ATTORNEY-CLIENT PRIVILEGE APPLIES

REPORT OF THE

SPECIAL INVESTIGATION COMMITTEE

REGARDING ALLEGATIONS

IN AUGUST 28, 2016 FDA COMPLAINT

Submitted on: November 7, 2016

***Prepared by*:**

Dr. Ian van Tets (Committee Chair)
Charles J. Coulson
Donald W. McClintock

A. INTRODUCTION

This serves as the investigation report ("Report") of the Blood Bank of Alaska ("BBA") Special Committee ("Committee") formed on September 21, 2016, by BBA Board of Directors ("Board") Chairman Ryan York. Mr. York formed the Committee for the express purpose of conducting an investigation into a Complaint made to the Food and Drug Administration ("FDA") on August 28, 2016 (hereafter, "the Complaint"), by one or more current and/or former BBA employees. The Complaint alleged various unsafe and/or improper blood banking conditions and practices at BBA.[1]

The Committee, consisting of BBA Board members Dr. Ian van Tets (Committee Chair), Don McClintock and Chuck Coulson, was given full authority to conduct a thorough investigation of the Complaint allegations and prepare a written report summarizing its findings. In doing so, the Committee enlisted the efforts of various internal and external resources, including other BBA Board members, members of BBA management, external legal counsel, and other third parties. During the course of the investigation, the Committee sought and received all data and information requested from various sources as deemed necessary to fulfill its objective. The Committee also interviewed various BBA staff members to obtain further information relevant to its investigation of the Complaint.

B. EXECUTIVE SUMMARY OF REPORT

The Committee's investigation did not or was unable to substantiate any of the allegations in the Complaint. A summary of relevant facts supporting the conclusions reached by Committee are as follows:

- On March 11, 2016, the FDA completed its annual audit of BBA's facilities and procedures (including recordkeeping) shortly after operations commenced in the new building (hereafter referred to as "Main Center"). There were no findings of substance and the observations were promptly addressed to the FDA's satisfaction. BBA continues to be regarded as compliant by the FDA. To the Committee's knowledge, the FDA has received the Complaint but has no plans to audit BBA again prior to its scheduled audit in March 2017. The FDA is legally obligated to intervene immediately if it has reason to suspect that there is a threat to the purity, potency and safety of the blood supply.

- On July 27, 2016, the American Association of Blood Banks ("AABB") completed its first accreditation audit of the Main Center. This audit assessed BBA's facilities and procedures (including collection, component manufacture, distribution and regulatory compliance). There were no findings of substance and the non-conformances identified were promptly addressed to the AABB's satisfaction. BBA continues to be regarded as compliant by the AABB. The AABB has been provided with a copy of

[1] The complaining party, former BBA Grant Writer Linda Soriano ("Complainant"), declined the Committee's request to provide the documents referenced as "Attachments" to the Complaint, which was published in the Alaska Journal of Commerce ("AJC") on September 14, 2016. The Committee's investigation was therefore based solely on the allegations published in the AJC article.

the Complaint but has, to the Committee's knowledge, no plans to audit BBA at this point.

- On September 26, 2016, Swalling & Associates PC presented a report of its Independent Audit of BBA's Financial Statements for the years ended December 31, 2015 and 2014. Swalling & Associates PC was provided with copies of the Complaint and was able to consider and discuss its contents with both staff and Board members prior to completing the audit. Swalling & Associates PC's report was unqualified.

- The Committee was unable to substantiate the claim that there is a "severe and ongoing shortage of inventory" at BBA. Two major facilities independently confirmed BBA fully filled all their orders in 2016 and BBA's internal records suggest this is true for all the other facilities that BBA serves. The Committee was also unable to substantiate the claim that hospitals have complained about insufficient blood product. There is no record of any written complaint.

- The Committee was unable to substantiate the claim that hospital orders were not filled in a timely manner during 2016. There was evidence of one informal complaint brought to the attention of BBA about a single incident where a routine delivery had been delayed by at most five hours. This delay had no effect on the hospital's ability to treat patients as it was simply adding to its existing stock as part of normal blood management.

- The Committee was unable to substantiate the claim that the "weekly exporting of blood to California" adversely affected BBA's inventory. The Committee reviewed the export contract with LifeStream and found it to be consistent with both responsible blood management and BBA's mission of service to the Alaskan community. It applies only to short-dated blood, ensures that short-dated blood is sent to facilities with immediate need, and is being applied in a flexible manner to ensure hospitals and other medical facilities in Alaska have sufficient blood for current needs and emergency situations.

- Although there was a nationwide shortage of O negative in mid-summer 2016, the Committee did not find any evidence to suggest BBA attempted to import ordinary O negative blood during this or any other period. BBA did successfully import some rare antigen negative blood units from Washington in 2016. According to BBA management, this is an ongoing issue that reflects the low donor base in Alaska which BBA is actively attempting to address.

- The Committee was unable to substantiate the claim that Chief Executive Officer Robert Scanlon ("CEO Scanlon") told a contracting hospital BBA would not help in an emergency if the contracting hospital purchased plasma from another source.

- The Committee was unable to substantiate the claim that there have been changes in donor recruitment "in response to the exporting requirements." Donor recruiting efforts have increased; however, the changes prompting the increase were planned before the move to the Main Center.

- The Committee was unable to substantiate any of the claims about alleged improper donor recruiting techniques. The Committee is satisfied BBA's communication techniques with donors are acceptable and appropriate. Glitches in the new cloud based calling system referenced in the Complaint that resulted in multiple calls to certain households with multiple donors have since been resolved. Management has assured the Committee that BBA respects the requests of donors who want to be removed from the donor call list.

- The Committee was unable to substantiate the claim that donor recruitment decreased after June 2016 due to donor irritation about BBA's donor recruitment efforts and press scrutiny of BBA's practices. Although there was an increased level of donation in May and June 2016, this level of donation was sustained in July and August of 2016.

- The Committee was unable to fully substantiate the claim that "critical needs alerts" were issued almost continuously since May 2016. BBA did issue one critical needs alert in May 2016, one in June 2016, and one in August 2016. The maximum time a critical alert remains posted is one week. The Committee is satisfied these alerts were consistent with past practice and good managements and were consistent with approaches used by other blood centers in other states.

