



State of Louisiana

**OFFICE OF
STATE INSPECTOR GENERAL**

HEART LUNG MACHINE

Report by

Inspector General Bill Lynch

Prepared for

Governor M.J. "Mike" Foster, Jr.

May 10, 2000

File No. 1-00-0006



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March 21, 2000

File No. 1-00-0006

Heart-Lung Machine

University Hospital in New Orleans, a facility operated by Louisiana State University, issued specifications for heart-lung machine supplies that restricted competition and would substantially increase the cost. The current three-year contract, plus additional necessary supplies purchased separately, cost the state \$647,850. Using University Hospital representations, the Office of State Purchasing estimated the cost of the new contract, which would include all necessary supplies, at \$1.3 million, an increase of \$652,150.

Because the specifications called for a type of product used infrequently elsewhere despite being marketed for about 20 years, and because of conflict of interest concerns relative to two individuals involved in preparing the bid package, the specifications are questionable.

While medical applications are best left to medical personnel to determine, operation of the medical facility also requires business decisions on cost justification. Staying on the “cutting edge” of medicine can be expensive. However, this cost may not be justified when the contribution to patient welfare is nominal. Funds spent in such a manner could be used to meet other patient needs. University Hospital administration should scrutinize the proposed perfusion supplies specifications and determine whether they are justified.

Background

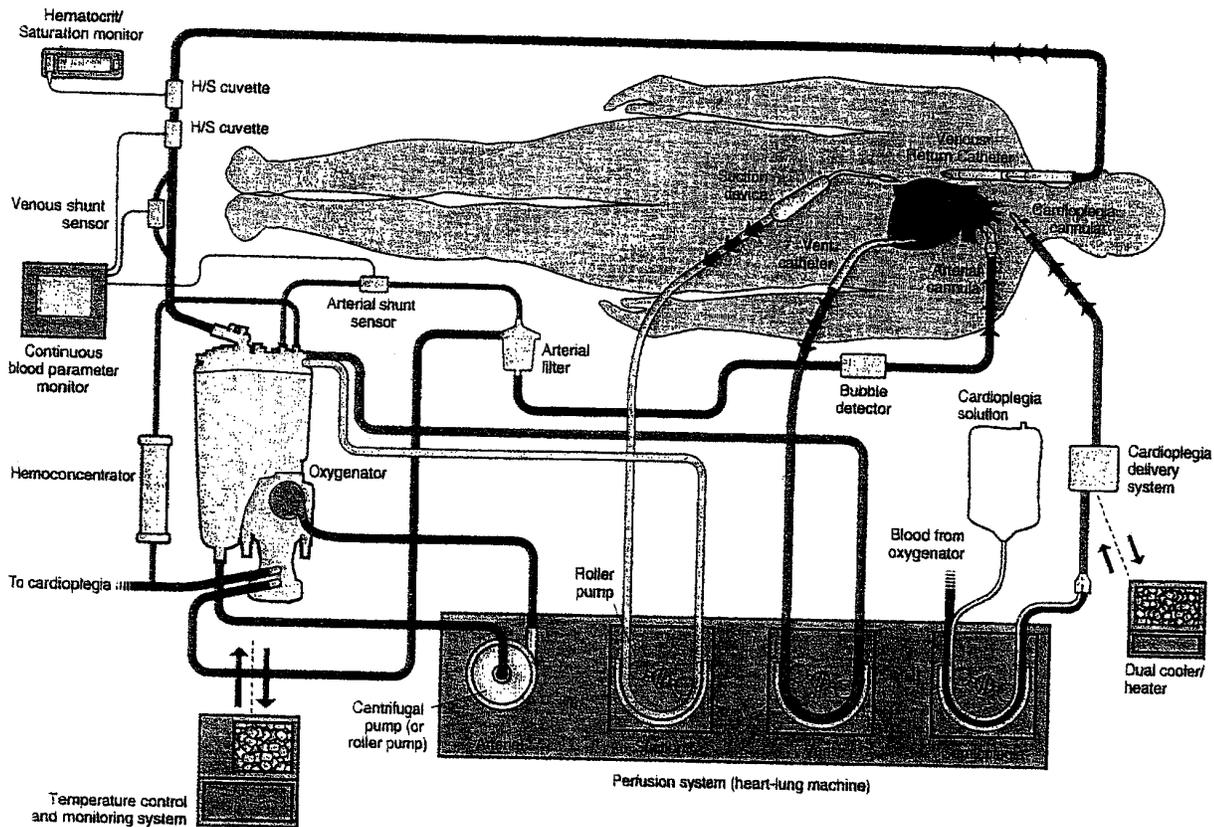
The Office of State Purchasing requested this office review recent circumstances surrounding bid specifications for perfusion supplies for the heart-lung machine in the Cardiothoracic Surgery section of the University Hospital, a state facility serving as the West Campus of the Medical Center of Louisiana in New Orleans.

