

Executive Summary

EREE IVE GETTING HARMFUL

CHEMICALS OUT OF IV BAGS AND TUBING

August 2024



EXECUTIVE SUMMARY

In hospitals across the country, Americans may be unknowingly receiving harmful treatments through intravenous (IV) bags and tubing.

IV bags offer a simple and quickly accessible delivery route for medicine, fluids, and nutrition for the 90% of U.S. hospital patients who receive IV therapy or infusion.

Yet, unbeknownst to many patients and practitioners, this ubiquitous, healthcare mainstay may also pose significant health risks. Most IV bags and tubes are made with Polyvinyl chloride (PVC) plastic, which requires a plasticizer like Di(2-ethylhexyl) phthalate (DEHP) to act as a softener, making the plastic more flexible. However, the science is clear: **PVC and DEHP are dangerous to our health** and to the environment, and it goes without saying that **toxic chemicals should not be used in IV bags or tubing.**

IV bags are harming patients when they are at their most vulnerable, receiving treatment and trusting that their doctors are improving their health—and not increasing their risk of harm. Equally troubling is the fact that sometimes physicians do not know what the IV bags and tubing they're working with are made from, as it's typically the nurse who hooks

up the IVs and a separate team of people handling the purchasing.

For almost half a century, research has highlighted the toxicity of DEHP, a phthalate that leaches out of the plastic IV bags and tubing into the medicine and fluids being transfused. It is a potent endocrine disruptor linked to many adverse health effects, including breast and other cancers, developmental and reproductive effects including lowered male fertility, metabolic disorders such as obesity and type 2 diabetes, and brain development issues including attention deficit hyperactivity disorder (ADHD). There is no safe level of exposure to

endocrine-disrupting compounds like DEHP, which, even at very low levels, can negatively affect fetuses, infants, and children, whose developing bodies are most susceptible.



Ortho-phthalates, also known as phthalates, are a group of chemicals used to soften and improve the flexibility and durability of plastics. They are endocrine-disrupting compounds (EDCs), and exposure has been linked to breast cancer, developmental issues, decreased fertility, obesity, and asthma.

Toxic IV bags and tubing represent a serious public health concern. Research indicates that DEHP is linked to <u>breast, liver, lung, and testicular cancers</u>, promotes <u>drug resistance</u> by inhibiting the effectiveness of breast cancer drugs, and <u>interferes with chemotherapy's ability to fight breast cancer cells</u> by making them 'immortal.' It's also been shown that patients with higher levels of DEHP in their system had <u>higher rates of relapse and mortality</u>. This is especially frightening for the <u>over 300,000 women each year</u> who are battling breast cancer in the United States.

Other countries have long been aware of DEHP's toxicity. Across Europe, DEHP-free IV bags have been the standard practice for decades and are now considered a market expectation. Their common-sense policies contrast with the U.S., where **approximately 70% of IV bags in use contain DEHP**.

The American Academy of Pediatrics, the American Medical Association, the American Public Health Association, and the U.S. Food and Drug Administration have been urging hospitals and physicians to reduce and phase out PVC medical device products, especially those containing DEHP. Notably, DEHP has been banned nationally from toys for years and more recently from beauty and personal care products sold in California.

DEHP, a toxic chemical found in the majority of IV bags in hospitals nationwide, has been banned from children's toys for years and more recently from beauty and personal care products sold in California. DEHP has been recognized as a California Proposition 65 chemical because it is known to the state to cause cancer and birth defects.



We know it's not safe for a toddler to chew on a rubber ducky made with DEHP or for people to slather it on their bodies, but it's still allowed in IV bags used to treat sick people and to nourish premature babies. This raises concerns about the lack of regulatory oversight and companies that are prioritizing their profits over public health.

The fact that **DEHP and other phthalates are not allowed in toys** because they're too toxic
for children to suck on, but we
allow them to be pumped into the
veins of patients from newborns to
people receiving cancer treatment
is insanity.