- The Committee did not substantiate the allegation that the rate of negative reactions had increased at the new Main Center. The evidence suggests the rate of negative reactions has *decreased* by 15% since moving into the new facility compared to the prior period despite an increase in donations. There is also no record of any donor ever falling and breaking bones anywhere within the new BBA facility.

- The Committee did not substantiate any of the claims of misrepresentation of financial information. The Committee also found no basis for the assertion that blood exports were driven by the need for BBA to raise additional cash to repay the loan for the new facility.

- The Committee either did not substantiate or was unable to substantiate any of the Complaint allegations. To the extent that certain factual statements in the Complaint were accurate, the statements were not relevant to any claims of unsafe or inappropriate blood banking or management practices, nor were the conclusions drawn from them supported by the record.

- The actions of the management team, and especially CEO Scanlon, throughout the process of moving into the Main Center and its day-to-day management have been reasonable, prudent and motivated solely by the desire to carry out the mission of BBA. BBA's management team continues to receive the full support of the Board.

C. COMPLAINT ALLEGATIONS[2] / COMMITTEE FINDINGS

1. Allegations Re BBA Blood Shortages Due to Excessive Exporting of Blood Outside of Alaska

a. *"The most significant problem at the Blood Bank of Alaska (BBA) today is the severe and ongoing lack of inventory due to the weekly exporting of large quantities of blood products (at least 100 units) to California and possibly other states."*

COMMITTEE RESPONSE: *The Committee was unable to substantiate the claim that there is a "severe and ongoing shortage of inventory" at BBA.*

Blood products are primarily stored at the medical facilities that BBA serves. This enables those facilities to use those blood products as soon as they become necessary. The blood products held by these facilities does, however, remain part of BBA's inventory and can be reclaimed and transferred to different facilities in response to emergencies.

The blood products stored at BBA represent a reserve and consist primarily of products that have just been collected or received and are awaiting shipping or being held prior to further processing. A relatively small number of additional blood products is held by BBA for emergency distribution or is being held temporarily at the request of a medical facility (examples of both practices are given in the Committee's response to Item 1(b)).

Two large facilities, Alaska Regional Hospital ("AKR") and Providence Alaska Medical Center ("PAMC"), have independently confirmed that BBA fully filled all their orders in 2016. BBA's internal records (which are audited annually by the FDA) suggest that this is true for all the other facilities that BBA serves. BBA is adjacent to the AKR and close to the PAMC and a third hospital complex, the Alaska Native Medical Center ("ANMC"). Blood stored at these facilities is readily accessible and can be redistributed at need.

There was, according to internal and external sources, a critical shortage of O negative blood nationwide in mid-summer 2016. BBA and its client hospitals were aware of this. BBA informed the hospitals that it would be difficult to obtain additional O negative blood products from outside the state during this period. BBA used a "critical needs alert" to encourage donations during this period and, thanks to its donors, was able to keep all its Alaskan facilities fully stocked during this period.

The Committee was unable to substantiate the claim that the "weekly exporting of blood to California" adversely affected BBA's inventory. The Alaskan facilities that store the majority of BBA's blood products routinely order surplus product so they can respond quickly to emergency situations that require a substantial quantity of a particular product.

Blood products have clearly defined and FDA-enforced shelf lives. To ensure donated blood is used appropriately, short-dated blood products that are not needed by the facility holding them are transferred to other Alaskan facilities in need. If there is no Alaskan need for

[2] All quoted language/allegations have been taken directly from the Complaint.

those products, BBA then attempts to send those products to out-of-state facilities to ensure they are used. The LifeStream contract is a flexible contract that facilitates this arrangement. It enables BBA to send approximately 100 units of short-dated blood with a relatively low proportion of O negative units to a processing center that then ensures that they are transferred to a facility with an immediate need. LifeStream reimburses BBA for the cost of collection and shipping. LifeStream ensures that this donated blood, that would otherwise be discarded, is used to help treat a patient at an American medical facility.

The contract (which is described in more detail below) has been applied flexibly in 2016. When BBA has had less than 100 units of short-dated blood available, it has shipped less and when BBA has had less than 12 short-dated units of O negative blood available, it has shipped less. To date, all the blood that has been sent to California has been short-dated blood that, with the possible exception of the short-dated O negative units, was unlikely to have been used in Alaska.

b. *"On May 20, 2016, BBA hosted its grand opening event for the new building, and early that morning I heard that there was not enough blood to fill the daily order from the Providence Alaska Medical Center."*

(i) *"Later, I visited Hospital Services with a fellow employee, and the 25 refrigerators were nearly empty. When my friend saw this she gasped, 'They took it all!' It turned out she was referring to the exporting of 100 units that had occurred the previous day."*

(ii) *"We had less than 10 units of 0 negative for the state and 4-5 trays of AB negative."*

COMMITTEE RESPONSE: *The Committee was unable to substantiate the claim that there "was not enough blood to fill the daily order from Providence Alaska Medical Center" on May 20, 2016.*

According to BBA management, AKR, PAMC, and other sources, on the morning of May 20, 2016, BBA filled and dispatched its daily orders. As mentioned above in the response to Item 1(a), BBA does retain a small amount of specific blood products as a reserve for emergency distribution. In the case of O negative, 6 units are always retained for this purpose.

BBA's practice of storing its blood primarily at the facilities where it will be used (AKR, PAMC and ANMC), while retaining the control of such blood, and the reduction of O negative units for a brief period following filling large orders, is consistent with its standard management practice.

The amount of AB blood stored at the BBA facility at a given point in time has no implications with respect to the ability of Alaska's medical services to respond to an emergency. AB blood is almost never used in emergency medicine. It cannot be given to anyone except individuals who are themselves AB and those individuals can receive blood from any of the four letter-based blood groups. AB blood is still valuable. It is set aside for the use of AB individuals with scheduled surgeries and it is used to make plasma (an important product with a short shelf life) and to provide the blood products necessary for the FDA-mandated calibration and testing

of BBA's equipment. A transient shortage of this blood type would not, however, be a cause for concern.

c. *"The dangerous shortage of blood due to excessive exporting has persisted throughout the summer, and now the contract with LifeStream in California has been extended through December."*

d. *"On numerous occasions since 5/20, BBA has run out of blood entirely and tried unsuccessfully to import from outside Alaska."*

COMMITTEE RESPONSE: *The Committee was unable, for reasons already described, to substantiate these claims.*

BBA is part of the National Blood Exchange, which facilitates the exchange of blood products across the United States to transfer surplus blood products from one location to blood centers with an urgent need for those products. There does appear to have been some concern (as mentioned previously) that the nationwide mid-summer shortage of O negative blood might affect BBA's ability to import O negative blood had importing become necessary. The Committee did not, however, find any evidence to suggest that BBA attempted to import ordinary O negative blood during this or any other period or that, had it done so, it would have been unsuccessful.

