HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 461 Uniform Commercial Code/Blood
SPONSOR(S): Clarke
TIED BILLS: None. **IDEN./SIM. BILLS:** SB 2036 (i)

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Standards (Sub)		Chavis	Collins
2) Health Care			
3) Commerce			
4) Judiciary			
5)			

SUMMARY ANALYSIS

Blood is needed every three seconds. An estimated one out of three people need donated blood in their lifetime. Derived from human tissue, blood and blood products can effectively transmit infections such as hepatitis, cytomegalovirus, syphilis, malaria, and HIV. Typically, blood is collected from voluntary donors through a network of nonprofit community and hospital blood banks.

The great majority of states have adopted "blood shield" laws. These laws designate blood as a service rather than a product. Blood suppliers, therefore, are normally judged not under a strict liability standard (where the blood supplier is responsible for damages their actions or products cause, regardless of any "fault" on their part), instead they are subject to a negligence standard (requiring the ordinary level of prudence used by blood suppliers in the same or similar circumstances).

HB 461 amends s. 672.316(5), F.S., relating to exclusion or modification of warranties under Florida's Uniform Commercial Code (UCC), which is Florida's "blood shield" law. The law specifies that "the procurement, processing, storage, distribution, or use of whole blood, plasma, blood products, and blood derivatives for the purpose of injecting or transfusing the same, or any of them, into the human body for any purpose whatsoever" is service and does not constitute a sale under the UCC. As a service these activities are excluded from the UCC implied warranty of merchantability (an implied warranty that guarantees that goods are reasonably fit for their ordinary purpose) and warranty of fitness for a particular purpose (an implied warranty that exists when a seller should know that a buyer is relying on the seller's expertise for a particular purpose). Typically, these warranties impose a "strict liability" standard of care (liability even when there is no proof of negligence). The bill clarifies that these activities are "medical" services and, thus, are excluded from these warranties.

Under current law, while the provision of these services are excluded from the strict liability of care, the actual product, the blood and blood products, have only a limited exclusion. Subsection (5) limits the exclusion to only those defects that cannot be detected or removed by a reasonable use of scientific procedures or techniques. This means that if the blood supplier fails to utilize the reasonable use of scientific procedures or techniques, the supplier is "strictly liable" for the damages. The bill expands the current limited exclusion to provide that such warranties do not apply to any defects found in the blood or blood products.

HB 461 specifies that Florida's current "blood shield" law, which limits claims for breach of implied "warranty of merchantability or fitness for a particular purpose" against a seller of blood by specifying that the procurement, processing, storage, distribution, or use of whole blood, plasma, blood products, and blood derivatives for the purpose of injecting or transfusing the same, or any of them, into the human body for any purpose is the rendering of a "medical" service, rather than simply a "service". In addition, the bill expands the exclusion of the implied warranties of merchantability and fitness for a particular purpose by removing the current limitation of application of these warranties to only those related to a defect that cannot be detected or removed by a reasonable use of scientific procedures or techniques; thus making the warranties inapplicable to any defect in the blood or blood product.

The bill takes effect upon becoming a law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. DOES THE BILL:

1. Reduce government?	Yes[]	No[]	N/A[x]
2. Lower taxes?	Yes[]	No[]	N/A[x]
3. Expand individual freedom?	Yes[]	No[x]	N/A[]
4. Increase personal responsibility?	Yes[]	No[]	N/A[x]
5. Empower families?	Yes[]	No[x]	N/A[]

For any principle that received a "no" above, please explain:

Reduce government
The bill eliminates the current "strict liability" standard relating to defective blood and/or blood products.

Empower families
The bill will make recovery from a blood supplier of defective blood or blood products more difficult. The bill eliminates the current "strict liability" standard relating to defects that could be detected or removed by the use of a reasonable use of scientific procedure or technique. The bill expands the exclusion from strict liability standard to all defects detectable or undetectable and removable or not removable by a reasonable use of scientific procedure or technique.

B. EFFECT OF PROPOSED CHANGES:

According to the National Blood Data Resource Center (NBDRC), about 13.9 million units (including approximately 695,000 autologous donations) of whole blood are donated in the United States each year. Approximately 8 million volunteer blood donors provide blood for about 4.5 million patients per year. Typically, each donated unit of blood, referred to as whole blood, is separated into multiple components, such as red blood cells, plasma, platelets, and cryoprecipatitated AHF (antihemophilic factor). Each component generally is transfused to a different individual, each with different needs.

