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Q&A: Public Citizen Petition to Ban Hydroxyethyl Starch (HES) Solutions

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What are HES solutions?

HES solutions are a type of intravenous fluid that are administered to patients in the hospital who need body fluid to be replaced or maintained, including replacing fluid in surgical and trauma patients who have experienced significant blood loss. The first HES solution, Hespan, was approved in the U.S. in 1972, on the basis of small, brief, and poorly designed studies. In addition to Hespan, two other HES solutions (Hextend and Voluven) are currently on the U.S. market.

Why does Public Citizen want the Food and Drug Administration (FDA) to ban HES solutions?

Since shortly after the first HES solution was approved in the 1970s, evidence emerged that the solutions could impede the blood's ability to clot properly and were stored in body tissues long after they were administered. Later evidence showed that HES solutions can cause kidney failure and death, leading to a 2013 FDA safety communication warning the public of these dangers and recommending against the use of HES solutions in critically ill patients, including patients with sepsis. However, the FDA, with no justification, allowed HES solutions to continue to be used in other patients, including those undergoing major surgery and treatment for trauma, despite evidence showing that HES solutions had the same dangers in all patients.

What are the arguments for keeping HES on the market?

HES manufacturers and some others maintain that the dangers of HES products are limited to critically ill patients, including those with sepsis, and do not apply to other patients, such as those undergoing major surgery or experiencing trauma. Public Citizen and many other experts point out that this distinction is entirely arbitrary and contradicted by a large body of evidence that demonstrates the same risks of HES in surgical and trauma patients. Some also claim that newer, lower-molecular-weight formulations of HES have fewer risks than older, higher-molecular-weight versions, or that lower doses of HES can mitigate the solutions' risks. However, the best evidence shows that all formulations and doses of HES carry similar life-threatening risks for all patients.

Are there alternatives to HES for patients?

There are several other types of IV fluids on the U.S. market, which are much safer and cheaper than HES and equally effective. These include so-called "crystalloid" solutions, such as salt water, that have been the mainstay of fluid treatment for decades and, contrary to industry claims, are just as effective as the more dangerous and expensive "colloids" (of which HES is one type), in replenishing the body of necessary fluids and minerals. In fact, according to a 2010 survey of 391 intensive care units, none of the respondents in the U.S. and Australia used HES.