BBA did successfully import some rare antigen negative blood units from Washington in 2016. This is, according to Management, an ongoing issue that reflects the low donor base in Alaska and BBA's Donor Recruitment department is actively attempting to address this issue.

e. *"Mr. Scanlon frequently [states] that all hospital orders have been filled - just not when the hospital wants them filled."*

COMMITTEE RESPONSE: *The Committee was unable to substantiate this claim.*

According to BBA management and staff, hospital orders were filled in a timely manner during 2016. The staff members that we spoke with clearly believe that timeliness is valued by both BBA's management and BBA's clients. The directors of blood banking at the hospitals work closely with BBA to ensure their specific requests are met and, according to BBA staff, respond quickly to any perceived delays.

The only relevant Complaint that BBA received in 2016 appears to have been an informal complaint to a BBA staff member by the Supervisor of Blood Banking at PAMC. This was in response to a single incident in which a routine delivery was delayed by a few hours (at most 4 to 5 hours). This incident occurred shortly after BBA moved to its new facility. This delay had no effect on PAMC's ability to treat its patients as it had adequate reserves of product on hand and was simply adding to its stock as part of normal blood management.

ADDITIONAL COMMITTEE FINDINGS:

Summary of Exporting Contracts

Export contracts have been in place since well before the new building was commissioned. Going back to 2011, we looked at examples of 4 contracts before the LifeStream contract commenced. Although they differed in quantities and product, they were similar in the sense that they were "put" contracts—the recipient was required to take a set amount of blood products on a weekly or sometimes other period, such as bi-weekly. Some were supply contracts as well, which meant that BBA was equally obligated to deliver a set amount of product on the contracted duration.

A summary of the contracts follows:

- January 1, 2013—[redacted]. This was a put contract and required [redacted] to accept 48 units of leucoreduced (LRBC) red blood cells for 52 weeks. The requirement lasted for 52 weeks. All product had to have a minimum of 21 days left except O negative, which could be 12 days (and with discussion even shorter). There were no consequences for failed delivery, as this was a pure "put" contract.

- January 1, 2013—[redacted] contract for 5 units of platelets. There were no consequences for delayed delivery.

- July 1, 2011—[redacted] amended again until 2013. This contract was for 20 units of Cryoprecipitate. The prices changed over time. Again, this was a put contract with no liability for shortfall.

- July 15, 2014—[redacted] This contract was for 50 units of LR RBC. Minimum requirement of 21 days of shelf life. This contract now had a slight change as a supply contract as any deviations, i.e., shortfalls, required negotiation and there was a responsibility to make up shortfalls. The failure to make up shortfalls could allow the importer to cover and charge back the increased cost.

- May 1, 2016—LifeStream contract--renewed again in September to year end. They required 100 units per week of LR RBC of a specific package of blood types. Some substitution of type was allowed and shortfalls could be made up the following week. This was also a put/supply contract like the Heartland contract and BBA was responsible for the cost difference in the event of a cover if a contract was not met.

- The need for export contracts flows from a "utility" model of blood banking. It is a utility model in the sense that utilities have to be built for peak demand rather than average demand—the obvious reason for an electrical utility is you want the power generation plant built for when all the air-conditioning is on at the same time, peak demand, etc., to avoid "brownouts." With blood supply, there are peak demand periods when casualty events happen or other events that increase the use of the blood

product inventory. But, conversely, there are periods when demand is average or even below average. So, BBA must prepare for the worst but also have a mechanism in place for dealing with the times of low demand. It is in these circumstances that a "put contract" is invaluable. This provides an outlet for excess product that ensures it will be put to use and the lost revenue "cost" of the product can be recovered. This provides a more cost competitive blood supply while maintaining sufficient product. In addition, it addresses the obvious goal that these lifesaving, donor provided products should not be wasted and, as addressed below, it allows BBA to use dated blood products that otherwise are at risk of exceeding their useful life. These contracts allowed a certain amount of excess product to be shipped out so it was not wasted and the best contracts—the put contracts—imposed no responsibility to ship product during local periods of higher demand. But even the put/supply contracts allow BBA to withhold product if it is needed here—the consequences are only to make it up later or to pay the cover charge. This is a commercially reasonable and prudent arrangement.

BBA Director of Hospital Services and Facilities Melissa Pearl described the cycling of product with the hospitals as follows:

> *The products can be returned at any time prior to expiration. The hospital contracts allow for RBC returns up to 24 hours from expiration. Several of the outlying hospitals (however not all) are on a standing order rotation. This means that depending on the hospital we send them their entire inventory every two to three weeks and they send back the older inventory to us after they receive the fresher products. The ones who are not on standing orders will call every couple weeks and ask to swap out their shorter dated inventory. Typically we request that they swap out when product has at least 3 weeks left however, per contract they can return at any time prior to 24 hours from expiration.*

A review of the history of supply and returns shows that (using RBC as the measure) from 2011 to 2015, 19,900 units (annual 2015) to 26,323 units (annual 2011) were delivered. The range of returned product was 3409 (2015) to 4256 (2011). However, these numbers include product shipped out-of-state, including under the above referenced contracts. But what is also evident under these statistics is that product is also delivered to other non-Alaska hospitals not on put/supply contracts. In other words, part of the work that has to be done at all times is to find a use for excess product so it is not wasted.

The contracts discussed above show that the earlier put/supply contracts existed well before the Main Center opened starting with the Heartland contracts. But the more significant point is that BBA has a historical relationship with outside blood centers to manage the use of its blood products and also to minimize the waste of excess product. That would be within the proper parameters of our mission and also efficient administration of resources.

