



March 26, 2018

Dear <Name>,

We write to you today with important new information and a heavy heart.

As you know, we have been assessing the circumstances surrounding the catastrophic failure at our fertility clinic and why this happened. Our investigation still hasn't led us to the ultimate answer that we know you and so many others want. Rather than waiting until we have all of the information and answers, we want to share some new and important facts with you now.

But first, we want to acknowledge the dismay we heard from some patients who were upset that the first letter they received from us didn't include a personalized greeting. We were trying to get word out to those affected by the situation as quickly as possible and, in the interest of time, we made the decision to do so without a formal salutation. We meant no offense and apologize.

We also want to say we're sorry to those who were offended that they learned new details from TV, newspapers and social media before receiving that information from us in the two previous letters we sent. We can't control the exact time when the letters arrive – or when a member of the media might receive a copy from a patient, thereby making the information public.

Here are the facts we have now confirmed:

- **We know that many more eggs and embryos were affected than first estimated and that it's unlikely that any are viable.** All of our records for the storage tank in question have now been reviewed. We now believe about 950 of our patients were affected by the failure of this storage tank. The technical manner in which the eggs and embryos are stored in these freezers complicated our initial determination of how many patients and specimens were affected, and after review, we have determined that the total number of affected eggs and embryos for these patients is more than 4,000, not the estimate of 2,000 previously used. We are heartbroken to tell you that it's unlikely any are viable.
- **We know that the remote alarm system on the tank, designed to alert a UH employee to changes like temperature swings, was off.** We don't know when the remote alarm was turned off, but it remained off through that weekend, so an alert wasn't sent to our employee as the tank temperature began to rise on Saturday night, when the lab isn't staffed. An alarm should have been sent and received. We don't know who turned off the remote alarm nor do we know how long it was off, but it appears to have been off for a period of time. We are still seeking those answers.
- **We know that the tank in question needed preventative maintenance.** Liquid nitrogen is added to the storage tank to keep the specimens frozen, and it can be added automatically or manually. Prior to the weekend in question, and for several weeks, we had experienced difficulty with what is called the liquid nitrogen automatic fill on the storage tank in question. We had been working with the tank manufacturer who had previously provided instructions on the necessary maintenance to "thaw" the storage tank to correct this difficulty. To do that required transferring all specimens to an extra

storage tank previously provided by the manufacturer. This process takes several weeks, and had begun when this event occurred, though no eggs or embryos had yet been moved to the extra tank.

- **We know that with the autofill not working, we were filling the storage tank by pouring containers of liquid nitrogen into the top of the tank.** While preparing for the transfer of specimens to the extra storage tank, the staff had been filling the storage tank containing the eggs and embryos with liquid nitrogen for several weeks through a series of manual fills, done by connecting the storage tank with a line to a tank of liquid nitrogen kept in the lab. For several days prior to the weekend in question, a manual fill could not be done using the line in the Embryology Lab because there were no liquid nitrogen tanks available. So, containers of liquid nitrogen were obtained from the Andrology Lab. Those containers were then manually poured into the top of the tank, while amounts of liquid nitrogen and temperature were monitored. On the Friday before the weekend of the failure, the liquid nitrogen was brought in a container from the nearby Andrology Lab and poured into the tank. The liquid nitrogen levels in the tank were monitored and appeared to be appropriate on Friday and Saturday, but we now suspect that may not have been the case. We do not yet know if this fill process may explain the rise in temperature over the weekend. This investigation continues.

These failures should not have happened, we take responsibility for them – and we are so sorry that our failures caused such a devastating loss for you.

Our patients are our first priority, and we will continue to provide you with clinical support and assistance. We encourage you to speak with your physician who stands ready to answer your clinical questions, or call our information line, at 216-286-9740, which will continue to be available weekdays 7 a.m. – 8 p.m. and Saturdays 8 a.m. – 1 p.m.

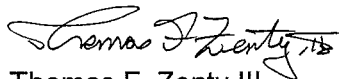
As we outlined in our last letter, we've offered our patients who had stored eggs or embryos with us a collection of medical services tailored to their individual clinical needs. We also will refund storage fees paid to date and we'll waive storage fees in the future for seven years. We are not asking that you sign a release of any claims to obtain these services.

In the meantime, our fertility center continues to operate and our clinic team is using new storage tanks, new alarm systems and robust policies for the monitoring of the storage tanks.

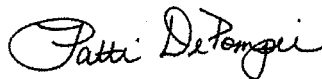
We have an important companion message to this letter. We encourage you to visit our University Hospitals Facebook page on Tuesday, March 27 in the afternoon to see that video message.

Even as we say, again, how sorry we are, we know that words are not enough. Our actions must now speak for us. We hope our actions will restore your trust in us.

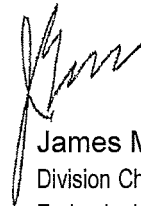
Sincerely,



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