Perfusion is the process of circulation of the blood during any medical procedure where life-support is necessary. A perfusionist is a person qualified to operate the heart-lung machine, or perfusion system. This system includes devices to pump, oxygenate and circulate blood to and from the patient during certain operations, primarily heart surgery. University Hospital surgeons require perfusion services about 350 times per year.

Baxter Healthcare Corporation (Baxter), a subsidiary of Baxter International, Inc., one of the largest providers of healthcare equipment and services in the world, manufactures and distributes perfusion equipment and supplies. Baxter provides perfusionists to hospitals

through Perfusion Services of Baxter Healthcare Corporation (Baxter Perfusion Services), a wholly-owned subsidiary. For the purposes of this report, we view Baxter, its operational units and its subsidiary as one entity.

Heart-Lung Machine (or Perfusion System)



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During certain operations, for example heart bypass or transplant surgery, where a patient will need life-support, a heart-lung machine (or perfusion system) is used. The patient's blood is circulated through tubing to a reservoir and oxygenator where it is oxygenated and temperature-regulated. The blood is then pumped back into the patient using either a centrifugal or roller type pump. The pumps, gauges and monitors are capital purchases, while the tubing, reservoir and oxygenator are disposable, single-patient supplies. Total cost of a perfusion system is about \$120,000.

Restrictive Bid Specifications

From September, 1998, through June, 1999, Dr. Herman Heck and Mr. Joseph Basha, Jr., worked together to develop specifications for the hospital contract for a different type of supplies for the perfusion system. The specifications limited the companies eligible to bid, and substantially increased the cost.

Dr. Heck has been an assistant professor of surgery and a cardiothoracic surgeon at University Hospital for about six years. He is the liaison for the Cardiothoracic Surgery section of the hospital for medical supplies and equipment, which requires his involvement in the acquisition of such items. Dr. Heck said he developed the new perfusion supplies specifications in concert with other staff surgeons.

Mr. Basha was an employee until July, 1999, of Total Blood Management, Inc., a contractor which provides the hospital with clinical perfusionists. Mr. Basha served for about two years as the hospital's chief perfusionist, which required his involvement in the acquisition of perfusion supplies and equipment. Mr. Basha said his role was to implement the medical staff's decision, which he said unanimously favored using "bio-compatible" perfusion supplies.

Bio-compatible coating of perfusion components has existed for about 20 years, and has had increased usage in the last few years, according to Baxter. The coating, usually the anticoagulant heparin, helps prevent clotting and reduces body inflammation, possibly reducing risk to the patient. There have been numerous studies conducted to examine the benefits of such coating, and the conclusions are mixed.

University Hospital's current perfusion supplies contract was awarded to Medtronic, Inc., in 1997. That company provides the hospital with the disposable components of the perfusion system, which include non-coated tubing and a non-coated blood reservoir bag through which a patient's blood flows during certain types of surgery. Two changes were made in the bid specifications. The new specifications written by Mr. Basha with Dr. Heck's input, required a bio-compatible coating on all components, including the tubing, and required the blood reservoir to be a coated, hard-shell reservoir instead of a bag.

The new specifications limited the number of potential bidders, since only Baxter and Medtronic make or sell bio-compatible coated tubing and a coated hard-shell reservoir.

Dr. Heck noted the University Hospital Purchasing Department approved the specifications.

La. R.S. 39:1655 requires that all specifications shall encourage competition and shall not be unduly restrictive.

Dr. Heck and Mr. Basha said coated components can be of significant benefit to the patient and that there is a trend towards their use in an increasing number of hospitals both in the United States and abroad. According to Baxter, its products are used by leading medical facilities.

However, coated components are rarely used in Louisiana hospitals, public or private. Twenty-seven percent (16 of 60) of the certified clinical perfusionists in Louisiana were surveyed and only one used coated components, and then only five percent of the time for liver transplant cases at Tulane Medical Center in New Orleans. Most felt the benefits of coated components had not been proven, and since coated components were more expensive than non-coated, routine use of coated products was not cost justified. Some stated the promotion of coated components was nothing more than a marketing plan by the few companies that make such products.

We contacted 18 major hospitals throughout the United States and found the use of coated components outside of Louisiana also seems limited. While several hospitals reported they occasionally use bio-compatible perfusion supplies, this was generally limited to a small percentage of procedures in which their use was specifically indicated. In contrast, the new University Hospital specifications required the contractor to provide 350 units per year of disposable bio-compatible coated perfusion components, which means that such coated components would be used for all perfusion cases at University Hospital.

The chief perfusionist for Johns Hopkins, one of the nation's leading hospitals and the home of the nation's largest School of Perfusion Science, said bio-compatible coating has received only marginal acceptance. He said it is used only about 10 percent of the time at Johns Hopkins in special cases where patients, such as those undergoing liver transplants, cannot be given heparin to prevent clotting. In most cases, use of coated components is not medically necessary and not cost justified, he said.

