Reducing Viral Contamination in Donated Blood

Solving the Problem of Contaminated Blood
Several sterilization procedures using heat, a chemical, or ultraviolet radiation are already in use, but each method has drawbacks: it may leave unsafe levels of some viruses, be very costly, or damage the blood or plasma. The Aphios sterilization technology, called critical-fluid inactivation (CFI), uses a fluid such as carbon dioxide that is raised above its critical temperature and pressure. Above these levels, the substance cannot be liquefied. In laboratory tests, such fluids exhibit a combination of liquid and gaseous properties, and they have been found to effectively inactivate prototypical viruses. Critical-fluid viral inactivation uses low temperatures and short process times, so it has a minimal impact on blood and blood-related products. And, at an estimated cost of about $1 per liter, it is much less expensive than existing technology.

Overcoming Parvovirus
The procedure Aphios developed during the ATP project has been able to achieve 99.9999 percent inactivation or more for most viruses in 20 seconds (99.99 percent inactivation by an individual viral inactivation technique is considered acceptable). The most difficult challenge has been parvovirus.

Parvovirus B19 in blood and blood products has proven difficult to inactivate, not only by the CFI process but by others as well. The virus is relatively benign for patients with healthy immune systems. But it can have serious consequences for those with weakened immune systems, as well as for pregnant women and persons with sickle cell anemia. The current Aphios procedure has achieved 90 percent inactivation of this virus. The company is working on a five-step procedure that is expected to achieve better than 99.99 percent inactivation.

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 Aphios Corporation, a small Massachusetts company founded in 1988 as BioEng, developed technology to improve the quality of donated blood in the United States. If the technology is fully developed and widely applied, substantial benefits would accrue to patients. The transfused blood or other therapeutic substances they receive would essentially be free of hepatitis virus, human immunodeficiency virus (HIV, which causes acquired immunodeficiency syndrome, or AIDS), and other viruses that may contaminate vaccines, donated blood, blood-related products, medical instruments, and recombinant-DNA proteins.

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deployment of the Aphios technology will be much easier if the company can demonstrate that its technology can inactivate parvovirus to an acceptable degree. If it succeeds with this task, Aphios will seek to join a larger pharmaceutical company or consortium to further develop and commercialize the process, with substantial investment coming from these sources. In 1998, Aphios sought an arrangement with a consortium of five pharmaceutical companies to complete development of the CFI process.

If a company wishes to commercialize a product for use with donated human blood, it must deal with the American Red Cross (ARC), the source of most blood products used in clinics and hospitals in the United States. Aphios has signed a letter of intent with the Northeast Region of the ARC to develop and field-test a virus inactivation prototype for individual units of blood and is seeking funding for the project.

Health Benefits to Patients and Those Close to Them
If the technology is fully developed and commercialized, benefits are expected to accrue to users of blood and blood-derived products that can be made virus-free with the Aphios technology. Reducing the spread of viral disease is expected to generate large health-cost savings and related benefits to the United States. Users will also benefit if the process based on the new technology is, as expected, less costly than current decontamination procedures. Economic benefits might also extend to people who avoid viral disease because users of blood or blood-derived products decontaminated with the Aphios technology do not become infected and spread the disease.

Without the ATP funds, Aphios officials say, the company would not have conducted the project.