# 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: The Uniform Commercial Code

DATE: March 26, 2003 REVISED:

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

## I. Summary:


This bill expands the exclusion from the implied warranties of merchantability and fitness for the procurement, processing, transfusion, storage, distribution and use of whole blood, plasma, blood products, and blood derivatives 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.

This bill amends s. 672.316, F.S.


## 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 does not have effect until the provisions are enacted by a state legislature. 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.

Florida's Uniform Commercial Code is found in chs. 670-680, F.S. Chapter 672, F.S., contains the provisions of the code that govern 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, that is, liability even when there is no proof of negligence. Under s. 672. 316(5), F.S., the exclusion is limited to only those defects that cannot be detected or removed by a reasonable use of scientific procedures or techniques. Many states have adopted this type of "blood shield" law that establishes these activities involving human blood as the provision of a service rather than the transfer of a product.

**Regulation of Blood Establishments**

Currently, blood establishments that collect blood for the purposes of transfusion, manufacture of a biological product or for other medical purposes are not regulated under Florida law. The federal Food and Drug Administration (FDA) regulates these facilities only if they ship blood or blood products across state lines. In the event the FDA prohibits such an establishment from the interstate transport of such materials, the FDA has no authority to prevent them from operating within a state.

The 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 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.

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. In another Florida incident in 2002, a blood bank in South Florida was shut down by the FDA after inspectors found poor-quality blood and unsanitary practices. There was no report of any individuals becoming ill from the blood bank's products in the South Florida incident.

## III. Effect of Proposed Changes:

This bill 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 bill 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 warranties would be inapplicable to any defect in blood or a blood product.

The bill takes effect upon becoming law.

## IV. Constitutional Issues:

### A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

### B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Art. I, s. 24(a) and (b) of the Florida Constitution.

### C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

## V. Economic Impact and Fiscal Note:

### A. Tax/Fee Issues:

None.

### B. Private Sector Impact:

Blood establishments would be granted a broader exclusion from the implied warranties of merchantability and fitness for services involving blood or a blood product.

### C. Government Sector Impact:

The provisions of this bill do not create a cost to government.

## VI. Technical Deficiencies:

None.

## VII. Related Issues:

None.

## VIII. Amendments:

None.