The Heart Institute of Texas, one of the busiest cardiac surgery centers in the United States, performs about 2,300 heart cases per year. The director of perfusion there said the cost benefits of using a coated system are not justified by clinical studies. That hospital uses a non-coated system 95 percent of the time. Coated components are used only in liver transplants and a few other special cases.

Other prominent hospitals in the United States routinely using a non-coated system include Duke University Medical Center, Bethesda Naval Hospital, Yale-New Haven Medical Center, Mt. Sinai Hospital, UCLA Medical Center, Cedar Sinai Hospital in Los Angeles, New York Hospital, Emory University Medical Center, University of Arizona Medical Center, Sacred Heart Hospital and Deaconess Hospital in Washington, University of Chicago, St. Lukes Hospital in Milwaukee, University of Illinois, Fairfax Hospital, Columbia Presbyterian Hospital of New York and Baptist Hospital at Little Rock.

Dr. Heck identified five hospitals that routinely use bio-compatible perfusion supplies: Memorial Hospital in Chattanooga, Tennessee; DCH Regional Medical Center in Tuscaloosa, Alabama; University of Alabama at Birmingham; Medical Center East in Birmingham, Alabama; and Huntsville Hospital in Huntsville, Alabama. He also provided a list of 15 institutions that have or are evaluating bio-compatible products.

An official with Baxter said hospitals in Louisiana using coated components included Lakeland Medical Center, Memorial Medical Center, North Monroe Community Hospital, Tulane University and Veteran's Hospital in New Orleans.

As previously stated, Tulane uses coated components only in specific cases five percent of the time, and Veteran's Hospital discontinued the routine use of coated components several years ago. North Monroe Community Hospital recently discontinued perfusion services and canceled its perfusionist contract with Baxter, according to the director of surgical services at the hospital.

Dr. Heck stated that Louisiana has not been very progressive in using improved medical technology. He said that if officials at State Purchasing did not approve the specifications as written, University Hospital would continue to operate successfully with non-coated components.

Dr. Heck also performs surgery requiring perfusion at Veteran's Hospital in New Orleans, and that facility does not use coated components. According to a perfusionist at Veteran's Hospital, coated components were used briefly several years ago, but were discontinued after being determined not cost justified.

Using information provided by University Hospital, State Purchasing estimated submitted bids would be for about \$420,000 for each year of this proposed contract, annually renewable for up to three years, or about \$1.3 million. The cost to the state would include the increase resulting from the use of coated tubing instead of non-coated tubing, and a coated hard-shell blood reservoir instead of a non-coated bag.

The cost comparison between the current and proposed contracts factors in \$183,700 in costs for items not included in the current contract. The cost difference between the current and proposed contracts is estimated at \$652,150. Baxter estimated the additional cost of its bio-compatible products averages about 20 percent, which would be about \$130,000.

Other estimates of the cost increase provided by perfusionists, companies that market coated products, and a University Hospital cost analysis ranged from 10 to 100 percent.

Bids have already been received by State Purchasing in response to University Hospital's perfusion supplies specifications. Because of a bid protest they remain sealed and the actual amount of the bids is not known.

Conflicts of Interest

Both Dr. Heck and Mr. Basha had apparent conflicts of interest involving Baxter.

Dr. Heck

In September, 1998, Dr. Heck received a three-day trip paid for by Baxter to observe the use of a Baxter heart valve at the Cleveland Clinic in Cleveland, Ohio. He said he observed and learned the techniques of minimally invasive open heart surgery as well as off-pump coronary bypass surgery, a procedure that does not require perfusion. Dr. Heck acknowledged that the company paid about \$2,200 for his expenses associated with the trip, including airline tickets, lodging and meals.

Dr. Heck said he does not usually accept gratuities or gifts from vendors, but in this case he had the opportunity to learn a great deal, and since there was no cost to the state, he accepted the gratuity.

Dr. Heck said he returned from the Cleveland Clinic with an interest in improving the perfusion system at University Hospital, and approached the hospital's chief perfusionist, Mr. Basha, with suggestions. In the fall of 1998, Mr. Basha began preparing the specifications for a public bid on a new contract for perfusion supplies. That process culminated in the public release of the specifications at the pre-bid conference June 24, 1999.

Whether Dr. Heck's receipt of paid expenses from Baxter violates the Louisiana Code of Governmental Ethics is a question to be determined by the Board of Ethics.

Mr. Basha

During the process, Mr. Basha approached Baxter Perfusion Services for employment with that company. In early April, 1999, he had conversations with a regional human resources manager and a chief perfusionist who later would be involved in interviewing him.

Mr. Basha approved a draft of the bid specifications April 26, 1999. A week later, he submitted a resume, formally applying for employment, and in mid-May, 1999, he told a vice-president of Total Blood Management, his employer, he would be leaving. In late May and early June, 1999, Mr. Basha was formally interviewed by Baxter Perfusion Services. A June 9, 1999, dinner for Mr. Basha, attended by several Baxter Perfusion Services managers and their wives, was described by one manager as "a celebration, because it was a foregone conclusion he would be hired."

