HOUSE OF REPRESENTATIVES STAFF ANALYSIS

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

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Standards (Sub)	8 Y, 0 N	Chavis	Collins
2) Health Care	19 Y, 1 N w/CS	Chavis	Collins
3) Commerce	15 Y, 0 N	Cutchins	Whitfield
4) Judiciary	14 Y, 0 N	Jaroslav	Havlicak
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, designating blood as a service rather than a product. Blood suppliers, therefore, are normally judged not under a strict liability standard (where the blood supplier would be responsible for damages their actions or products cause, regardless of any "fault" on their part); rather, they are instead subject to a negligence standard (requiring the ordinary level of prudence used by blood suppliers in the same or similar circumstances).

This bill amends Florida's "blood shield" law, which is actually a portion of Florida's version of the Uniform Commercial Code ("UCC") relating to the exclusion or modification of warranties. 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 of goods under the UCC. As a service these activities are excluded from the UCC's implied warranties of merchantability (an implied warranty that guarantees that goods are reasonably fit for their ordinary purpose) and 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 in selecting goods for a particular purpose). Typically, these warranties impose strict liability (liability when there is no showing or even contention of negligence). The bill specifically eliminates the application of these implied warranties to blood and blood-related products and services.

Under current law, only the provision of services is excluded from strict liability; the actual blood and blood products have only a limited exclusion. Current law also 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. This bill expands the current limited exclusion to provide that the implied warranties of the UCC do not apply to any defects found in the blood or blood products.

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[x]	No[]	N/A[]
4. Increase personal responsibility?	Yes[]	No[]	N/A[x]
5. Empower families?	Yes[]	No[]	N/A[x]

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

B. EFFECT OF PROPOSED CHANGES:

Background: America's Blood Supply

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 ("FDA") has regulatory authority over plasma collection establishments, blood banks, and all blood products. The Centers for Disease Control and Prevention ("CDC") has responsibility for surveillance, detection, and warning of potential public health risks within the blood supply. The National Institutes of Health ("NIH") 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.

"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 ensuring a voluntary and inexpensive blood supply. Under blood shield laws, blood suppliers are thus not subject to the strict liability standard imposed in many sales of goods, but instead to a negligence standard. 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 courts that blood banks, including hospitals which act as such entities, may be liable in negligence for transfusion of contaminated blood.[1]

[1] For example, several courts have found in favor of plaintiffs who allegedly contracted HIV from blood transfusions subject to negligently-set standards. Some courts have also permitted claims to be brought not only against the blood bank, but also against their trade associations. *See, e.g.*, *Snyder v. American Assn. of Blood Banks*, 676 A.2d 1036 (N.J. 1996); *Weigand v. University Hospital*, 659 N.Y.S.2d 395 (N.Y. Sup. Ct. 1997). *But see N.N.V. v. American Assn. of Blood Banks*, 89 Cal.Rptr.2d 885 (Cal. App. 4 Dist. 1999) (holding that the trade association could not be held to even a negligence standard).

Regardless of the protection provided to 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.

Florida's Blood Shield 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 exclusion or modification of warranties with respect to the collection, testing, and storage of blood under Florida's version of the Uniform Commercial Code ("UCC").[2] Under this statute, the 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*.[3]

Typically, products under the UCC come with the implied warranty of "merchantability" and often the implied warranty of "fitness for a particular purpose."[4] These warranties do not apply to services (including blood-related services) because the UCC applies only to goods and not services; however, the implied warranties do apply to blood itself. Therefore, if a recipient receives defective blood—i.e., 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 for not utilizing the technique or procedure to detect or remove the defect.[5] 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 negligent failure-to-warn products liability claims against a supplier of blood or any other alternative liability theories, although under those theories it may be much more difficult for a plaintiff to obtain relief.

Alternative Liability Theories

A number of courts have held that Florida's blood shield statute does not preclude an individual from recovering under other theories of liability. For instance, in *Walls v. Armour Pharmaceutical Co.*,[6] the U.S. District Court for the Middle District of Florida found that while the Florida blood shield statute limited claims for breach of implied warranty of fitness or merchantability, it did not limit the products liability claim of negligent failure to warn and, thus, the products liability statute of limitation rather than

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

[3] Obviously, blood banks do not "make" blood, as a manufacturer would "make" a product; however, what they do could obviously be as easily analogized to the sale of a good as to the provision of a service.

[4] Although there are other factors, the primary determinant of whether goods are merchantable is whether they "[a]re fit for the ordinary purpose for which such goods are used." Section 672.314(2)(e), F.S. Goods are subject to the implied warranty of fitness for a particular purpose if the seller has reason to know of such a purpose and the buyer relies on the seller's skill or judgment in selecting the appropriate to satisfy that purpose. *See* s. 672.315, F.S.

[5] 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 has been considered to have met the standard of care.

[6] 832 F. Supp. 1467 (M.D. Fla. 1993).

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.

