

To: U.S. Food and Drug Administration Office of the Commissioner, Dr. Margaret Hamburg
10903 New Hampshire Ave
Silver Spring, MD 20993

Via FedEx Overnight: **794157022043**

28-Nov-2010

RE: Order from CBER (Center for Biologics Evaluation and Research) to CEASE MANUFACTURING OF SEMEN and Hearing Request

Dear Dr. Hamburg,

This Christmas season, a number of new parents in the Bay area are left wondering if their children will grow up having a brother or sister. I believe that you, Commissioner, were fortunate enough to be raised around the Stanford University campus and may share much in common with these Bay area families. However, there are some key differences that affect the voice of these people which I ask you to consider when granting a hearing:

- 1.) Many of these families have been given limited rights. Only until recently has it been legal for many of them to marry.
- 2.) The affected are private citizens, many on limited incomes, who met out of kindness and the desire to see a child born into a loving home. There are no wealthy medical boards, huge family trusts, or assets of a hedge fund manager to help them and the biological father to come into forced reproductive compliance.

Some may argue that these new types of families do not fit the traditional role of marriage and deserve to be treated like second-class citizens with laws that select their reproduction. Yet I cannot think of any better way to show compassion to such people in need by offering them a chance to the most precious gift in life, and find more purpose to reaffirm their vows and commitments to each other.

As the family structure begins to change in these times, a new group of men is fulfilling a needed role as women realize that anonymous biological fathers often deprive their offspring a needed identity during the child's formative years. Society may be wrong to target the men who step out and honor and love these women by taking responsibility; some will dedicate their lives to abstinence out of respect and safety for women. The message that is sent today is the creation of two classes of children, one actively denied by the state knowledge of their biological fathers, and the rest who the state believes should have access to the concern and identity of a biological father.

Years from now, some may look back to see how many disadvantaged families it would take before controlling their course of evolution through policy became wrong. Right now it is seventy families that could be affected by the first cease manufacturing order. History has repeatedly shown when a powerful group limits the population of another, the results are often disastrous for the weak ones.

When the time comes to making a decision to allow a hearing process for voices to speak out for these and other families, my wish is that there will be another Reason to celebrate hope this Christmas season.

Best Regards,



Trent Arsenault

cc: Mary Malarkey, Director, Office of Compliance and Biologics Quality, CBER: 794157012888
cc: Luarie Lenkel, Director, Office of the Ombudsman: 796491512649

Attachments (6)

- **CBER Order to Cease Manufacturing of HCT/Ps**, 01-Nov-2010
- **28-Nov-2010 Follow-up letter to Mary Malarkey**, Director, Office of Compliance and Biologics Quality, CBER
- **Hearing Request to Mary Malarkey**, Director, Office of Compliance and Biologics Quality, CBER, 01-Nov-2010
- **Request for Extension of FDA Form 483 to Barbara Cassens**, Director, San Francisco District Office, 01-Oct-2010
- **Form 483 Inspection Observations**,
- **Form 463a Signed Affidavit**