These dates were obtained from company executives and employees who were involved in Mr. Basha's hiring, including a regional director of human resources. Dates concerning Mr. Basha's employment with Baxter Perfusion Services supplied by his attorney are consistent with this chronology. Baxter Perfusion Services has responded that he applied for a job on July 1, 1999, and further states our dates "contain errors," but declined to further explain.

On June 24, 1999, the pre-bid conference was held and the specifications were officially made public. Five days later, Mr. Basha resigned from Total Blood Management to go to work for Baxter Perfusion Services.

Mr. Basha said his negotiations for employment were unrelated to the specifications on which he worked. He said he was dissatisfied with Total Blood Management and even turned down a pay raise to work for Baxter Perfusion Services. He provided documents to support that.

According to Baxter Perfusion Services, it was unaware of Mr. Basha's role at University Hospital in working on perfusion supplies procurement.

Whether Mr. Basha's participation in the bid process while he was seeking employment with Baxter Perfusion Services violates the Code of Governmental Ethics is a question to be determined by the Board of Ethics.

Other Louisiana Hospitals

Baxter reported its Louisiana sales include sales of perfusion products in Louisiana to three New Orleans area hospitals. The perfusionists at these three hospitals are Baxter Perfusion Services employees provided by contract.

La. R.S. 51:916.B(3)(b) states, "It shall be unlawful for a business entity which sells products or equipment used in the performance of clinical perfusion services to a hospital or other medical institution to perform perfusion services at that medical institution."

Legally, because Baxter Perfusion Services is a wholly-owned subsidiary of Baxter, both might be considered a single business entity for the purpose of this statute.

Baxter Perfusion Services asserts that the companies are sufficiently separate to satisfy the law. Nonetheless, Baxter has advised us that it intends to discontinue the product sales to the three hospitals, and has begun steps to do so.

Conclusions:

1. Dr. Heck and Mr. Basha developed specifications for a hospital contract for perfusion system supplies which limited the competition, and is estimated to substantially increase the cost of the contract.
2. Dr. Heck accepted travel and related expenses totaling about \$2,200 from Baxter Healthcare Corporation, a potential vendor, to observe surgical procedures which included use of Baxter products.
3. Mr. Basha negotiated employment with Baxter Perfusion Services while he helped prepare specifications for a contract for which Baxter would be eligible to bid.

4. Baxter supplied some Louisiana hospitals with both perfusionists and perfusion supplies.

Recommendations:

4. The medical director of Healthcare Services for the LSU Medical Center should review the proposed specifications for patient benefits and cost justification.
5. This report should be referred to the State Board of Ethics.
3. The report, along with a list of the three hospitals to which Baxter provides perfusion products and, through its subsidiary, perfusionists, should be referred to the Attorney General's Office.

Responses:

Responses from Baxter, Dr. Heck, Mr. Basha and University Hospital are attached. Some changes were made in the report in light of these responses.

Mr. Basha's second response refers to his first response. The first response is not attached because it contains several comments concerning third parties which we decline to publish. Requests for Mr. Basha's first response should be made to his attorneys, identified in the attached response.

ADAMS AND REESE LLP

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Brace B. Godfrey, Jr.
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October 19, 1999

Mr. Bill Lynch
Mr. Peter Wright
Office of State Inspector General
State Capitol Annex- First Floor
Baton Rouge, Louisiana

Dear Gentlemen:

This correspondence constitutes the official reply of Perfusion Services of Baxter Healthcare Corporation ("Perfusion Services") to your draft report. I have attached, and do incorporate by reference, the letter dated this date addressed to you, in which I informed you of the action Baxter Healthcare Corporation ("Baxter") has taken to discontinue the business activity you outline in your draft report. I reiterate the request of the two companies, that at least that action be made part of your report.

What follows is a summary treatment of your draft, generally tracking the broad subject headings you employ. This approach is made extremely difficult by your patent refusal to even acknowledge the existence of the two companies we have described for you. It is not until the end of the document that you matter-of-factly attribute a statement, erroneously to Baxter, concerning the existence of Perfusion Services. It would seem that though you will ultimately assert an "alter ego" argument, you would first provide the reader with the accurate state of affairs. Nevertheless, this summary is presented as a means of highlighting a separate and extensive treatment of the substance and process of this matter that we will need to use as this matter progresses to the governor and other officials.

BACKGROUND

You have set out to describe the perfusion process so as to explain the roles of Dr. Herman Heck, Mr. Joseph Basha and Baxter. Amazingly, at this stage you find no need

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to even disclose to the reader, the very existence of Perfusion Services as a business entity.