Likewise, in *Sicuranza v. Northwest Florida Blood Center, Inc.*,[7] the First District Court of Appeal held that a 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 (rather than in contract under the UCC); thus, 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 that patient, precluding entry of summary judgment for the blood bank.

Proposed Changes

This bill expands Florida's current blood shield law to broaden the exclusion of the implied warranties of merchantability and fitness for a particular purpose by removing the current limitation on application of these warranties to only those defects that cannot be detected or removed by a reasonable use of scientific procedures or techniques. This bill thus makes the implied warranties inapplicable to any defect in blood or blood products.

This bill does not limit other existing alternative legal theories of liability. In particular, this bill does not limit suits alleging "negligent 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 is satisfied (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 proximately caused by the defendant).

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

C. SECTION DIRECTORY:

Section 1. Amends s. 672.316, F.S., relating to exclusion or modification of warranties under the UCC, to provide that specified implied warranties are not applicable to the procurement, processing, storage, distribution, or use of blood or blood products.

Section 2. Provides an effective date of upon becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

[7] 582 So.2d 54 (Fla. 1st DCA 1991).

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

This bill will benefit blood banks and other blood suppliers by making it considerably more difficult to impose 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 appear to require counties or municipalities to take an action requiring the expenditure of funds, does not appear to reduce the authority that counties or municipalities have to raise revenue in the aggregate, and does not appear to reduce the percentage of state tax shared with counties or municipalities.

2. Other:

Impairment of Contracts

Both Article I., section 10 of the United States Constitution and Article I, section 10 of the Florida Constitution forbid state impairment "of the obligation of contracts."[8] Florida courts have generally treated the requirements of the state and federal Contract Clauses as identical, although they have suggested that the provision in the state constitution is probably stronger.[9]

Applying the effects of this bill to contracts entered into before its effective date may raise concerns about legislative impairment of these contracts, which might be held subject to prior law.[10] Courts use a balancing test to determine whether particular legislation violates the Contract Clause,

[8] *See generally* 16 AM. JUR. 2D CONSTITUTIONAL LAW §§ 708-744; 10 FLA. JUR. 2D CONSTITUTIONAL LAW §§ 348-373.
[9] *See, e.g.*, *Pomponio v. Claridge of Pompano Condominium, Inc.*, 378 So.2d 774 (Fla. 1980) (accepting as persuasive an interpretation of the federal Contract Clause by the Supreme Court of the United States in *Allied Structural Steel Co. v. Spannaus*, 438 U.S. 234 (1978)).
[10] *See, e.g., Marion Mortgage Co. v. State ex rel. Davis*, 145 So. 222 (Fla. 1932); *Ex parte Amos*, 114 So. 760 (Fla. 1927); *Columbia County Comm'rs v. King*, 13 Fla. 451 (1869) (all holding that, under Contracts Clause, articles of incorporation were subject to law in effect when they were first promulgated). *Cf. Trustees of Dartmouth College v. Woodward*, 17 U.S. (4 Wheat.) 518 (1819) (holding that, by attempting to transform Dartmouth College into a public university, the State of New Hampshire had unconstitutionally impaired obligations of contract that the state had inherited as successor-in-interest to the British Crown, which granted Dartmouth's corporate charter in 1769).

measuring the severity of contractual impairment against the importance of the interest advanced by the regulation, and also looking at whether the regulation is a reasonable and narrowly tailored means of promoting the state's interest.[11]

However, even if an attempt to retroactively apply the effects of this bill were held not to unconstitutionally impair the obligations of contract, Florida common law does not allow government to adversely affect substantive rights once those rights have vested;[12] moreover, unless the Legislature states otherwise, a statute is presumed only to operate prospectively, especially when such operation would impair vested rights.[13]

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On March 19, 2003, the House Subcommittee on Health Standards recommended one amendment to this bill, removing the word "medical" from the description of the type of services covered by the subsection. The Subcommittee then recommended this bill favorably.

On March 26, 2003, the House Committee on Health Care adopted the amendment recommended by the subcommittee and reported the bill favorably with a committee substitute.

On April 14, 2003, the House Committee on Judiciary reported this bill favorably without amendment.

[11] *See Allied Structural Steel Co. v. Spannaus*, 438 U.S. 234 (1978); *East New York Savings Bank v. Hahn*, 326 U.S. 230 (1945); *Ruhl v. Perry*, 390 So.2d 353 (Fla. 1980); *Pomponio v. Claridge of Pompano Condominium, Inc.*, 378 So.2d 774 (Fla. 1980); *Yellow Cab Co. v. Dade County*, 412 So.2d 395 (Fla. 3d DCA 1982).
[12] *See Bitterman v. Bitterman*, 714 So.2d 356 (Fla. 1998).
[13] *See State Farm Mut. Auto. Ins. Co. v. Laforet*, 658 So.2d 55 (Fla. 1995); *Alamo Rent-A-Car, Inc. v. Mancusi*, 632 So.2d 1352 (Fla. 1994).