FDA MODERNIZATION TELECONFERENCE
APRIL 28, 1999

As president and co-founder of Chemically Associated Neurological Disorders, a non-profit organization dedicated to raising funds for education and unbiased research on the toxic effects of silicone, silica, and it's components including platinum, I applaud FDA Commissioner Dr. Jane Henney's use of new communication technology to enhance communication between stakeholders and FDA officials. This is an important first step for identifying problems, getting feedback and evaluating ongoing modernization efforts.

Current research and diagnoses are contradicting each other. While some research (paid for in part by the manufacturers of the medical devices) indicates little or no correlation between implants and disease; common diagnoses of implanted patients indicates significant correlation. Research suggests mothers with implants may unknowingly be passing toxic residue to their unborn children through the placental barrier, as well as to newborns through breast feeding.

I represent the thousands of women who believe their health has been effected by ruptured leaking breast implants. We, like the general public today, believed and trusted the FDA was protecting us as consumers. Only after doing extensive medical research did we learn that no breast implant has ever been approved by the FDA because manufacturers have never been able to prove them to be either safe or effective, as is required by law of a class III device.

In answer to your question "What actions do you propose the agency take to expand FDA's capability to incorporate state-of-the-art science into its risk-based decisionmaking?", I propose consumers be allowed to submit published research to the FDA and receive timely written answers regarding levels of risk tolerated by the FDA and to have those levels of risk be accurately reflected in "informed consent forms" and product inserts. For instance a failure rate of 5 percent was regarded as "not a safety standard the FDA can accept" according to former FDA Commissioner David Kessler (JAMA 1993). However, a failure master curve from eleven research papers of 1,652 explanted protheses, shows a significant direct correlation of failure rate with implant time and can be used to predict a failure rate of 50 percent at 8 years. Nevertheless, the FDA has allowed the manufacturers to quote a 1% rupture rate in their package inserts. This kind of misinformation on the part of manufacturers in under-reporting of complications is serious and cannot be tolerated, along with other protocol violations which are currently occurring in Mentor's adjunct study on breast implants.

In November of 1997, in a meeting with the FDA, a Baylor College of Medicine researcher presented data documenting the release of low molecular weight silicone and platinum from intact implants which spread to ten major organs in

the body including the brain in mice. Baylor's recent research published February 1999 documents fatal liver and lung damage in mice. Dr. Lieberman states "Injection of 0.2 ml (about 4% of a teaspoon) kills approximately 50% of the mice in 7 days. This degree of toxicity is about the same as that of carbon tetrachloride and trichloroethylene, two compounds that are widely recognized as model toxins and in fact are used by many researchers in their work to understand how toxic chemicals harm the body." Does the FDA have a safe level of risk associated with the implantation of silicone, silica, or it's components such as platinum which can leak before it becomes toxic in the human body?

In 1997, Dr. Louise Brinton with the NCI and Dr. Lori Brown with the FDA published an article (Journal of NCI 9/17/97) reporting "Silicone gel has been found to migrate into both surrounding and distant tissues as a result of rupture or bleed, with reports of evidence of silicone found in the breast, implant capsule, axillary lymph nodes, arms, fingers, groin, blood and liver...recent evidence, has documented that it is immunogenic."

You ask what actions do I propose to facilitate the exchange and integration of scientific information to better enable FDA to meet its public health responsibilities? I propose if the FDA does not have scientific information about the safety or effectiveness of a medical device, it has an obligation to inform the consumer of this fact to meet its public health responsibilities. I propose that the FDA mandate the use of percentages of risk from reported published comlication rates in manufacturer's "informed consent" forms and product inserts, to better enable consumers to determine the rate of risk they are willing to assume. The FDA is currently allowing McGhan to state "Most women who have had breast implants have had satisfactory results" and "Complications are uncommon".

You ask "What actions do you propose for educating the public about the concept of balancing risks against benefits in public health decisionmaking?" I propose the FDA issue public health information on a regular basis to television and media contacts to counterbalance the misinformation provided by the public relations firms of the manufacturers and plastic surgeons who regularly tout all the benefits and none of the risks of breast implants and other cosmetic surgury in the media.

You ask "What actions do you propose to enable FDA and its product centers to focus resources on areas of greatest risk to the public Health?" I propose the FDA allocate its resources based on the products with the highest percentage of complaints or serious adverse events. In 1992 30.3% of the total mandatory adverse events reported to the FDA on medical devices was on breast implants alone. Over 170,000 adverse events have been reported to the FDA on breast implants. The Wall Street Journal on June 24, 1998 in an

article titled MedWatch System Comes Under Fire quotes Brian Strom, chairman of the University of Pennsylvania's biostatistics department as saying "Basically nobody is looking for problems, the system has turned into a big wastebasket." The FDA states "The process for adverse event/injury reporting is the most urgent task facing FDA." Who at the FDA is looking at long term consequences of breast implants? With a reported latency factor of an average five to fifteen years for symptoms to appear, the current MedWatch system is inadequate. It appears it was designed as an early warning system only and a problem accurs when the doctor who put in the device is not the doctor who is seen for systemic disease symptoms. What modernization efforts have been put into place in this area?

Lastly, you ask "What additional actions do you propose for enhancing communication processes that allow for ongoing feedback and/or evaluation of our modernization efforts?" Periodic live satellite teleconferences are a great start at communication processes which include consumer participation. More open communication with feedback, regardless if negative or positive, to problems identified by consumers is essential. I am still waiting for feedback on my proposals made at the August 18, 1998 compliance public meeting.

Respectfully,

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