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America's Blood Centers Responds to Court Striking Down FDA Overreach on In Vitro Diagnostics Unlawful

Decision is a victory for patient care and laboratory innovation

Washington, DC – America’s Blood Centers (ABC), the national organization of community-based, independent blood centers that supply 60 percent of the nation’s blood supply, today released this statement following the U.S. District Court for the Eastern District of Texas’ determination that the Food and Drug Administration’s (FDA) 2024 final rule subjecting in vitro diagnostic products (IVDs) to unprecedented regulatory scrutiny is unlawful:

“The court’s ruling marks a significant victory for the laboratory community and the patients they serve, protecting in vitro diagnostic products (IVDs) from unprecedented regulatory scrutiny. America’s Blood Centers has long advocated that FDA does not have the authority to regulate laboratory developed tests. FDA’s final rule would have delayed patient care, increased costs, stifled innovation, and resulted in resource diversion—all of which would have compromise the efficiency and effectiveness of blood center operations. We will continue to oppose any effort that unnecessarily restricts access to life-saving tests for patients in need,” said Kate Fry, CEO of America’s Blood Centers.

As part of its [Advocacy Agenda](#), ABC has been working to [exempt LDTs](#) used by blood centers from new diagnostics regulations and will remain vigilant to protect patient access to life saving- care while maintaining a safe and reliable blood supply.

Founded in 1962, America’s Blood Centers (ABC) is the national organization bringing together community-based, independent blood centers across North America. These organizations operate in more than 1,100 communities and provide close to 60 percent of the U.S. and a quarter of the Canadian blood supply. ABC member organizations serve more than 150 million people and provide blood products and services to more than 3,500 hospitals and healthcare facilities. All ABC U.S. members are 501(c)(3) organizations licensed and regulated by the U.S. Food and Drug Administration or Health Canada. For more information, visit www.AmericasBlood.org.

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