BLOOD SHIELD STATUTES

Origins, Applications and Emerging Implications

In the early 1950s, a woman named Gussie Perlmutter sued a New York City hospital, alleging it infected her with jaundice and hepatitis viruses during a blood transfusion. She considered the transfusion, which cost $60 at the time, the sale of a product, for which the hospital would be liable.

BY DANIEL BRETTLER
Senior Partner
National Life Science Practice Leader
Conner Strong & Buckelew

Contributions by:
Joy Chen and Eimi Watanabe

Perlmutter argued that while restaurants can be said to provide a service, you really go there and pay to consume the food, so it's truly the sale of a product. The New York State Court of Appeals agreed with that point, but said it was not analogous to hospitals. When a patient enters a hospital, "He goes there, not to buy medicines or pills, not to purchase bandages or iodine or serum or blood," the court said, "but to obtain a course of treatment in the hope of being cured of what ails him."

The court held that providing blood is considered a service, and in the following decades almost every state legislature in the U.S. created laws to make that clear. These statutes are referred to as blood shields, because they protect manufacturers, producers and providers of blood from unlimited liability, with the intent of ensuring a reliable supply of blood and related resources. The threat of potentially devastating lawsuits from a transfusion or transplant gone wrong could put a chilling effect on this lifesaving industry, so legislators have made sure to protect this public service.

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These laws and subsequent cases also hold that blood shields extend far beyond blood. Blood products and derivatives, bodily tissue, organs, parts of organs and even semen have all fallen under these laws, depending on the situation and jurisdiction. Today, stem cells and cell therapy continue to evolve and shape the way we apply blood shield statues to new technologies.

How Life Science Companies Aren't Completely Shielded

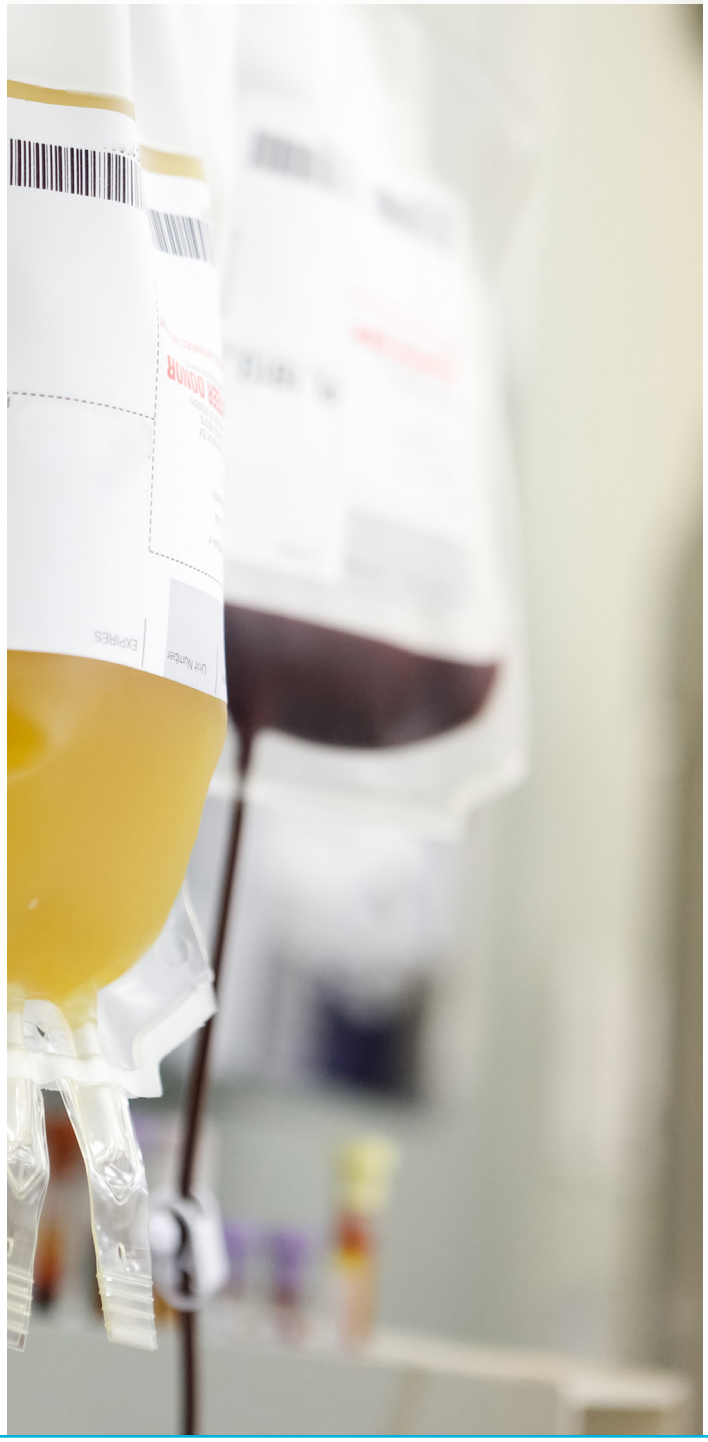
While blood shields protect against unlimited liability, they don't provide unlimited protection. Instead, legislators have balanced the need to protect supplies with the public need for accountability in the medical professions by permitting suits based on negligence and other definitions of "fault." Manufacturers, producers and providers still need to follow all established protocols and best practices to ensure safe services as much as possible.

