Dear [Salutation],

As communicated in early October, the FDA released the Final Guidance "Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion" on September 30, 2019.

The FDA has provided 18 months – until March 2021 – as a reasonable timeframe for guidance implementation. Execution of Vitalant's response to this guidance will require substantial planning and collaboration with our hospital partners. Your Vitalant Regional Account Manager and Medical Director will be your primary points of contact throughout this process.

How did Vitalant approach our response and evaluate options?

As stated in the Final Guidance, "Room temperature stored platelets are associated with a higher risk of sepsis and related fatality than any other transfusable blood component." While the blood supply is the safest it's ever been, transfusion-associated sepsis is a persistent (and underreported) issue.

All methods of bacterial mitigation as proposed in the Final Guidance that reduce bacterial contamination risk by more than 50 percent result in higher cost and fewer available units. Bacterial mitigation must be balanced in a way that reduces the risk of bacterial contamination while not compromising platelet supply.

Vitalant evaluated all options listed in the Final Guidance with three key considerations in mind:

1. Provide a safe and sufficient supply of platelets
2. Provide cost-effective options for our hospital customers
3. Minimize options to improve inventory management and facilitate customer ease of use

Each option listed in the Final Guidance negatively impacts platelet availability through a combination of one or more of the following variables: shortened usable shelf life, production losses due to larger testing samples, added testing at the hospital and/or complicated logistics required to meet patient demand. Vitalant is moving forward with a limited number of options to meet the key considerations listed above and to leverage our national footprint.

In considering the experience for our hospital partners, we prioritized transfusion-ready options that do not require additional testing. We aim to minimize testing now and create a pathway to altogether eliminate testing required in the hospital.

What options will Vitalant offer?

Vitalant will offer both Large Volume Delayed Sampling (LVDS) and Pathogen Reduction Technology (PRT) platelet product options to our hospital customers.

Large Volume Delayed Sampling

Vitalant has been an industry leader in large volume sampling as we were already sampling larger-than-required volumes before release of the Final Guidance. LVDS provides the best combination of usable product life and availability for our customers and patients.

Although a 7-day LVDS platelet is an option listed in the guidance, the FDA has not yet approved the testing technology to allow for the extended shelf life. Vitalant is closely monitoring this situation so we can add this product to our offerings in the future. Rapid bacterial testing is compatible with 5-day LVDS and represents a viable opportunity for hospitals to extend dating up to 7 days.

Pathogen Reduction Technology (PRT)

PRT is a treatment rather than a test and has a broad spectrum of protection against bacteria, viruses and parasites. PRT eliminates the need for irradiation and CMV testing. As one of the first blood centers to adopt PRT, Vitalant currently offers PRT platelets in select markets and is expanding our capacity to meet growing patient needs throughout 2020.

Regardless of whether you select LVDS, PRT or some combination of the two as your platelet product strategy, Vitalant requests all hospital partners be prepared to accept both products so we can maximize inventory management effectiveness across the nation. This means updating your computer systems to accept both products.

What about new platelet product innovations?

As a leader in transfusion medicine, Vitalant remains committed to assessing and providing innovative blood products to our hospital customers. There are several innovations on the horizon we are closely monitoring or actively part of developing:

- **7-day LVDS:** As mentioned, 7-day LVDS is an option listed in the guidance, however the FDA has not yet approved the vendor's safety claim. Vitalant plans to make available 7-day LVDS platelets when approved by the FDA.
- **6- or 7-day PRT:** As PRT evolves and the useful life of PRT platelets are extended, Vitalant will provide updates to you and make available these extended-life products.
- **Cold-Stored Platelets:** Vitalant is closely monitoring FDA's review and guidance on the approval of 7- to 14-day cold-stored platelets (in platelet additive solution).
- **Frozen Platelets:** Vitalant is assisting in the development of frozen platelets, however FDA approval of this product is not likely in the near future.

What's next?

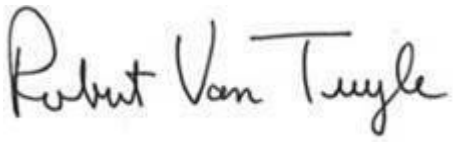
Vitalant, like all blood centers, is facing significant operational challenges from this Final Guidance that will impact platelet inventories and pricing. We remain committed to providing regular updates on new regulatory guidance to our hospital customers.

If conversations have not yet begun with your organization about this guidance, please reach out to your local Vitalant contact. Again, your Vitalant Regional Account Manager and Medical Director will be your primary points of contact throughout this process.

You can expect additional communication and updates on this topic. More detail will be provided from your Regional Account Manager and Vitalant Medical Director as individualized solutions are developed.

Thank you for your continued partnership.

Regards,



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