In this same general part of the draft report you allude to a twenty-year marketing effort related to "a product" called for by new procurement specifications. This reflects a fundamental misunderstanding that biocompatibility is not a product. Too, your twenty-year marketing comment "winks and nods" at the fact that while the concept of biocompatibility may be approximately that old, its application to the perfusion process, and thus to this matter, is closer to five years old. Thus your attempt to couch this whole matter as a scheme to advance "a product" that twenty years of marketing has failed to promote, is replete with error, misunderstanding, and half-truths.

A further example of this is in the calculation of increased costs. You use the numbers so as to reflect on Baxter. Yet the current cost is that of the incumbent (which is not Baxter), and that figure along with the purported increase cannot bear any relationship to Baxter. It remains Baxter's position that its average increase of cost associated with biocompatible costing is approximately twenty percent.

Your conclusions concerning "a product" used infrequently elsewhere, and spending of funds needed for other patient needs should cry out for reconsideration. As to the former, there are numerous highly reputable facilities that favor biocompatible coating that you know not of, nor seemingly do you care. As to the latter, in the rapidly advancing field of major organ surgery, this administrative process can, in no way, conclude as to how to spend money on the needs of critically ill men and women who, but for the medical advancements like biocompatibility, would likely not survive.

RESTRICTIVE BID SPECIFICATIONS

In this area, you cite R.S. 39:1655 for the general principle that specifications shall encourage competition and shall not be unduly restrictive. The report then goes on to pretend that the law has absolutely not another word to say on the matter. You ignore all other related statutory provisions as well as decades of jurisprudence that interpret those provisions.

Nevertheless, you conclude that the specifications drafted would restrict capable bidders to two. There are two primary matters that need be considered. First, in the

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area of products for perfusion care, the universe as to manufacturers is extremely "small." Of that limited number, no less than three can provide biocompatible coating, and of the very few remaining companies, some are proceeding through the research and development stages of biocompatibility. Second, you have not determined through whom these products are acquired. Your reference to eleven previous bidders is a clear indication that distributors as well as manufacturers were included. Therefore, you do not and cannot know if and how bids will be restricted.

CONFLICTS OF INTEREST

Dr. Herman Heck was not compensated by Baxter for the performance of his duties as is prohibited in R.S. 42:1111. Nor was Dr. Heck compensated for any nonpublic service as prohibited by Subsection (C) of the same Section. Likewise, Dr. Heck was not given a gift related to any attempt to do business with him or his agency.

Dr. Heck was interested in a particular cardiac repair surgery. He was allowed to view a particular procedure at the Cleveland Clinic, perhaps the finest program of its type in the world. The CardioVascular Group of Baxter manages its educational activities through its Reference Center Program. Through this program, physicians are invited to view surgical procedures conducted by surgeons internationally renowned in their fields. It was as a participant in the Reference Center Program that Dr. Herman Heck traveled from New Orleans to Cleveland, Ohio, to observe surgery by Dr. Delos Cosgrove, one of the preeminent heart surgeons practicing today. The trip was of a purely educational nature and was not offered in conjunction with any product promotion, nor was purchasing product ever a condition of participation in the Reference Center Program. These are routinely sponsored in some form by every major manufacturer in the country, and permitted under all governmental regulations and requirements addressing health care fraud and abuse issues. It is only through programs such as this that physicians are able to ensure that they are aware of the latest developments in their fields, and that they have the opportunity to learn state-of-the-art techniques from the masters in their fields.

Mr. Joseph Basha submitted his application for employment on July 1, 1999. He was advised that Perfusion Services did have an opening for a perfusionist in New Orleans. Perfusion Services did know that Mr. Basha was an employee of Total Blood Management and that he provided services as the chief perfusionist at the University

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Hospital in New Orleans. At no time did Mr. Basha mention having written specifications for the University Hospital's perfusion products Request for Proposals. Since the issue of drafting the specifications never came up, there was naturally no mention of specifications being written for biocompatible product. Therefore, it is clear that the process of Mr. Basha's hiring, and the bid specification development had no relationship to each other. More importantly, and perhaps crucial to a decision to make any implication as to Baxter in the draft report, is the fact that neither Baxter, nor any of its divisions or subsidiaries had any knowledge of the activities of Dr. Herman Heck or Mr. Joseph Basha in the bid specification process.¹

POSSIBLE VIOLATION

This is perhaps where your draft takes the unkindest cut of all against Baxter while not addressing explanations given you by officials of Perfusion Services. Your unreasonable refusal to at least acknowledge Perfusion Services as a corporate entity causes you to constantly allege, "Baxter states." This all leads to the ultimate allegation that Baxter provides both perfusion care and perfusion products to the applicable hospitals. In our meeting on October 15, you continuously cited the Glazer case as to justify this conclusion. But Glazer is not apposite. The Glazer case is clearly limited to interpretation of the Code of Ethics for Government Employees, and to conflicts of interest where the abuse of the public trust is at issue. The fact that the instrumentality that created the potential for abuse was a corporation is merely anecdotal and has no relevance to admit the comparison of issues in the perfusion situation. It is off point to suggest that the fact that Mr. Glazer acted through a corporation to pursue activities that he was prohibited from carrying out as an individual is any more than incidental to the ruling in the case. The issue in the Glazer case is not at all the same issue that is raised when one evaluates whether the requirements of Title 51 are being met. In fact, Footnote 3 in Glazer expressly limits the ruling to the facts of that case, and more specifically states that the court does not decide whether the use of the corporate entity is appropriate outside the application of the conflict of interest situation. In other words, although 100% ownership and control of the corporate entity resulted in the nullification of the entity for purposes of interpretation of the requirements of the Code

¹ Please note that your recitation of dates and events related to bid specifications and the Basha interviews and hiring contain errors, but we will treat these in our extensive brief as this process continues.

