SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

BILL: CS/SB 2036

SPONSOR: Health, Aging, and Long-Term Care Committee and Senator Smith

SUBJECT: Uniform Commercial Code/Blood

DATE: March 31, 2003 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Harkey	Wilson	HC	Favorable/CS
2.	Kruse	Maclure	CM	Favorable
3.			FT	
4.				
5.				
6.				

I. Summary:

This committee substitute deletes the current statutory provision that excludes a blood or blood product defect that cannot be detected or removed by a reasonable use of scientific procedures or techniques from the implied warranties of merchantability and fitness.

This committee substitute amends section 672.316, Florida Statutes.

II. Present Situation:

The Uniform Commercial Code

The Uniform Commercial Code (UCC) is a comprehensive code addressing most aspects of commercial law. The UCC draft laws are written by experts in commercial law and submitted 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 and must be enacted by a state legislature. The UCC has been implemented, with some local variations, in 49 states, the District of Columbia, the Virgin Islands, and partially in Louisiana.

Florida's Uniform Commercial Code is found in chs. 670-680, F.S. Chapter 672, F.S., contains the code provisions governing sales. Under s. 672.316(5), F.S., 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 a 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, meaning liability even when there is no proof of negligence. However, this "strict liability" standard of care does not apply in all cases. The current statute does not apply this standard of care when a defect cannot be detected or removed by a reasonable use of scientific procedures or techniques. Florida courts have held current s. 672.316(5), F.S., to mean that a plaintiff may maintain an action for damages on the grounds of breach of implied warranty of fitness or merchantability only if he alleges and proves that the defect of which he complains is detectable or removable by the use of reasonable scientific procedures or techniques.[1] Many states have adopted "blood shield" laws that establish these activities involving human blood as the provision of a service rather than the transfer of a product.[2]

Regulation of Blood Establishments

The U.S. Food and Drug Administration (FDA) and the Center for Biologics Evaluation and Research (CBER) are responsible for regulatory oversight of the U.S. blood supply. CBER regulates the collection of blood and blood components used for transfusion or for the manufacture of pharmaceuticals derived from blood and blood components, such as clotting factors, and establishes standards for the products themselves. CBER initiated a Blood Action Plan in July 1997, which addresses highly focused areas of concern such as emergency operations, response to emerging diseases, and updating of regulations. The U.S. Department of Health and Human Services (HHS) accepted this plan in March 1998.

Typically blood is collected from voluntary donors through a network of nonprofit community and hospital blood banks. Human blood and blood products can transmit infections such as hepatitis, cytomegalovirus, syphilis, malaria, and human immunodeficiency virus (HIV). Over a period of years, the FDA has progressively strengthened overlapping safeguards that protect patients from unsuitable blood and blood products. Blood donors are asked specific, direct questions about risk factors that could indicate possible infection with a transmissible disease. The FDA reports that this "up-front" screening eliminates approximately 90 percent of unsuitable donors. FDA also requires blood centers to maintain lists of unsuitable donors to prevent the use of collections from them. Blood donations are tested for a number of different infectious agents. [3]

Even with all of these procedures to safeguard the blood supply, there is still some risk associated with the transfer of blood and blood products. In 2002, two people became infected with HIV when they received transfusions of blood from a donor whose disease was not detected by the Tampa area blood bank where the blood was donated.[4]

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[1] *Raskin v. Community Blood Centers of South Florida, Inc.,* 699 So. 2d 1014 (Fla. App. 4 Dist., 1997).
[2] *See, e.g.*, Ala. Code s. 7-2-314, *available at* http://www.legislature.state.al.us/CodeofAlabama/1975/7-2-314.htm (last visited March 28, 2003); Vt. Stat. Ann. Tit. 9A, s. 2-108, *available at* http://www.leg.state.vt.us/statutes/fullsection.cfm?Title=09A&Chapter=002&Section=00108 (last visited March 28, 2003).
[3] U.S. Food and Drug Administration, CBER, *Blood*, *available at* http://www.fda.gov/cber/blood.htm (last visited March 28, 2003).
[4] St. Petersburg Times, July 19, 2002, *Tainted donor blood infects two with HIV*, *available at* http://www.sptimes.com/2002/07/19/State/Tainted_donor_blood_i.shtml (last visited March 28, 2003).

Alternative Liability Theories

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. In *Walls v. Armour Pharmaceutical Co.*, the U.S. District 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.[5] In addition, in *Sicuraza v. Northwest Florida Blood Center, Inc.*, the plaintiff brought a negligence action against a blood bank for supplying her with HIV-positive blood. 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. Summary judgment was denied for the blood bank because it was a material question of fact whether screening procedures utilized by the blood bank met the applicable standard of care at the time the tainted blood was drawn and administered to the patient.[6]

III. Effect of Proposed Changes:

This committee substitute amends s. 672.316(5), F.S., which specifies that the procurement, processing, transfusion, storage, distribution, and 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 service. The committee substitute expands the exclusion of these activities from the implied warranties of merchantability and fitness for a particular purpose by removing the current limitation which states that the exclusion applies to a defect that cannot be detected or removed by a reasonable use of scientific procedures or techniques. With this change, the described warranties would be inapplicable to any defect in blood or a blood product.

The committee substitute takes effect upon becoming law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

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[5] *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).

[6] *Sicuranza v. Northwest Florida Blood Center, Inc.*, 582 So. 2d 54 (Fla. App. 1 Dist. 1991).

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Blood banks will not be subject to liability involving the implied warranties of merchantability and fitness for a particular purpose for any defect in blood or a blood product. Plaintiffs will not be able to use this liability theory but would retain alternative theories of liability when seeking compensation for damages as a result of receiving defective blood or defective blood products.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Amendments:

None.