Since the criticism is leveled at the activity at the new Main Center since it opened, a few statistics are helpful. First, the Main Center is designed to increase capacity for collection—that is, one of the goals of modernizing the facility was to alleviate earlier bottlenecks in the

collection process. The center opened on February 15, 2016, and BBA Director of Collections Wes Dahlgren noted the following improvements in increased capacity of the Main Center:

> *The previous Collection site had 8 chairs and 3 screening rooms, the new location has 10 chairs and 5 screening rooms. The bottleneck in the donation process is the screening aspect. There is an increased capacity to see donors based on those 2 factors. In addition, there is more waiting room capacity for donors pre/post donation.*
>
> *Mobile collections improvements are as follows: Having all staff under one roof has increased efficiencies, end of day batch drop-offs are no longer needed, better location to highway access and have lengthened certain blood drives as a result, garage area is more adequate for needs then previous location, and the new facility is larger for growth and an additional mobile coach can fit in the bay.*

Collections have increased since the new Main Center opened, but only on average. Collections at the Main Center from March to September have ranged from 851 to 1025 (July). Collections for the same period in 2015 have ranged from 852 to 897. These peaks, however, are not unprecedented—December 2014 had 1051 collections and August 2014 had 1090—which appears to be the "record." Clearly there has been an improvement in collections capacity, which in and of itself is a positive result.

The allegation that this has been at the cost of increased negative reaction by donors is not supported by the evidence: during this same time period, there have been 20 negative reactions at the Main Center compared to 23 reactions during the preceding period at the Laurel Street facility. In effect, average collections increased by about 15% and negative reactions went down by 15%.

The LifeStream contract has increased the supply requirements from earlier contracts. However, these contracts are short term in nature and it is a reasonable management tool to allow management to size the contracts to meet projections of both collections and demand. Based upon the other matters reviewed, we consider this a reasonable management approach and one that can be fine-tuned on a continuous basis to allow for the efficient use of donated blood product and staff, who in the absence of a set put/supply contract, will have to physically find other users for the blood before expiration.

2. Allegations Re Alaska Hospitals Complaining About Insufficient Blood Supply and Consequences of Purchasing Blood Outside of BBA

a. *"The week after the Grand Opening, I notified Bruce Lamoureux, CEO of Providence Health & Services Alaska, and he immediately insisted that BBA keep his hospitals fully stocked."*

COMMITTEE RESPONSE: *The Committee was unable to substantiate this claim.*

We were unable to discuss it directly with either the Complainant or with Mr. Lamoureux. We acknowledge, however, that the CEO of Providence Health & Services Alaska expects BBA to fulfill its contractual obligations. The Committee further notes, as described

earlier in the response to Item 1(a), that PAMC confirmed BBA has fulfilled all of its orders in 2016.

b. *"Unbeknownst to me, one of my colleagues was warning her contacts at the state's other 3 largest hospitals."*

COMMITTEE RESPONSE: ***The Committee was unable to substantiate this claim.***

The Complaint lacked sufficient factual information to investigate this allegation.

c. *"Hospital representatives are calling every day to complain that we are not keeping enough blood on hand."*

COMMITTEE RESPONSE: ***The Committee was unable to substantiate this claim.***

As described earlier in the response to Item 1(a), blood products are stored primarily at the hospitals and other medical facilities and not at BBA itself. This reflects the desire of both BBA and its clients to locate the products as close to the service providers, and in particular emergency service providers, as possible. In consequence, Hospital representatives are primarily concerned with optimizing the blood product stores within their facilities and not with the transient or reserve stores held by BBA itself.

We are also unable to substantiate the more general claim that "*Hospital representatives are calling every day to complain."* This claim is not consistent with the experiences of the staff we spoke with. That said, we were told that one particular hospital representative does push unusually hard on behalf of his organization to ensure that blood product orders are delivered in full and on time and will phone and pressure distribution staff whenever he feels concerned. This claim may reflect this situation.

d. *"During a disagreement about supplying liquid plasma, Mr. Scanlon told representatives of Fairbanks Memorial Hospital that if they purchased plasma from another source he 'would not help in an emergency.'"*

COMMITTEE RESPONSE: ***The Committee was unable to substantiate this claim.***

CEO Scanlon denied making any such statement to any representative of Fairbanks Memorial Hospital ("FMH"). CEO Scanlon explained to the Committee that, in the event of a statewide emergency, BBA would be obligated to supply blood and blood products to its contracting hospitals before it could provide such items to non-contracting hospitals or entities. If no exigent situation was present, BBA would certainly be willing to assist any non-contracting hospital with its blood needs. FMH is a contracting hospital with BBA.

3. Allegations Re Increased Drive for Blood Donations + Complaints by Donors Re Excessive Donor Calls

a. *"In response to the exporting requirement, BBA has pushed blood donation in ways never used in Alaska in the past."*

COMMITTEE RESPONSE: ***The Committee was unable to substantiate this claim.***

The Committee found no evidence of changes in donor recruitment *"in response to the exporting requirement."* Rather, BBA has increased its recruiting efforts by adopting new approaches as described below. By way of background, there are currently approximately 130,000 donors in BBA's donor base. Many of these donors have not donated for several years. Prior to 2016, only donors who had donated at least once within the last two years were called as this was the longest practical timeframe. There also appears to have been some underlying tension with respect to HIPAA requirements, with some long term donor callers believing they needed more donor information than they would normally be entitled to under HIPAA. Since calling donors individually requires substantial time and resources, BBA's donor recruitment team has been working for several years now to optimize their practices by adopting new approaches.

<u>New Approach 1 – The Use of Text Messaging</u>:

In 2014, donor recruitment started using text messaging. This was, and remains, an "opt in" system that requires donors to request text messaging reminders via BBA's website. Accumulating "opted-in" individuals took time and this time was further increased by the switch to Medaware. As a result, 2016 was the first year that texting has been used extensively.

This is a relatively new "opt in" system that is only being used with donors who have opted-in within the last two years. It is being used primarily for appointment reminders at this point and, at the end of every message, donors are reminded that they can opt-out.

This Committee is satisfied that this is an acceptable form of donor communication.