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of Ethics, the Court allowed for the possibility that the same ownership and control would not necessarily result in the same finding in all factual situations. The Court itself limited the precedential value of this case to its own facts. Consider the footnote in its entirety:

“Out of an abundance of caution, we specifically note that our decision is limited to the facts of this case. In considering whether assertion of the privilege of separate corporate capacity constitutes an improper use, each situation must be examined within its own context. Moreover, our determination that Mr. Glazer may not assert the separate corporate entity privilege to avoid the strictures of the Code of Ethics has no effect upon his use of the corporate entity for all of its proper functions and objectives.”

Your decision to refer the applicable hospitals to authorities is a critical decision. They are not objects of the Title 51 provision you cite. Understandably, their names will unavoidably arise in considering the merits of this matter. Nevertheless, to refer them to the authorities as you do in your particular possible violations section does them a terrible injustice.

Please understand, while Baxter has acted post haste to discontinue the activities you outlined, Perfusion Services and Baxter submit, no wrong has been done. You argued during our meeting on October 15, that the Glazer case will sustain an alter ego argument when necessary to achieve the ends of a statute. I could not agree with you more for you need only apply that reasoning here. The Title 51 provision you cite was aimed at situations in which companies that provide perfusion care entered agreements with hospitals under which they provided them in one package, a perfusionist for services and the products required for the process. This business model is still practiced in thirty-seven other states in which Perfusion Services does business, at a substantial cost savings.²

The fear in Louisiana was two-fold. The first was that perfusionists might be receiving kick-backs for advancing the sale of particular products. After this proved pointless, the second became that the services and the products should be “unwrapped” so as to allow hospitals to procure them separately to avoid the turnkey service from favoring

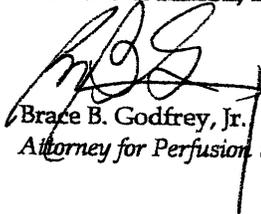
² The concern with money availability for other needs of patients could be addressed here.

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those who could provide a single package. All of these ends have been accomplished by the legislation. To now read more into the law to penalize companies that went through considerable losses to comply with the law in order to continue to save lives in Louisiana is a travesty.

Very truly yours,

ADAMS & REESE, LLP

A handwritten signature in black ink, appearing to read "B. Godfrey, Jr.", written over a horizontal line.

Brace B. Godfrey, Jr.

Attorney for Perfusion Services of Baxter Healthcare Corporation

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October 16, 1999

Mr. Bill Lynch
Mr. Peter Wright
Office of State Inspector General
State Capitol Annex- First Floor
Baton Rouge, Louisiana

Dear Gentlemen:

The representatives of Perfusion Services of Baxter Healthcare Corporation (Perfusion Services) extend their gratitude for the opportunity to share in discussions with Peter last week. While the subsequent draft of the report afforded us little in terms impacting your conclusions, the time was well spent as to the value of exchanging ideas and ideals.

Therefore, it became incumbent upon the representatives of Perfusion Services to provide officials of Baxter Healthcare Corporation (Baxter) with notice of the conclusions you have reached. Officials of Baxter, on the basis of your conclusion that Baxter is prohibited, under the Title 51 provisions you cite, from supplying perfusion products at any hospital in which Perfusion Services provides perfusion care, have pursued a solution that addresses your conclusion. Thus Baxter hereby formally requests that you include in your report, **the decision to discontinue providing perfusion products** in the applicable hospitals. In fact this process has already begun this date.

Because we as counsel, along with Baxter and Perfusion Services, are so unalterably convinced that your conclusions are faulty, this is an extremely difficult step to make. It is difficult because it affects business, but two much greater and more crucial considerations exist.

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First, these two companies are in the business of saving lives, and in perfusion care this occurs when there is little time and almost no room for error. Therefore, any attempt to alter the mode of service delivery must be approached meticulously, and in the normal case, with much more time than is available here.

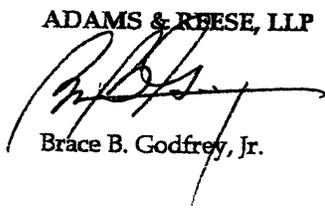
Second, Baxter is a multi-national, publicly traded company with a tremendous respect for the laws of the states in which it operates, as well as those of the foreign nations involved. As such, it is crucial that the company not appear callous when an accusatory body issues a conclusion that the company is in violation of the law.