Furthermore, states do not all provide the same level of protection. New Jersey, for instance is an outlier state that does not have a blood shield statute. Neighboring Pennsylvania's law covers a broad range of blood and related products, whereas New York has less expansive language. That means a company doing business in all three may be facing varying levels of liability.

Combined with the hodgepodge of state laws and ongoing innovation in the field, it's clear that many risks still remain for life sciences companies affected by these statutes. Businesses selling or researching products in multiple states are left in a position of uncertainty. Shields provide significant potential protections to those in a position to take advantage. Variances on a state by state basis present a challenge to insurance companies in pricing the coverage that they offer their insureds, and also in adequacy of policy language that needs to be considered.

Importantly, insurance policies have to be created with full knowledge of blood shield statutes in each state a company does business in, also grasping how they are interpreted and how the policy language must be crafted to be in sync with the laws.

WHILE BLOOD SHIELDS PROTECT AGAINST UNLIMITED LIABILITY, THEY DON'T PROVIDE UNLIMITED PROTECTION.



Understanding Your Policy in Light of Blood Shields

While blood shields were designed to provide protection for life science companies, they also add a layer of complexity while crafting insurance policies.

Life sciences companies generally have a set of core liability insurance policies, and most often rely on general liability, products liability, medical malpractice, and errors and omissions coverage to provide defense and pay damages from any claims. How these policies are compiled varies by sector; for example, manufacturers and distributors that do not have regular exposure to medical professionals may have simpler, condensed policies.

Exactly what these policies cover may not always be obvious when it comes to blood and blood products. For example, it's customary that product liability policies contain a healthcare professional liability exclusion, meaning that insurance carriers may not cover loss when professional services are provided. These professional services are typically defined in policies as various, broadly stated medical service offerings – but may include blood transfusions depending on the blood shield laws in that particular state.

Similarly, general liability insurance policies can leave companies exposed to risk if they are not properly crafted. These policies are designed to handle claims for bodily injury and property damage, but may contain exclusions for products liability and the use of healthcare professional services.

The result is that life sciences companies working with blood products and their derivatives may be exposed to risk even if they are insured. That's certainly not intuitive for the business person who may be in the business of producing what they consider their "product" or "work," whereas the statutory definitions consider the same thing a "service" or "medical service."

But even having extensive knowledge of policy exclusions may not be enough – life sciences companies also must be diligent in understanding how blood products are classified in their states. For example, Indiana's blood shield statute considers the transfusion of human tissue by a hospital or blood bank to be a service, but it does not include pharmaceutical companies that commercially produce blood products for mass distribution, as this process is characterized as "sale of a product" rather than "provision of a service."

Yet another wrinkle is that because providing blood is classified as a service in most states, it is not subject to products hazard exclusion of general liability policies. This means that life sciences companies are protected should an insurance carrier claim that a blood product is intrinsically dangerous and should be omitted from standard coverage. However, blood shield statutes are not uniform across all 50 states, and in fact New Jersey and the District of Columbia do not have statutes at all, so constructing an insurance program needs to be carefully considered with regard to where business is taking place.

This field is constantly evolving. As the industry continues to innovate and generate interest around stem cell research, the FDA and individual states may be well-served to reconsider its classification and establish updated guidelines and protections similar to blood shields. Currently, stem cells are widely considered "products" and are regulated as such. This was reinforced in a case involving Regenerative Sciences, which argued that cell therapies are considered medical practices ("services") rather than drugs ("products"), and therefore the company's therapy procedure for the treatment of arthritis was not subject to FDA regulations. However, the U.S. Court of Appeals confirmed in February 2014 that Regenerative's stem cell mixture fell within the FDA's definition of a drug, upholding the FDA's continued regulation of "more than minimally manipulated" stem cell therapies.

In the same vein, the industry may be approaching its tipping point in regard to state versus federal standards for blood products. With so much uncertainty surrounding blood shields, it may be time to advocate for a uniform standard at the federal level. Until then, life sciences companies should work closely with their carrier and broker to understand and integrate protections from local blood shield laws into their policies.

CONNER STRONG & BUCKELEW

CONNECT WITH US

Daniel S. Brettler
SENIOR PARTNER
National Life Science Practice Leader

Conner Strong & Buckelew

P 973-659-6456
E dbrettler@connerstrong.com

NATIONAL HEADQUARTERS

TRIAD1828 CENTRE
2 Cooper Street
Camden, NJ 08102

MAILING ADDRESS

PO BOX 99106
Camden, NJ 08101

connerstrong.com

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