and neonatal departments in 2012.²⁸ Over the past decade, Europe has been steadily phasing out its use of DEHP and PVC in IVs and other medical devices and PVC and DEHP-free IV containers are used almost exclusively in Europe today. In November 2023, the European Commission extended the deadline for removing DEHP from all medical devices from May 2025 to July 1, 2030.²⁹ Because the use of DEHP-free IV bags has been the standard practice in Europe since 2009 and is now considered a market expectation, the extended deadline for medical devices in Europe is not aimed at IV bags because DEHP-free IV bags are already the standard there, but rather other DEHP containing medical devices.³⁰ Many healthcare providers across Europe have made considerable progress by adopting phase-out policies and committing to using products that are less harmful for patients and demonstrating that the majority of uses have PVC-free alternatives.³¹

We applaud the New York State legislature's efforts to promote healthier environments for our patients and communities. Switching to the use of non-PVC plastics would

²⁶ U.S. Congress. (February 18, 2021). Letter to Dr. Janet Woodcock, M.D., Acting Commissioner of Food and Drug Administration from Congresspersons Porter, Wild, Speier, Schakowsky, Roybal-Allard & Eshoo
<https://roar-assets-auto.rbl.ms/documents/8190/Letter%20to%20FDA%20about%20DEHP%20IV%20Bags.pdf>

²⁷ Breast Cancer Prevention Partners. (2024, September 26). CA Governor signs bill into law banning toxic chemicals from IV bags and tubing. [Press release]. <https://www.bcpp.org/ca-governor-signs-bill-into-law-banning-toxic-chemicals-from-iv-bags-and-tubing/>

²⁸ Safeguards SGS Consumer Testing Services. (2013). France bans BPA in all food contact products.
<https://newsletter.sgs.com/eNewsletterPro/uploadedimages/000006/sgs-safeguards-00813-france-bans-bpa-in-all-food-contact-products-a4-en-13.pdf>

²⁹ Commission Regulation (EU) 2023/2482. (November 13 2023). Amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards the substance bis(2-ethylhexyl) phthalate (DEHP) in medical devices.
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ%3AL_202302482

³⁰ See citation 2 [BCPP, 2024]

³¹ Healthcare Without Harm. (May 2023). Towards PVC-free healthcare.
https://europe.noharm.org/sites/default/files/documents-files/7382/2023-05-Towards-PVC-free-healthcare_0.pdf

eliminate both the health hazards associated with PVC and also eliminate the use of DEHP. We urge legislators to support [NY A02133](#), which will prohibit the manufacture, sale or distribution in New York of medical solution containers or tubing containing intentionally added PVC or DEHP used to house or administer medicine, fluids or nutrition therapy.

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