The safety of the blood supply is a shared responsibility of many organizations, including the plasma fractionation industry, community blood banks, the federal government, and others. The U.S. Food and Drug Administration has regulatory authority over plasma collection establishments, blood banks, and all blood products. The Centers for Disease Control and Prevention has responsibility for surveillance, detection, and warning of potential public health risks within the blood supply. The National Institutes of Health supports these efforts through research. In addition, private-sector organizations such as community blood banks, the American Red Cross, blood and plasma collection agencies, blood product manufacturers, groups like the National Hemophilia Foundation, and others establish suggested "best practice" standards.

The bill does not limit other existing alternative legal theories of liability, including the warranty of "failure to warn" which imposes upon a seller a duty to provide a warning after the time of sale or distribution of a product if a reasonable person in the seller's position would provide such a warning, and if:

- The seller knows or reasonably should know that the product poses a substantial risk of harm to persons or property;
- Those to whom a warning might be provided can be identified and can reasonably be assumed to be unaware of the risk of harm;

- A warning can be effectively communicated to and acted on by those to whom a warning might be provided; and
- The risk of harm is sufficiently great to justify the burden of providing a warning); or
- The tort theory of negligence (the negligence of one or more individuals has lead to loss or damages of another; there was a duty of care; there was a breach of that duty; and the resulting damages were foreseeable by the defendant).

In addition, there may be other theories by which an injured plaintiff may seek redress.

The bill becomes effective upon becoming a law.

Florida Law

Florida was one of the first states to adopt a Blood Shield law. In 1967, the Legislature adopted s. 672.316(5), F.S., relating to the Florida Uniform Commercial Code[1] – exclusion or modification of warranties, the collection, testing, and storage of blood. Under subsection (5), the blood procurement, processing, storage, distribution, or use of whole blood, plasma, blood products, and blood derivatives for the purpose of injecting or transfusing into the human body for any purpose is defined as the *rendering of a service* rather than *the sale of a product*.[2]

Typically, products under the UCC come with implied "warranties of merchantability and fitness"[3] for a particular purpose; however these warranties do not apply to services because the UCC applies only to goods or products and not services; however, the warranties do apply to the blood itself. Therefore, if a recipient receives defective blood, blood that had a defect that could have been detected or removed by a technique or procedure that was available at the time, the blood bank or other entity can be held "strictly liable"[4] for not utilizing the technique or procedure to detect or remove the defect. These warranties are applicable regardless of whether the technique or procedure has been approved for use by the FDA or some other authorizing authority or whether its potential side effects have been fully determined. Under s. 672.316(5), F.S., the mere availability of an unapproved or unreviewed technique alone can render a blood bank or other entity "strictly liable" under a warranty claim. Thus, Florida's blood shield statute limits claims for breach of implied warranties of fitness or merchantability, but does not limit failure-to-warn products liability claims against seller of blood. However, even with the exclusion of the warranties under the UCC, the statute does not prevent an individual's ability to recover under alternative liability theories, although under those theories it may be much more difficult for a plaintiff to obtain relief.

"Blood Shield" Laws

For policy reasons, the great majority of states have adopted "blood shield" laws. These laws designate blood as a service rather than a product. Legislatures have reasoned that the doctrine of strict liability would defeat the important state goal of insuring a voluntary and inexpensive blood

[1] The Uniform Commercial Code (UCC) is a comprehensive code addressing most aspects of commercial law. The UCC text and draft revisions are written by experts in commercial law and submitted as drafts for approval to the National Conference of Commissioners on Uniform State Laws (now referred to as the Uniform Law Commissioners), and the American Law Institute. The UCC is a model code so it does not have legal effect unless UCC provisions are enacted by the individual Legislatures as statutes that are applicable to their respective jurisdictions. Currently, the UCC has been enacted (with some local variations) in 49 states, the District of Columbia, the Virgin Islands, as well as partially in Louisiana.

[2] Blood banks do not "make" blood, as a manufacturer would "make" a product; instead, blood banks perform "services" which make available blood for transfusions to patients.

[3] Typically, an "implied warranty of fitness or merchantability requires that goods be fit for the ordinary purposes for which the goods are used."

