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Blood Systems: A Case Study of Cross Culture Issues and Challenges

ABSTRACT

In the wake of the "Mad Cow" disease tragedy in the United Kingdom, it became apparent that the UK would need to look elsewhere for its country's blood plasma needs, particularly as the possibility of transfusion-related transmission surfaced. They turned to providers of blood products in the United States and reached a contractual agreement with Blood Systems, Inc. in 2003. Thus, Legal, logistical, and cultural challenges were addressed and overcome in this international humanitarian-business relationship.Addressing the cultural differences between the United Kingdom and the United States in negotiating the contract was only the beginning of the challenges facing Blood Systems in this international venture. The contract itself had to be written to deal with European Law and medical /technical regulatory policy, the logistics of international shipping, currency valuation fluctuations, and contract renewal/extension.

1. BACKGROUND

Health issues can be a national tragedy, regardless of the initiating factor. Compounding the tragedy is the need to address these issues internationally when there are significant differences in regulations and cultures. When the Blood Systems, Inc. negotiated a contract with the National Blood Service of the United Kingdom for Fresh Frozen Plasma, it had to address the "Mad Cow" disease tragedy in the UK. Much of the research regarding "mad cow" disease is controversial and it can be argued that the UK underestimated the risk factors, putting the population in danger.

Healthcare issues are emotional and cannot be addressed thru economic indicators alone. What is the value of a human life? How many dollars or pounds are spent to save a few lives? Humanitarian efforts, which cannot be valued monetarily, have been the mainstay in addressing world-wide healthcare issues. Blood Systems approached the UK tragedy from both a humanitarian and business position, exploring relatively new territory in its endeavor.

The full extent of the "mad cow" impact is yet to be seen, and may affect additional countries in the future as more is learned about the disease. Moving forward with international agreements may be the only way to safely deal with this devastating healthcare issue.

Blood Systems, Inc.

Blood Systems, Inc. was founded in Phoenix, Arizona in 1943 as the Salt River Valley Blood Bank. Today it is the second largest non-profit blood collection organization in the United States, providing blood, blood components, and special services to more than 25 million people in 18 states. As a 501(c)(3) non-

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profit organization, its mission is both pragmatic and encompassing:

"Blood Systems exists to make a difference in people's lives by bringing together the best people, inspiring individuals to donate blood, producing a safe and ample blood supply, advancing cutting-edge research and embracing continuous quality improvement."

Blood Systems has four business units which are interdependent and support its mission and strategic plan:

- *United Blood Services* which provides access to blood donors and blood products;
- *Blood Systems Research Institute* providing research and development in the areas of testing and transfusion services;
- *Blood Systems Laboratories* providing testing services to United Blood Services centers and outside customers in order to provide the safest blood components possible; and
- *BioCare*, which provides pharmaceuticals and derivatives to area hospitals and physicians.

Although Blood Systems does not have an International Business Profile, or specific International Business Plan, increasing globalization of blood banking is a significant part of the company's 2005-2007 Strategic Plan.

Prior to entering into an agreement with the United Kingdom's National Blood Service for Fresh Frozen Plasma (FFP), Blood Systems already had international contracts with ZLB Behring based in Berne, Switzerland for 115,000 liters of recovered plasma, and with the Scottish National Blood Transfusion Service based in Edinburgh, Scotland for 10,000 liters. ZLB and SNBTS use the plasma for fractionation into plasma therapy pharmaceuticals. Annual recovered plasma sales from these two sources alone reflect four percent of Blood Systems' total annual revenues. Blood Systems Laboratories also has a two-year West Nile Virus testing contract with the United Kingdom's National Blood Service.

National Blood Service – United Kingdom

The National Blood Authority, a special health authority of the National Health Services, oversees the National Blood Service (NBS) and is responsible for the collection, processing, testing and distribution of blood components in England and North Wales.

NBS operates 15 blood centers and collects over 2.4 million voluntary blood donations per year, providing blood and blood products to each of the 310 hospitals in its coverage area. The core purpose of the NBS is "to save and improve patients' lives".

"Mad Cow" Disease in the United Kingdom

In 1986, cattle in the United Kingdom began to suffer from a condition nicknamed "mad cow disease" due to the behaviors exhibited by cattle that were infected with Bovine Spongiform Encephalopathy, or BSE. The British government insisted throughout the early 1990's that the disease posed no threat to humans. Then in May of 1995, a nineteen-year-old British man died of variant Creutzfeldt-Jakob Disease (vCJD), a condition similar to BSE.

The British Health Secretary announced that the most likely explanation for the disease was transmission of vCJD from eating the meat of cattle that were infected with BSE. In late 2003 the first

probable case of a patient being infected with vCJD from a blood transfusion was announced and the British government banned anyone who had received a blood transfusion since 1980 from donating blood.