Thus, we request the record and the report reflect that when you concluded that Baxter or Perfusion Services be investigated for violation of the law, that the companies took immediate action to cease those activities you outlined. Yet, the record and the report should also reflect the companies' adamant position that no wrong has been done.

We will submit, within the delay you fixed last Friday, the balance of our response to the draft. We also value deeply, the opportunity to pursue our averments, arguments and positions with counsel for the Governor as you discussed, before being publicly cast in a light we believe to be unjust and certainly undeserved.

Very truly yours,

ADAMS & REESE, LLP

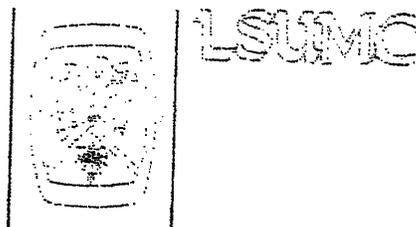


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Department of Surgery
Section of Cardiothoracic Surgery

Herman A. Heck, Jr., M.D.
Asst. Professor of Surgery

October 14, 1999

Mr. Bill Lynch
State Inspector General
P.O. Box 94095
State Capital Annex
Baton Rouge, LA 70804-9095

Re: File #1-00-0006

Dear Mr. Lynch:

I am in receipt of the revised draft of your office's investigation of the University Hospital perfusion pack bid specifications. In reviewing this draft, I see four areas where the facts are still incorrect, despite my response to your first draft in my letter of September 14, 1999, or where the facts are otherwise presented incompletely or out of context, thereby giving a false impression to whoever might read them.

First, and foremost, paragraphs 7 and 8, page 5, under the Conflicts of Interest Section do not fairly represent my motivation for going to Cleveland at Baxter's behest. As I stated in my letter of September 14, 1999, my reason for going to Cleveland was to observe and learn the techniques of minimally invasive open heart surgery and off-pump coronary artery bypass surgery, the latter technique being one which does not require perfusion. It never was for the purpose of reviewing any Baxter products and the trip was not an informational program to promote the use of Baxter products. The wording in paragraphs 7 and 8, page 5, strongly imply that this was the case and unfairly represents not only my intentions, but also the basic facts of the matter.

Secondly, as stated in a letter from Dr. Dwayne Thomas, Medical Director of the Medical Center of Louisiana at New Orleans sent to you September 17, 1999 (copy enclosed) as an institutional response to your first draft, though I as a representative of my

School of Allied Health Professions School of Graduate Studies
School of Dentistry

School of Medicine in New Orleans

School of Medicine in Shreveport
School of Nursing

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specialty group developed and requested the specifications alleged, in no way did I have the authority to impose these specifications on the University Hospital Purchasing Department to be let out for public bid. As Dr. Thomas' letter clearly explains, my requests were scrutinized in a pre-bid conference by the Purchasing Department and let for public bid only when, in their opinion, it was determined that appropriate bid protocol was followed and adequate competition was available. I think it only fair that this be mentioned in the final draft to place my participation in the bid process in proper context.

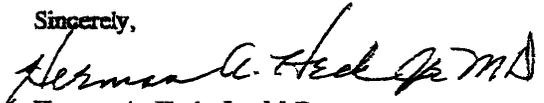
Third, paragraph 1, page 1, and paragraph 1, page 3, imply that the bid was publicly let knowing that only two companies were eligible to bid for the perfusion packs with the new specifications. As Dr. Thomas' letter clearly states, three of four companies present at the pre-bid conference indicated that they would be able to supply the requested changes, they being Baxter, Cobe, and Medtronic. While subsequent investigation by your department may have found fault with one of the companies by virtue of the fact that they acted as a vendor for Baxter, this apparently was not obvious during the pre-bid conference when the bid was approved. Accordingly, I think it only fair that the final draft contain some mention of the fact that the pre-bid review committee at University Hospital considered that there were at least three vendors available to supply the requested changes prior to approving the bid specifications.

Finally, paragraph 3, page 4 of the revised draft mentions numerous hospitals which use a non-coated system. However, there is no paragraph mentioning several other hospitals, which I have provided in previous correspondence (and herein enclosed), which do use or are seriously evaluating biocompatible systems. This paragraph, taken in the present context, implies that most major prominent medical centers do not approve of the biocompatible surface when in fact there are many that do. Fairness would dictate that either this paragraph be removed or that another paragraph be inserted enumerating these several other institutions.

Mr. Lynch, I appreciate your giving me the opportunity to add additional input into your revised draft before sending it on to the Governor. Should you feel that no substantive changes to the draft should be made as I have outlined, I would appreciate your appending a copy of this letter to the draft when it is sent to the Governor so that the draft may be put in appropriate context.

Thank you for your consideration.

Sincerely,



Herman A. Heck, Jr., M.D.