<u>New Approach 2 – The Use of Cloud Calling</u>:[3]

The decision was made in either 2014 or 2015 to implement cloud calling as a more practical way to reach out to the donor base. The system was brought on in January and then progressively rolled out, effectively going live in April 2016. BBA uses cloud calling to contact donors whose phone numbers are in BBA's database. Included with every call is information on how to opt-out of receiving further calls. This was a major change with two obvious benefits:

1) It enabled the reallocation of human donor callers to specific tasks. Human donor callers were no longer used for routine calling and instead assigned to focused tasks, such as calling donors within a region to encourage them to donate at a regional drive and calling donors from priority blood groups.

[3] Cloud calling refers to automated donor calling.

2) It enabled BBA to contact donors whose last donation was more than 2 years ago. BBA is now contacting donors in our pool who last donated as far back as 2000. By doing so, BBA donor recruitment has, according to management, encouraged approximately 250 previously-dormant donors to return and donate every month since April. Many of these donors were, by their own account, individuals who thought that BBA had lost interest in them and who were delighted to be remembered.

b. *"Literally thousands of robo-calls are being placed every week, and 'critical need' alerts have been posted almost continuously since the Grand Opening in May."*

COMMITTEE RESPONSE: *The Committee did not fully substantiate this claim.*

It is accurate to state that large numbers of cloud calls are being placed each week. When cloud calling was rolled out in April, calls were being made to the numbers in the database at a high frequency (maximum 1 call per week), and this was further exacerbated for homes that had multiple donors sharing the same phone number. This was subsequently addressed by adjusting the software to reduce the frequency to a maximum of 1 call every 3 weeks and by removing the bug that caused the software to call multiple donors at the same number.

It is not accurate to state that "critical need" alerts have been posted almost continuously since May. Perhaps ironically, it appears that BBA was overusing critical need alerts prior to 2012. According to BBA Director of Marketing and Communication Ashere Chait, BBA responded to this by insisting from 2012 onward that such alerts be limited to times when one or more blood types was in, or likely to be in, unusually short supply.

Since 2012, BBA has typically issued two or three critical need alerts per year. In 2016, it has issued three: one shortly before the Memorial Day weekend, one in June (reflecting the national shortage of O negative blood and the importance of ensuring that BBA could meet Alaska's needs without having to draw on the rest of the nation's blood supply), and one in August. The maximum time a critical alert remains posted is one week. Therefore, the allegation is exaggerated and inaccurate.

The Committee is satisfied that these three alerts were genuine efforts by BBA to encourage donations of urgently needed blood types and were consistent with recent past practice and good management. Moreover, the Committee examined "critical needs" advertising produced by other Blood Centers in other states and found that the advertising approach used by BBA was consistent with the approaches used by the other Blood Centers.

c. *"Donations were at record levels in May and June but have since begun to taper off as donors become irritated by the constant calls and emails, as well as press scrutiny of BBA's practices."*

COMMITTEE RESPONSE: *The Committee did not substantiate this claim.*

It is true that donations rose in May and June of 2016, however, the donations did not then taper off. The number of individuals registering to donate is shown in Table 1. Registrations (total) refers to the total number of registrations state-wide. Registrations

(Anchorage) refers to the number of registrations made at any of the various locations in use in Anchorage during the time period (e.g. the Dimond Mall facility, the Laurel Street facility and the new facility).

Table 1 – The Number of Individuals Registering to Donate at BBA Sites and Facilities in 2016

Month	Registrations (Total)	Registrations (Anchorage)	Major Events
January	[redacted]	**875**	
February		**853**	Includes the opening of the new facility in Anchorage
March		**851**	
April		**954**	Introduction of cloud calling
May		**1059**	
June		**1018**	
July		**1025**	
August		**1002**	

Table 1 does show an increase in May and June of 2016 following the introduction of cloud calling in April. However, it also shows that this increased level of donation was sustained beyond June and on into July and August.

d. *"Donors are calling to be removed from the call list due to multiple contacts in one day."*

COMMITTEE RESPONSE: ***This statement is accurate.***

It is true that some donors received "*multiple contacts in one day*" as a result of the software issue mentioned previously in the Committee response to Item 3(b). As noted, this problem has been addressed and the maximum call frequency should now be one call every three weeks. Nevertheless, the fact that donors have called to be removed from the call list is neither surprising nor concerning. The cloud calling system is an "opt-out" system. Every call includes a message encouraging the recipient to phone (or otherwise contact BBA) and opt-out of further calls, if they wish. Since this system was implemented in April 2016, and is reaching back to contact individuals who last donated as far back as 2000, it is not surprising that some individuals are phoning to inform BBA that they no longer wish to receive further calls.

The Committee has been assured by BBA's Director of Donor Recruitment that the wishes of individuals who do so are being respected. Consequently, in light of the benefits of

using BBA's human resources more effectively and reaching out to everyone within our donor base, the Committee endorses this new approach to donor recruitment.

4. Allegations Re Risks to Donor Health + Donor Reactions (Onsite)

a. *"[The Medical Director asked] if I could get grant funding for soft furniture and carpeting in the donor recovery area as the 'donors keep face planting.' She said that reactions were increasing, and one woman had broken a bone or bones in her face when she fell."*

COMMITTEE RESPONSE: *The Committee did not substantiate this claim.*

BBA Medical Director Megan Ritter, M.D. asked for funding for *"soft furniture and carpeting in the donor recovery area[,]"* but she did not make the request for the reasons alleged in the Complaint. Rather, Dr. Ritter met with the Complainant to discuss her wishes with respect to grant funding. According to Dr. Ritter, she suggested to the Complainant that BBA seek funding to enhance the furniture and fittings in the Canteen Area (the more usual term for the donor recovery area) for the following reasons:

- to give the Canteen Area a softer, warmer and more inviting feel as this would encourage donors to stay longer and spend more time relaxing and recovering post-donation; and

- to reduce the risk of a donor injuring him/herself in the event of a fall.

Dr. Ritter denied making such a request because '*donors keep face planting*' or because '*reactions were increasing*' or because '*a woman had broken a bone or bones in her face when she fell.*' Dr. Ritter informed the Committee that it was very unlikely she would ever use the term *"face planting,"* and that she would not have made the other statements as reactions were not increasing at that time. Dr. Ritter recalled one donor fainting in the Canteen Area prior to her conversation with the Complainant. That individual neither required emergency care nor broke any bones. There is no record of any donor ever falling and breaking bones anywhere within the new BBA facility.

