N.W. Andrology & Cryobank, Inc.

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Secretary Tommy Thompson
Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

Dear Secretary Thompson,

I am delighted to be writing to you and that sensible government has returned to Washington.

I am writing to you about proposed FDA regulations that have not yet been finalized. The Food and Drug Administration is proposing to register and regulate tissue banks. This covers the procurement and storage of human organs for transplant, reproductive cells (sperm and ova) and storage of human milk.

On it's face, regulating tissue banks for medical safety seems reasonable. However, the Centers for Disease Control already have long established guidelines which the tissue banking industry already follows. Indeed, the tissue banking industry has been self regulating without any serious incidence for a very long time. The rare incidence that occur are due to human error that an extra layer of FDA bureaucracy would not impact. So why is the FDA willing to spend our money and drive up the price of human organs, sperm, ova and human milk (which is needed for premature babies) to fix a system which is not broken? Well, it certainly guarantees the FDA a larger budget and work force. Unfortunately, the consumer will pay the price in dollars without any added benefit.

In it's proposal the FDA admits that the extra cost of this bureaucracy will force smaller tissue banks out of business. I own one of these smaller banks. I may well be forced to close my doors after 15 years of business because of the new regulations. This appears to be why the larger banks are not opposed to these proposed regulations. Many of the smaller banks have not been informed that this is about to happen. When questioned about this, FDA officials have consistently said they have only worked with the larger institutions such as the American Association of Tissue Banks (AATB). The AATB is a fine organization and it, too, has guidelines which are followed by most of the industry. However, most in the tissue banking industry, while following the AATB guidelines are not AATB members. For example, in the area of reproductive tissue, only nine

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out more than 100 sperm banks in the country are AATB members. And those nine are the largest of the sperm banks because only they can afford the AATB's $5,000 annual membership fee, and additional inspection fees. Smaller institutions simply cannot afford this, and there is no reason for the patients to bear increased costs for needless regulation that neither increases availability, affordability, safety, or choice. Yet, it is only the AATB and other large organizations that the FDA has worked with. With an OK from Secretary Shalala and the Clinton administration, the FDA has consistently ignored smaller institutions even when information was requested. It is important to remember that these smaller banks have as good a safety record as the larger ones. Closing them will mean less competition and, once again, higher prices for us all. These regulations are modeled after New York State's regulations enacted during the Cuomo administration. Clearly, this is good example of Democrat-inspired government regulation run amuck. The first part of this three part proposal was finalized on January 19, 2001 along with hundreds of other regulations (FEDERAL REGISTER Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing; Final Rule Posted: 1/19/2001, Publish Date: 1/19/2001 http://www.fda.gov/cber/rules.htm). Although this first part has been finalized it only requires tissue banks to register with the FDA. The following two parts are the actual regulations. It is those two parts which you still have authority to stop. The last part of this three part proposal was published January 8, 2001 months before it was originally due out (FEDERAL REGISTER Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement; Proposed Rule Posted: 1/8/2001, Publish Date: 1/8/2001 http://www.fda.gov/cber/rules.htm#gtp).

California is one of three states that, like New York, requires tissue banks to be licensed. However, California's one page of safety requirements, enacted while Pete Wilson was governor, is a simple and sensible formula that everyone in the industry supports. The nearly 100 pages of new regulations that the FDA is proposing will be a burden on the industry.

I would suggest you call any small tissue bank director in the country that does business in both California and New York and ask them to contrast the problems the California versus New York regulations cause them. You will be amazed at just how upset many are with the ridiculously, complex web of New York's regulations. Now, some of the same bureaucrats who work for both for the New York State tissue banking program and the FDA want to bring this mess to Washington and to the rest of the country.

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You were governor of a state that did not have any of these regulations. Yet all the tissue banks in your state, like elsewhere, were self-regulating and followed the CDC and AATB guidelines. They had no safety problems. They did not need Federal regulation then. They do not need Federal regulation now.

Again, the bottom line is: Why is the FDA trying to regulate an industry that has not had any problems? I am asking you to put a stop to this FDA waste of money which will only hurt health care consumers and drive up costs for all of us.

Sincerely,

Sam Henrichs
NW Andrology & Cryobank