[4] A patient suing for damages must generally show that a blood bank did not comply with the standard of care. Typically, if the blood bank complied with FDA regulations, American Association of Blood Banks standards, or American Red Cross practices it was considered to have met the standard of care.

supply. Under blood shield laws, blood suppliers are not subject to a strict liability standard, but instead under a negligence standard.[5] As a result of such laws, it is difficult and often impossible for individuals to obtain compensation for infections acquired from blood or blood products. There is no dispute among the courts that blood banks, including hospitals which act as such entities, may be liable in negligence for transfusion of contaminated blood.[6]

Regardless of the protection provided blood banks and similar entities by blood shield laws, blood banks and hospitals still owe a duty to the donors of the blood and the recipients to comply with reasonable industry standards in questioning prospective donors and in testing the blood for evidence of disease. In addition, compliance with the industry standard is not an absolute defense to tort claims and some courts have allowed plaintiffs to present expert testimony that the industry's standard of care is inadequate.

Alternative Liability Theories

Florida's "blood shield" statute does not preclude an individual from recovering under other theories of liability. In *Walls v. Armour Pharmaceutical Co.,* the court ruled that while Florida's "blood shield" statute limited claims for breach of implied warranty of fitness or merchantability, it did not limit the failure-to-warn products liability claim against a seller of blood and, thus, the products liability statute of limitation rather than the negligence statute of limitation applied to a personal injury action filed on behalf of an hemophiliac patient who allegedly contracted acquired immune deficiency syndrome from a plasma product. *Walls v. Armour Pharm. Co.*, 832 F. Supp. 1467 (M.D. Fla. 1993), aff'd sub nom., Christopher v. Cutter Lab., 53 F.3d 1184 , reh'g denied, 65 F.3d 185 (11th Cir. 1995).

In addition, in *Sicuraza v. Northwest Florida Blood Center, Inc.,* the plaintiff brought negligence action against a blood bank for supplying her with HIV-positive blood. The Circuit Court granted the blood bank's motion for summary judgment, and patient appealed. The District Court of Appeal, held that, the patient did not have to prove that the defect in the blood was detectable or removable by reasonable scientific procedures or techniques in order to recover in tort; and it was a material question of fact, as to whether screening procedures utilized by the blood bank met applicable standard of care at time that tainted blood was drawn and administered to patient, precluded entry of summary judgment for blood bank. *Sicuranza v. Northwest Florida Blood Center, Inc.,* 582 So.2d 54 (Fla.App. 1 Dist.,1991).

C. SECTION DIRECTORY:

Section 1. Amends s. 672.316, F.S., relating to Uniform Commercial Code – exclusion or modification of warranties.

Section 2. Provides the act becomes effective upon becoming law.

[5] The negligence standard is typically the ordinary level of prudence used by blood suppliers in the same or similar circumstances.

[6] Several courts have recently found in favor of plaintiffs who allegedly contracted AIDS from blood transfusions subject to negligently set standards. These courts have permitted claims to be brought not only against the blood bank, but also against their trade associations. For example, in *Weigand v. University Hospital of N.Y.*, 659 N.Y.S.2d 395 (N.Y. 1997), the court denied the trade association's motion to dismiss, finding that it owed a duty of ordinary care to a patient who received blood from a member blood bank because the trade association had set the standards used for blood collection. The court, however, found that the trade association, American Association of Blood Banks, had no duty to warn the patient of the risks of blood transfusions or to advise the patient of medical options. The court also determined the complaint sufficiently stated that the negligent standard setting of the trade association resulted in the transmission of HIV. Also, in *Snyder v. American Association of Blood Banks*, 676 A. 2d 1036 (N.J. 1996), the plaintiff sued the defendants for damages suffered due to the negligent standard setting of blood transfusions, and for negligent enhancement of the recipient's risk of contracting AIDS. The court held that the trade association, A.A.B.B., did owe a duty of care to the plaintiff and it was liable to the plaintiff under theories of negligent standard setting and negligent enhancement of risk.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

HB 461 will benefit blood banks and other blood suppliers by making it much more difficult to prove liability relating to the provision of defective blood or defective blood products. The bill will also increase the difficulty of plaintiffs seeking compensation for damages as a result of receiving defective blood or defective blood products.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or to take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenues.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES