FDA Calls for More Efficient Pathogen Detection in Blood Supply

In a recent statement, the Food and Drug Administration underscored the need for better technologies to protect the nation's blood supply.

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This week, outgoing Food and Drug Administration (FDA) Commissioner Scott Gottlieb, MD, PhD—whose recently announced resignation takes effect next month—issued a statement calling for better safety measures to mitigate potential risks to the country's donated blood supply. The statement was cowritten by Peter Marks, MD, PhD, the director of the FDA's Center for Biologics Evaluation and Research.

Issued March 26, the statement notes that pathogens of concern regarding donated blood products include ongoing risks such as hepatitis B virus, hepatitis C virus and HIV as well as seasonal and local risks for West Nile virus and Babesia. The statement suggests that cumbersome screening technologies ought to be streamlined and the cost of pathogen reduction lowered.

Importantly, Gottlieb notes that current pathogen reduction technologies address more than 95 percent of the existing and emerging pathogens that are of concern for donated blood in the United States (including hepatitis and HIV). However, the statement argues, they do not inactivate certain viruses—for example, parvovirus, which in children causes a fever and face rash but can be much more serious in adults, or protein-based infectious agents called prions.

Gottlieb also argues in the statement that many of the technologies used to remove pathogens from the blood supply are "somewhat cumbersome" and costly to use, in some cases requiring the separation of different blood components in donated blood products and separate testing on those components.

"The ideal pathogen reduction technology would be relatively inexpensive, simple to implement on Whole Blood, and would allow the blood to subsequently be easily separated into the different components," write Gottlieb and Marks. Such a technology, they add could one day help reduce or remove existing donor requirements, such as those facing people who travel to malaria-endemic areas.

Unfortunately, current technology does not achieve these ideal goals, but, the statement points out, "preliminary work shows that achieving something close to the ideal is potentially possible."

According to the health officials, the Center for Biologics Evaluation and Research is currently partnering with multiple organizations to develop these new technologies.