Dr. Ritter is responsible for reviewing all donor reactions and her account is consistent with BBA's records. There were 118 Donor Reactions in 2015. There were 74 Donor Reactions in 2016 as of August 31, 2016. The 2016 Reactions include only two "severe" reactions, neither of which occurred at the new BBA facility (both were associated with mobile collections). The remaining 75 reactions were all either "mild" or "moderate."

Donor reactions for 2016 are summarized in Table 2 alongside Donor Registrations.

Table 2 – The number of individuals registering to donate at BBA sites and facilities in 2016

Month	Registrations (Total)	Reactions	Registrations (Anchorage)	Reactions	Major events
January	[redacted]	**13**	**875**	**2**	
February		**16**	**853**	**3**	Includes the opening of the new facility in Anchorage
March		**7**	**851**	**5**	
April		**6**	**954**	**3**	Introduction of cloud calling.
May		**8**	**1059**	**3**	
June		**9**	**1018**	**5**	
July		**10**	**1025**	**3**	
August		**5**	**1002**	**1**	

5. Allegations Re Financial Motivations for the Above Referenced Activities

a. *"[The] decision to export was made because BBA cannot afford the interest-only payment of $40,000-$47, 000 a month on a line of credit (now fully expended) of $8.5M from the Alaska Industrial Development & Export Authority."*

COMMITTEE RESPONSE: ***The Committee did not substantiate this claim.***

We found no basis for the assertion that blood exports were driven by the need for BBA to raise additional cash. Indeed, the financials show that the incremental interest expense due to the increased, temporary loan amount is a trivial element of the budget. As noted in Item 1, export contracts have been in place since long before the move to the new building and are a necessary and prudent measure to manage the blood inventory at BBA.

Revenues Associated with Blood Exports

The Complainant asserts that the reason for exports was because BBA needed the cash to cover the increased cost of debt service due to the new building. Other parts of this Report discuss the rationale for exports and the fact that it is standard practice in blood banking. The Committee also took the time to look at the gross revenues generated by BBA from exporting blood and blood products from 2010 to 2016 (ytd). The numbers below represent gross revenues from blood exports only and do not include the costs associated with collecting and processing

these products. Hence, they say nothing about what, if any, incremental cash these sales generated that could be applied to other cash costs like debt service.

Calendar Year	Monthly Avg. Revenue, $1000's
2010	$128
2011	138
2012	131
2013	122
2014	88
2015	89
2016 through October	127

The data show that monthly export revenues are volatile. However, in no month was there no export revenue: the lowest being [redacted] in March of this year (about the time of the move) and the highest being [redacted] in January of 2010, with most months approaching the averages above. While 2016 export revenues are broadly in line with historical averages, they are a material increase from 2014 and 2015 and the data show a marked increase from the three months before the move ($44,000-$82,000 per month) to after ($132,000-$181,000 per month). This step-change can probably be attributed to the move preparations that were underway in the first quarter of this year.

BBA Budgets

The full Board receives monthly income statements detailing the revenues and expenses of BBA. These monthly statements are reviewed in detail by the Board Finance Committee with BBA staff before being submitted to the full Board. In addition, BBA's financial results are audited annually by the firm of Swalling & Associates PC, a licensed CPA firm. The full Board recently received the audit report for 2015. Of note, the auditor stated:

> *In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Blood Bank of Alaska, Inc. as of December 31, 2015 and 2014, and the changes in its net assets and its cash flows for the years then ended in accordance with the accounting principles generally accepted in the United States of America.*

While the audit does not cover calendar year 2016—that will not be done until after year-end—the "unqualified" opinion does speak to the effectiveness of the financial controls currently in place and should give stakeholders confidence in the truthfulness of our financial reports.

BBA's operating budget averages around $900,000 per month before any debt service expense (interest). These expenses are usually matched dollar for dollar by revenues with BBA on average running either a small surplus or deficit each month. Through September 2016, interest expense has averaged $38,000 monthly which, as the Complainant noted, is higher than budgeted in the 2016 budget which was developed in the Fall of 2015. This has been due to the delay in the sale of the old building and the requested delay in pledge payments made by our largest capital donor. Further, while the operating budget is remarkably stable at the above level, individual elements of the budget do vary significantly seasonally and monthly based on activity. To allege that the temporary increase in interest expense relative to the budgeted amount (~$11,000/month through September) could be a driving force for blood exports shows a remarkable lack of understanding by the Complainant regarding both the size and complexity of BBA's operations.

Finally, while it is correct that the current AIDEA loan has a balance of ~$8.5 million (actually $8.2 million as of end September), this amount will drop significantly once all currently pledged donations are received and the building sale closes.

b. *"It seems to most of the staff that Mr. Scanlon, who is under great pressure from the Board to make the AIDEA payment, has lost his way."*

COMMITTEE RESPONSE: *The Committee did not substantiate this claim.*

After reviewing email records and conducting interviews with staff, the Committee found no basis for the assertion that CEO Scanlon was under any increased pressure from the Board due to the temporarily increased AIDEA amount. As members of the BBA Board, the Committee also notes that Board discussions have been devoid of any mention of the use of blood export contracts as a revenue source relative to the new building costs.