2. CULTURAL CHALLENGES

Blood Systems made an important strategic move early in its decision to move into the international arena by naming Michael Lamb Vice-President of Business Development. Mr. Lamb was raised and educated in England. He is keenly aware of, and sensitive to, the European culture. This was and continues to be a big factor in Blood System's international success. "Harmonization" is the plasma industry buzzword. "From a business development perspective, my job is to make sure our recovered plasma contractually conforms," said Mr. Lamb. It is also a significant business strategy for Blood Systems – placing high quality, EU specification plasma with European fractionators who can provide finished products to Blood System's BioCare division.

A number of American blood centers looked at the Request for Proposal issued by the NBS and decided that they would discuss the economics of the contract first. To the British, this was a significant breach of etiquette. The NBS was first and foremost interested in the medical/technical elements of the contract, and compliance with the National Health Service requisites. Mr. Lamb, knowing the culture and penchant for precise statistical process control, was instrumental in setting the tone for the negotiations. Realizing that this was both a humanitarian and business opportunity, Blood Systems approached the discussions recognizing that the UK was facing a national tragedy with vCJD. The company discussed solving the UK problems first and then put numbers together last. It was critical to establish trust with the British and have them meet virtually every member of the management team, including management at the regional blood centers from which they would be receiving FFP.

3. CONTRACT ISSUES

Addressing the cultural differences between the United Kingdom and the United States in negotiating the contract was only the beginning of the challenges facing Blood Systems in this international venture. The contract itself had to be written to deal with European law and medical/technical regulatory policy, the logistics of international shipping, currency valuation fluctuations, and contract renewal/extension.

Conforming to Specifications

All recovered plasma that is provided by Blood Systems to fractionators is moving toward conforming to European Union specifications. Early in 2005, a special procedures development group will be re-writing Blood Systems Standard Operating Procedures to conform to EU specifications. Blood Systems is regulated by the Food and Drug Administration, and that policy withstood the careful scrutiny of the NBS in establishing the initial relationship. Subsequently, NBS audits Blood Systems on a regular basis referring to EU policy.

UK and EU regulatory policy is currently more stringent than US policy. Such was not the case when the initial FFP contract was negotiated, but Blood Systems has consistently met the more rigorous requirements.

Logistics of International Shipping

Plasma is a perishable biologic which must be frozen within a very strict time frame, at very specific temperatures, and maintained at specific temperatures to meet the FFP requirements of the contract. The logistics themselves are a study in creativity, which so far has worked perfectly. UBS centers throughout the country ship units in validated shipping containers every day via Federal Express to Walton, Kentucky where they are "staged" in a gigantic freezer warehouse. Every two weeks, two pallets of boxed FFP are shipped to England. The pallets are trucked to Chicago's O'Hare airport on a Sunday afternoon and by Sunday evening they are shipped airfreight on direct flights to London's Heathrow airport.

At Heathrow, customs officials release the FFP to a freight handler that trucks them directly to the door of the NBS. All of the units in the shipment must be maintained at a temperature of -18C or colder, so each shipment contains at least one temperature data logger to record minimum and maximum temperatures during the journey. Electronic Data File Transfers are sent from Blood Systems to the NBS for downloading into their systems, tracking the units being shipped to them. The whole process from Sunday afternoon to the NBS door takes 36 hours.

Currency Valuation Fluctuations

Currency valuation fluctuations were written into the contract which is expressed in US dollars. Any currency float outside of a ten percent swing either way is reconciled at the end of each contract year and settlement is made. Any fluctuation inside the parameter is built into the contract.

Renewal/Extension

The contract between Blood Systems and the NHS is for three full years with six-month status review points written in. There is an option for one contract extension period for two additional years, making the maximum contract period five years.

4. COMPETITIVE CHALLENGES

The National Blood Service is working within a framework of socialized medicine and had a difficult time understanding the competitiveness and economics of the blood banking industry in the United States. Blood Systems collects plasma only from volunteer donors. For-profit plasma facilities in the United States compensate individuals for the plasma they collect for fractionation. This presented an interesting "twist" during the course of the negotiations.

The NBS also does fractionation of plasma into pharmaceuticals, as well as over-seeing transfusion to humans, and had purchased a source plasma group in the United States to ensure a safe and secure source of plasma for fractionation. Decision makers in the UK suggested using the plasma from that source for transfusion to humans rather than entering into a contract with Blood Systems. Medical/technical experts at NBS had to explain to those decision makers that using the source plasma was not an option because all of those donors are remunerated, and that the Standard of Care in the UK for transfusable Fresh Frozen Plasma is from voluntary blood donors only. Discussions with Blood Systems were resumed once the critical differences and transfusion practice reasons were explained.

5. FINDINGS

It is vitally important when dealing in international negotiations to have someone at the forefront who understands both cultures. The agreement between Blood Systems and the National Blood Service has been both a humanitarian and business endeavor showing that we are more alike than different when it comes to what is truly important, and that when human life is at stake common ground can be found and almost any obstacle can be overcome.

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