- Suzanne Price, CEO, Breast Cancer Prevention Partners

Fortunately, legislation in California that has received bipartisan support and is expected to be voted on at the end of August 2024, would ban DEHP from IV bags and tubing, transforming the healthcare industry nationwide. If passed, the California Toxic-Free Medical Devices Act (AB 2300), introduced by Assemblywoman Lori Wilson, would eliminate the unnecessary exposure of millions of Californians to toxic DEHP. AB 2300 would prohibit the manufacture, sale, or distribution of IV bags and tubing

in California with intentionally added DEHP, effective 2030 for IV bags and 2035 for IV tubing. It would also prevent the practice of 'regrettable substitution,' in which manufacturers replace a banned chemical with an alternative that is equally or more toxic - by prohibiting the replacement of DEHP with any of the other 11 chemicals that make up the class of ortho-phthalates.

No regulation of any kind on the use of DEHP in IV bags and tubing exists at the state or federal level. California is the 5th largest economy in the world, so any state changes in the health arena would naturally impact the U.S. health system as a whole. California's AB 2300 would create a first-ever regulatory floor for patient safety by banning intentionally added DEHP from IV bags and tubing, raising the bar for patient safety across the country.

The good news is that making IV bags and tubing without PVC or DEHP is entirely possible and cost-effective, and many suppliers have already done so. Three out of four of the nation's major IV bag manufacturers already have a large portfolio of FDA-approved DEHP-free IV bags, meaning they will not have to develop or certify new technology to comply with the AB 2300 ban. This includes B. Braun and Fresenius-Kabi,

which exclusively manufacture DEHP-free IV bags. <u>ICU Medical</u> also offers a portfolio of FDA-approved, DEHP-free bags. By investing in new and modernized manufacturing facilities and through strategic supply collaborations, these companies have significantly expanded their ability to manufacture and provide DEHP-free IV solutions for patients.

Health care providers should not have to be concerned that the medical device being used to treat their patients' illness might be making them sicker or contributing to an even worse health condition. To protect the health of the millions of Californians who receive medical infusions every year, the California Senate should support this urgently needed, common-sense legislation.

- Dr. Lisa Bailey, MD, 40-year veteran breast cancer surgeon

Although the California legislation allows 5-7 years to phase DEHP out of IV bags and 10 years for tubing, switching to toxic-free IV bags does not have to be an expensive, multi-year process for hospitals. Leading California health systems, including Kaiser Permanente, Loma Linda University Health, and City of Hope, made the change years ago. In fact, Kaiser Permanente converted its entire hospital system to DEHP-free IV bags and tubing in 2012. The transition took them six months and saved them \$5 million in annual costs.



HOW TO TAKE ACTION It's time to prioritize patient health. The most vulnerable populations across America need protection and change now. The good news is that making IV bags without PVC or DEHP is entirely possible and costeffective; in fact, some companies have been making these safer alternatives for decades and major healthcare systems have already made the switch. TOXIC-FREE IV: GETTING HARMFUL CHEMICALS OUT OF IV BAGS AND TUBING



FOR PATIENTS: ASK WHAT'S BEING USED, DEMAND SAFER OPTIONS

All patients, but especially pregnant women, infants, and patients seeking breast cancer treatment or chemotherapy, should request IV bags and tubing that are DEHP-free. Patients can advocate for safer medical devices by taking the following steps:

- 1. Communicate with Your Healthcare Provider. Openly and respectfully discuss your safety concerns with your healthcare provider. You have the right to request that your hospital provide you with the safest treatment possible.
- **2. Request DEHP-free IV bags and tubing.** Tell your physician you prefer DEHP-free IV bags and tubing to prevent DEHP exposure.
- **3. Advocate for Change.** Write to the CEO of your hospital or health care system and insist they go DEHP/PVC-free.

FOR CALIFORNIA RESIDENTS: URGE YOUR LEGISLATOR TO SUPPORT THE TOXIC-FREE MEDICAL DEVICES ACT

AB 2300 will ban DEHP from IV bags and tubing sold in California. This crucial bill has already passed the Assembly, but it needs your support to ensure its passage in the Senate.

Everyone deserves toxic-free medical devices. Write to your California Senator today and urge them to support AB 2300 (Wilson) – the Toxic-Free Medical Device Act. Together, we can raise a higher bar for patient safety and ensure safer medical devices for all Californians.

Learn more about the bill. Visit our action center to take action.



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Breast Cancer Prevention Partners (BCPP) is the only science-based policy and advocacy organization working to prevent breast cancer by eliminating our exposure to toxic chemicals and other environmental exposures linked to the disease.

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