

## Miscellaneous Healthcare Spotlight

### Blood, Organ & Tissue Professional Liability Risks

by Evan Smith

*Blood, organ and tissue donation, processing and distribution is lifesaving work and booming business. It's also fraught with professional liability risks.*

Operations in this miscellaneous healthcare niche run the gamut from cord blood and dental pulp harvesters, to sperm bank, blood processors and organ procurers. They may be publicly or privately held, for profit or non-profit organizations. And their potential liability claims are as diverse as the sector itself.

Consider the common scenario of a blood donor fainting at a collection site. While the vast majority of donors receive first aid and recover, claim severity can soar in the rare case when an individual suffers permanent brain damage from a subdural hematoma caused by a fall after a donation is made. A different set of risks arise on the recipient side: donated blood could be contaminated with a lethal virus, bacteria or pathogen that goes undetected until after the blood is transfused into one or multiple patients. Blood, organ and tissue donation is a global business, and screening standards vary widely in jurisdictions around the world.

Operations that touch blood, tissue and organs also face regulatory risks. For instance, if the FDA determines that a particular human or animal tissue form is an unapproved medical device; plaintiffs' attorneys may very well see the government investigation as an invitation to product liability and negligence claims or allegations. When something goes wrong, whether tainted blood is transfused or contaminated tissue is transplanted, there may be the question of whether the blood or tissue at the root of the problem represents a product or a service. Plaintiffs' attorneys frequently have the flexibility to plead professional negligence or strict products liability, creating uncertainty about whether traditional insurance coverages alone are enough to protect this sector.

### Zeroing in on Blood-related Risks

Advances in medical science and pathogen screening help mitigate the risks to this sector, but they can take decades to come to fruition. When the AIDS epidemic emerged in the early 1980s, the human immunodeficiency virus (HIV) was widely publicized as a threat to the blood supply. A significant number of people became infected after receiving HIV-tainted blood or blood products. While the enzyme-linked immunosorbent assay (ELISA) test gave the industry the first leg up on HIV screening back in 1985, it was not until 1999 that a new technology, called nucleic acid amplifications testing (NAAT), revolutionized the ability to detect HIV in donated blood by shrinking the window of time tainted blood could pass screening undetected. The discovery of NAAT expanded the universe of viruses detectable in donated blood and tissue. Recent developments have made testing for HIV even faster and easier, yet even now the U.S. universally bans male homosexuals from donating blood.

Moreover, while pathogen reduction technology and screening tests continue to advance, new threats are always entering the mix. Global travel makes vigilance ever more challenging. Consider:

- ✓ the mosquito-borne Chikungunya virus, imported to the U.S and Europe from Africa in the past several years, has been identified as a potential threat to the blood supply.
- ✓ multiple reports of dengue fever, a rarity in the U.S., have emerged in Key West, Florida.
- ✓ babesiosis, a parasitic infection, has been linked to ten U.S. deaths through blood transfusions since 2006.
- ✓ the currently-unscreenable retrovirus XMRV -- which is in the same family as HIV and linked to Chronic Fatigue Syndrome (CFS) -- is creating uncertainty in the transfusion world. Canada recently banned blood donations from anyone with CFS. The US has yet to formally weigh in on this issue.

In an effort to improve transfusion safety, the U.S. Centers for Disease Control has launched the first-ever national surveillance system to monitor adverse events in patients receiving blood transfusions. The new Hemovigilance Module, part of the CDC's National Healthcare Safety Network, allows healthcare-associated infection data to be tracked and analyzed. As it makes more data on transfusion reactions and errors more readily accessible, the new system also has the potential to elevate the standard of care -- and consequently the potential frequency and severity of professional liability claims -- for those in the blood business.

*Shelf life of blood is an issue to watch -- one that could open a new avenue of liability for the blood industry.*

The Federal Drug Administration and the American Association of Blood Banks require nearly 50 questions of blood donors to weed out risks to the blood supply. Still, important answers remain elusive, leaving blood-related operations at substantial risk.

## How Insurance Can Help

Fortunately for those working with blood, organs and tissues, the insurance market for these types of miscellaneous healthcare professional liability risks has expanded significantly in recent years. Sound insurance is available, but buyers should take care to secure protection broad enough for their particular exposures.

A leading provider of healthcare professional liability insurance, Beazley keeps close watch on the ever-changing exposures of diverse healthcare providers. We have a strong commitment to underwriting blood, organ and tissue related risks and proven claim and litigation management experience that informs our underwriting and protects our insureds.

To address the multi-faceted liability risks of this market niche, Beazley offers various combinations of miscellaneous medical professional liability coverage, coupled with general liability, errors and omissions, and employee benefits liability insurance. Importantly, we combine our professional liability insurance with products liability/completed operations coverage, so our policyholders are protected whether they are targeted in a claim of professional negligence or strict products liability. Excess and umbrella policies are available as well.

Beazley also has an Intelligence Network which conducts ongoing research and analyses to keep our underwriters, brokers and customers ahead of emerging risks. This network is central to Beazley's ability to create insurance contracts that keep pace with the fast-moving exposures of blood, organ and tissue operations and other niches, and to respond effectively to the dynamic needs of customers.

We encourage you to bring the professional liability risks of the blood, tissue and organ field to Beazley. Our underwriters understand the exposures these operations face today ... and are constantly unearthing and analyzing the exposures of tomorrow.

To learn more about Beazley's solutions for Miscellaneous Healthcare Professional Liability Risks, contact Evan Smith at [evan.smith@beazley.com](mailto:evan.smith@beazley.com).

DISCLAIMER: Beazley Miscellaneous Healthcare Spotlight is prepared and edited by Beazley Group. The opinions of the author are solely those of the author. Beazley Miscellaneous Healthcare Spotlight is published and distributed by Beazley Group with the understanding that neither it nor the editors or authors is responsible for inaccurate information. The information set forth in Beazley Miscellaneous Healthcare Spotlight should not be construed nor relied upon as legal advice and is not intended as a substitute for consultation with counsel.