6. Allegations Re Financial Information Inaccuracies and Representations to the Public and Donors

a. *"Early this spring, I requested a copy of the current year's budget to use with grant proposals and was surprised when both the CEO and Controller refused."*

COMMITTEE RESPONSE: *The Committee did not substantiate this claim.*

The Complainant requested a copy of the budget on March 18, 2016. That same day, CEO Scanlon asked the Complainant to provide him with the reasons for the request, as well as identify to whom she was going to supply the information. After further discussions, CEO Scanlon authorized releasing a copy of the budget to Complainant on March 21, 2016.

b. *"The budget they eventually provided was clearly incorrect and showed the monthly LOC payment as $26K when it was actually $47K a month per an email I later received from the CEO."*

COMMITTEE RESPONSE: *The Committee did not substantiate this claim.*

The email record indicates the Complainant received the correct budget, but probably did not understand that budgets are forward looking and frequently vary from the actual amounts as the year progresses. The Complainant also received in-year financials in May and July showing variances from budget through April and June respectively. The Complainant requested an explanation of the variances. CEO Scanlon prepared a draft response and ran it by the Chair of the Finance Committee before replying to the Complainant. Our review of those responses shows them to be consistent with both the Finance Committee reports to the Board and the financial reports themselves.

c. *"The budget also projected $25,000-$41,000 a month in unrestricted gifts, which BBA has no history of receiving."*

COMMITTEE RESPONSE: *This statement is accurate.*

The Complainant is correct that the budget showed a marked increase in gifts from years past. They were shown as "unrestricted" because at the time, no one knew what, if any, restrictions would be placed on the gifts. This increase in the 2016 forecast was consciously put into the budget in the Fall of 2015 to reflect the expected increase in revenues from the hiring of a full-time fund raiser and a full-time grant writer (the Complainant herself). CEO Scanlon and the Finance Committee discussed this at the time and a benchmark of added revenue equal to 3 times the new positions' salaries was used. It is curious that the Complainant appeared to view this performance expectation for her own work as unreasonable. It will be up to the Board to decide whether or not those two positions should be retained in the organization if that benchmark is not achieved.

d. *"When I finally received a 2016 budget with YTD actuals thru 4/30/16, the actuals conformed with the budget but were not truthful."*

COMMITTEE RESPONSE: *The Committee did not substantiate this claim.*

A review of the email records shows that the Complainant received at least two financial updates during the year showing actuals versus budget variances. Again, it appears the Complainant may not have understood that a budget is a forecast and that there are always variances. Given the audit opinion noted above, and the frequent and detailed reporting made by BBA staff to the Board, we can find no basis for Complainant's assertion that the documents she received "were not truthful."

e. *"Just recently, I received an 'updated' budget with YTD actuals through 6/30/16, which seems to be more in line with reality but differ from the previous version. The financials are definitely being manipulated to make BBA's financial situation appear more stable than it is. The two documents are included as Attachment A."*

COMMITTEE RESPONSE: *The Committee was unable to substantiate this claim.*

The Complainant refused to provide the Committee with the documents she sent to the FDA so we have no knowledge as to what she is basing the allegations on in the second sentence of this claim. However, as with the previous assertion, given the audit opinion noted above and the frequent and detailed reporting made by BBA staff to the Board, we can find no basis for her assertion.

f. *"BBA also has an additional $3M loan from a local bank although records of this transaction cannot be obtained."*

COMMITTEE RESPONSE: *The Committee did not substantiate this claim.*

The Committee interviewed both the Chair of the Finance Committee and the external Auditor and both confirmed that there is no evidence of any undocumented BBA indebtedness beyond what is shown in BBA's books and records. Indeed, both commented that given the financial controls in place it would be nearly impossible for BBA to incur debt without the knowledge of the Board and senior BBA leadership.

7. Allegations Re Issues About Management Decisions and Interactions with Staff and Public.

a. *"I pointed out the inaccuracies to Mr. Scanlon and asked for a corrected budget. Instead I was sidelined with no work for nearly 3 months."*

b. *"When I finally received a 2016 budget with YTD actuals thru 4/30/16, the actuals conformed with the budget but were not truthful. I explained to the CEO that submitting false information to a grant maker for financial gain would be a fraud, and I could not participate. Again, I was marginalized and couldn't submit grant proposals."*

COMMITTEE RESPONSE: *The Committee was unable to substantiate these claims.*

The Committee confirmed that the Complainant sent CEO Scanlon an email to inform him of possible "*inaccuracies"* and stated in another email that "*submitting false information to a grant maker for financial gain would be fraud."*

The Committee was unable to substantiate the claim that the Complainant was *"sidelined"* or *"marginalized"* as a result, and CEO Scanlon denied taking such action(s). Rather, CEO Scanlon responded to the Complainant's questions and/or addressed her concerns so the Complainant could perform her assigned tasks. The Committee also found that CEO

Scanlon continued to ask senior members of BBA to meet with the Complainant to discuss her needs. An example of this can be found in the Committee's response to Item 4.

c. *"BBA's CEO, Robert Scanlon, was infuriated when the hospitals' demands (to keep shelves fully stocked) reached him and complains constantly about their insistence on being fully stocked."*

COMMITTEE RESPONSE: ***The Committee was unable to substantiate this claim.***

As described in the response to Item 1, BBA preferentially stores the majority of its blood product at hospitals and other medical facilities so that it is ready for use. There was, as mentioned in the Committee's response to Item 1, a nationwide shortage of O negative blood in mid-summer. Since BBA was aware of this, and took it upon itself to inform the hospitals and initiate a critical need alert to donors, it is unlikely, in the Committee's opinion, that the CEO would have been angry about receiving higher-than-normal demands from BBA's hospital clients during this time. In addition, CEO Scanlon has denied this allegation in its entirety.

d. *"The resulting article was published in the Alaska Journal of Commerce in July and was a bombshell at BBA. Mr. Scanlon had been less than truthful when he was interviewed, particularly about the amount of blood being exported."*

COMMITTEE RESPONSE: ***The Committee did not substantiate this claim.***

There is no evidence that CEO Scanlon was *"less than truthful"* as to anything he told the AJC, including the amount of blood being exported. As discussed in the Committee's response to Item 1, the export contract referenced: (i) applies only to dated blood; (ii) ensures that short-dated blood is sent to a facility with an immediate need; and (iii) is administered in a flexible manner that ensures that the only blood exported is blood that is likely to be wasted if kept in Alaska. The CEO's statements to the AJC are consistent with the Committee's analysis of the export contract.

The Committee notes that, following the publication of the AJC article, the CEO wrote to a number of agencies, including the Alaska State Public Health Laboratories ("ASPHL"), to clarify in detail BBA's practices and to correct a number of the article's erroneous statements.

