President and CEO Dr. Jim AuBuchon Discusses New Initiative

Video Transcript March 2019

I wanted to share with you today some very exciting news about a new initiative that we are planning. This is important not only to increase the availability of platelets and correct a problem that we have had in our donor deferral system for many years, but offer a new opportunity for engagement by important members of our community.

We have proposed to the FDA that we allow MSM, men who had sex with men, to donate platelets and have these platelets treated with the pathogen inactivation system called INTERCEPT. We believe this will not only allow these men to donate when they've been deferred for many decades, but also provide a safe and increased platelet supply for our platelets.

So what's this all about? Well, MSM had been deferred since the mid-1980s because of concern that they may have an increased risk of having HIV. We have tests, of course, that are used now. They are very sensitive in picking up HIV. That sensitivity had increased greatly over the years and today, the time period during which we might miss someone who was recently infected is very small. In less than two weeks, after someone has become infected with HIV, one of the tests that we perform routinely out of every donation would come up positive. So the time period that we're worried about now is really a very small time period right after infection. And for that reason, the blood supply is incredibly safe. You don't hear about HIV transmission anymore because of the sensitivity of this testing. However, there still is concern that someone might donate right after being infected and therefore be missed in our testing. As a result, the FDA still has in place a ban on MSM from donating blood. Now, the time period over which that is applied is now shorter than it used to be, which is a step in the right direction, but any MSM who's had sex within the last 12 months still cannot donate blood, so in effect, MSM are not allowed to donate still.

I have long been an advocate, Bloodworks has been an advocate of applying scientifically sound objective evidence to deciding the donor qualification criteria. The step of the FDA a couple of years ago in reducing the deferral period to 12 months is a step in the right direction, but we're still not where we'd like to be. The FDA would like to gather more information before changing the donor history questionnaire to focus more specifically on risks that an individual donor may have exposed himself to. So that's for the future. But for the time being, we have an approach that will allow us to use newly available technology to solve this problem.

The INTERCEPT pathogen inactivation technology was recently licensed by the FDA. It involves adding a chemical to a platelet unit, an apheresis platelet unit, and exposing that unit to ultraviolet light. That ultraviolet light activates the chemical compound which then crosslinks the RNA or the DNA, the genetic material, of any infectious agent that may be in the unit, including bacteria or viruses including hepatitis and HIV.

Now, for recipients, this is very important news because the major risk of pathogen transmission, the major infectious disease risk for platelet recipients is bacteria. Now, though we culture every unit of platelets that we send out, there is still a risk that we can't avoid of about 1 in every 1500 platelet units having bacteria. We'd like to get rid of that. And by using pathogen-reduced platelets, that eliminates the risk of bacterial contamination.

We can also apply that same technique to eliminate the risks of HIV or hepatitis transmission. Donation by an MSM will, of course, be tested with all the usual test techniques that we use. If the unit is negative in all of those tests, we know that if there is any hepatitis or HIV present, it's at a very low level, and that level will easily be overwhelmed by a factor of 10 to the 4th, that is 10,000, to 10 to the 6th, which is a million. So up to a million-fold safety margin and that the pathogen deactivation technique will eliminate any residual viruses that the testing may have missed. Therefore, the recipients are not only going to receive a licensed and safe product, they're actually going to receive a safer product, because they won't need to worry about bacterial contamination.

We're working now with gay advocacy groups in the areas that we serve, particularly in the Peterson, King County areas to begin to recruit donors for this new opportunity and we hope they will take advantage of it. We can't begin today, however, because the FDA has not yet given us official clearance to begin this program. I will be speaking at the Blood Products Advisory Committee meeting of the FDA toward the end of March and we expect that the FDA will make a final determination on our request sometime in the early autumn. Until then, anyone who presents as an MSM wanting to donate blood will continue to be deferred but we're creating a system whereby we can capture their information so that we can get back in touch with them later, when they can actually donate.

As I said, this is a very exciting advance for blood banking in this country. Bloodworks is taking a unique step forward in identifying a way to get past a deferral criterion which should have been changed long ago and creating a different means for MSM to donate blood, and we look forward to having them join us in the donor room pretty soon. Thank you.

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