HAH:ccd
Cc
Enclosures

HAILEY, MCNAMARA, HALL, LARMANN & PAPALE, L.L.P.

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October 18, 1999

VIA FACSIMILE: 1-225-342-6761

Office of State Inspector General
Division of Administration
State of Louisiana
Post Office Box 94095
State Capitol Annex
Baton Rouge, Louisiana 70804-9095

Attention: **Bill Lynch**
State Inspector General

Re: **University Hospital in New Orleans
Heart-Lung Machine Report**
Your File: **1-00-0006**
Our Client: **Joseph W. Basha**
Our File: **6010-49978-RTS**

Dear Mr. Lynch:

We are in receipt of a second letter which asks us to comment on the revised draft of a report to the governor. Within the one day turnaround allowed, we have reviewed the revisions and find that it does not reflect careful consideration of our previous response. It appears that you are merely going through the motions of giving us "the opportunity" to respond so you can state that we had such an opportunity.

The basis of this complaint is a disgruntled competitor who might be adversely affected by the changing technology. Through our submissions and others, we have presented a case that the specifications are consistent with

Mr. Bill Lynch
October 18, 1999
Page 2

technological developments in the practice of medicine. Those left behind will always complain because of their vested interest. It appears to us that you have merely adopted the cries of the competitor in order to create an illusion of some type of legal or ethical violations by Dr. Heck and our client, Mr. Joseph Basha. Given the absence of any incorporation of our response in your revised report, a further reply would be useless.

Because we feel that this investigation has been off-base from its inception and has been "prejudged", we would merely ask that you provide us with a copy of the final report when it is submitted to the governor. We would ask that you fax a copy of it to 504-836-6565 immediately upon its transmission in order that we might write our separate response to the governor's office. We have many criticisms of the entire investigation and believe that we must set the record straight before the matter becomes one of public controversy.

Furthermore, we reserve all legal rights against the Inspector General's Office based on its failure to properly investigate this matter and the anticipated libel and slander which may be generated by this draft report.

We have offered you the opportunity of further discussion. Since the matter has already been prejudged, such a meeting would probably be useless.

We formally object to your conclusions with regard to Mr. Joseph Basha's "ethical" violation, especially when he is not even a state employee. Mr. Basha's change of employment for a reduced salary of \$15,000 runs against the grain and leads to the inescapable conclusion that the specifications in question were advanced by Mr. Basha as a matter of ensuring that medical care in Louisiana advanced with new technology and not a matter of "greed" by some unscrupulous individuals.

Please reconsider your position.

Very truly yours,



RICHARD T. SIMMONS, JR.
W. GLENN BURNS

RTS/WGB/sc



September 17, 1999

Mr. Bill Lynch
State Inspector General
P.O. Box 94095
State Capitol Annex
Baton Rouge, LA 70804-9095

Re: File #1-00-0006

Dear Mr. Lynch:

As Medical Director of the Medical Center of Louisiana at New Orleans, I am writing to provide you with some additional factual information that will potentially help you as you review the above-related file regarding Dr. Herman A. Heck.

I would like to outline the process that is followed in the hospital regarding the purchasing of equipment and supplies. It should be noted that any physician within our organization can make requests for specific supplies that will assist them in delivering appropriate and excellent care to their patients. Once this request is made, it is forwarded to a Nurse Manager for the area. That request is subsequently forwarded to an Assistant Nursing Administrator who evaluates the request with the assistance of our Materials Management Department. At that point, information regarding the availability of the products, pricing, and specifications are obtained and then put into the State ISIS System (Order Inventory Request System). That information is subsequently transferred to our Purchasing Office within the hospital and then the information is forwarded to the Health Care Division Services Purchasing Office in Baton Rouge.

A Pre-Bid Conference was subsequently held regarding the request for the biocompatible tubing and four (4) companies were present. When questioned, three of the four companies indicated that they would be able to supply the requested items and it was determined at that point that the bid process would provide for fair competition. It is, therefore, my opinion, that the appropriate mechanisms were followed in the request of the special tubing. In addition, the potential benefits to our patients can be clearly outlined in the medical literature.

It is the goal of all physicians within the Medical Center of Louisiana at both the LSU and Tulane Schools of Medicine, to provide the highest quality of care possible to our patients. Given the fact that three of four companies were able to provide the stated materials, we felt that the bid process was indeed fair. I would like to specifically point out that Dr. Heck was not and could not be directly involved in the selection process of any particular company. We strongly believe that our current process is fair and that it should not be hampered by companies that cannot provide the technological advances necessary to provide excellent care to our patients.

If I can be of any additional assistance to you or provide additional information, please do not hesitate to contact me (588-3493).

Sincerely,

A handwritten signature in black ink that reads "Dwayne A. Thomas, MD". The signature is written in a cursive style with a large, looping initial "D".

Dwayne A. Thomas, MD
Medical Director
Medical Center of Louisiana at New Orleans

/jk