The Committee also notes that all members of BBA management whom the Committee interviewed referred to the CEO as "*honest*," "*trustworthy*" and/or "*of high integrity*." Moreover, management representatives who worked under the prior CEO stated that, since assuming the CEO role at BBA, CEO Scanlon has succeeded in making BBA "*more professional*" and more closely aligned with hospital policies and procedures.

e. *"The crackdown at the office began immediately with Mr. Scanlon telling employees that the Journal of Commerce piece was, 'An attack on each of you.'"*

f. *"From that point forward, the employees Mr. Scanlon thought might be leaking information to the press were written up for the slightest infractions, and signs were posted in Hospital Services cautioning employees not to discuss BBA business outside the building."*

g. *"Virtually all meetings were canceled, and following publication of the second article the Anchorage Dispatch News (on the front page of the Sunday edition) the atmosphere at BBA became even more oppressive."*

COMMITTEE RESPONSE: *The Committee was unable to substantiate any of these claims.*

The BBA staff members and directors interviewed by the Committee did not agree with the allegations set forth in Items 7(e), (f) and (g). In addition, the documents reviewed by the Committee provided no evidence to support any of these contentions.

BBA Director of Hospital Services & Facilities Melissa Pearl acknowledged posting a copy of an email in the Hospital Services area that she had previously transmitted to her staff. The email consisted of a reminder that staff was not to provide confidential or proprietary information about BBA to any third parties, including hospitals. Apparently, Ms. Pearl learned that a few new staff members in Hospital Services were providing proprietary blood banking information to third parties. The email reminded employees that they all signed a Confidentiality Agreement prohibiting the disclosure of confidential and/or proprietary data. CEO Scanlon had nothing to do with the drafting or posting of Ms. Pearl's email.

CEO Scanlon did send an email to the staff of BBA on September 14, 2016, that concluded with the following paragraphs:

> *We are being unjustly attacked and I am sorry about this. It is apparent that many of you are concerned about the organization and your employment. I can assure you of the good standing, integrity and solvency of BBA. To provide further assurances that we are operating lawfully, safely and at the highest levels of integrity, BBA has invited the FDA to conduct an audit of our operations.*
>
> *We work hard each day to save lives, do the right thing, and ensure the best interests of Alaskans. Thank you for your commitment, effort and hard work. We are BBA, and we help make miracles of life happen each day.*

The Committee is satisfied that intent of these two paragraphs was to reassure BBA employees who had been unsettled by the article in the AJC. The Committee also confirms the CEO sent an email to FDA on September 14, 2016, requesting an immediate audit of BBA, that he did so again on September 15, 2016, and that he attached a copy of the email that he had sent to the staff of BBA to the second email to the FDA.

h. *"During the meeting, Mr. Scanlon became belligerent with the Senator's staff and demanded that Ms. Murkowski go to Senate leadership and arrange a special allocation for BBA. The Senator's staff tried to explain that earmarks are no longer available, and Mr. Scanlon responded, 'Well then she at least needs to get me a waiver to import blood from Canada.'"*

(i) *"When one of the aides asked how he would spend $2M in federal funds, Mr. Scanlon could not answer with any detail and the meeting ended abruptly. Later the Senator's staff contacted me personally and we met to discuss the difficult situation at BBA."*

COMMITTEE RESPONSE: *The Committee did not substantiate this claim.*

CEO Scanlon denied acting in any way "belligerently" during the referenced meeting. The Committee interviewed BBA employees and Board members who were present at this meeting and was told, without exception, that the atmosphere in the meeting was friendly and collegial and that subsequent interactions with the Senator's staff had been equally positive. None of those interviewed had any recollection of any rudeness on the part of the CEO or of an abrupt or awkward end to the meeting.

i. *"It seems to most of the staff that Mr. Scanlon, who is under great pressure from the Board to make the AIDEA payment, has lost his way. A bunker mentality has developed within leadership that is both unhelpful and dangerous."*

COMMITTEE RESPONSE: *The Committee did not substantiate this claim.*

As the Board is aware, CEO Scanlon is not *"under great pressure from the Board to make the AIDEA payment."* The Board made an informed decision to authorize CEO Scanlon to accept the AIDEA loan and, in doing so, enabled the CEO to oversee the completion of the new facility on time and under budget. The Board made this decision because it was confident that the sale of the Laurel Street Building, the fulfillment of pledges made during the Capital campaign, and other fund-raising activities would substantially reduce the size of this loan and it was also confident that the income that BBA receives for its regular operations would be sufficient to meet its loan obligations. The CEO is aware of the Board's confidence with respect to both aspects of the loan's repayment.

The Committee interviewed the Medical Director, several BBA Department Directors, and a number of other staff members over the course of this investigation. In doing so, it found no evidence of a *"bunker mentality"* on the part of the CEO. On the contrary, the Committee found that the CEO is generally regarded as "*very accessible*" and "*very polite,*" and that if he can be faulted for anything, it would be for being "*too open*" or "*too polite.*"

D. CONCLUSION

BBA's procedures were audited by blood banking experts at the points in time that were most relevant to this investigation and those experts were satisfied that BBA's operations were being carried out in a safe and appropriate manner. Furthermore, when those experts were subsequently provided with details of the claims discussed in this Report, they made no change to their routine audit schedule even though the FDA, at least, is legally obligated to intervene immediately if it has reason to suspect that there is a threat to the purity, potency and safety of the blood supply.

Swalling & Associates PC recently completed its financial audit of BBA. It was made aware of the claims that were made in this Complaint. Swalling & Associates PC's report was unqualified, and when its representative discussed its report and the Complaint allegations with the (entire) Board and the Board's Finance Committee, no concerns were raised with respect to the financial management of BBA.

When this Committee interviewed three members of BBA management as part of this investigation, one of them emphatically stated "*there is not one thing, one thing, that I have a regulatory concern with.*" This opinion was clearly shared by the other two members present and similar opinions were voiced by many of the other employees interviewed by the Committee.

This Committee has found credible and persuasive: the FDA audit, the AABB audit, the unhurried response of both organizations following their receipt of the allegations, the Independent Financial Audit, the reassurance of the independent auditor, and the statements of the BBA employees interviewed. The Committee's own review of the specific allegations (described above) found no evidence of inappropriate blood banking management, no evidence of inappropriate financial management, and no evidence that BBA's management is acting in any way contrary to BBA's mission of service to the Alaskan community.

The Committee ultimately did not or was unable to substantiate any of the allegations in the Complaint. The Committee has closed its investigation of the Complaint.