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Dennis Newman
9305 Blue Mountain Drive
Golden, Colorado 80403

Distribution:

Domini Cassis (2 written copies)
Center for Devices and Radiological Health (HFZ-215)
Docket No. 2004P-0329
1350 Piccard Drive
Rockville, MD 02850
Phone: 240-276-2342

Division of Dockets Management (2 written copies)
(HFA-305)
Docket No. 2004P-0329
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Mr. Newman and Ms. Cassis:

As I have notified each of you, I have had considerable wishes to participate in this important Public Workshop (Docket No. 2004P-0329) dealing with some of the issues surrounding the Over the Counter (OTC) sale of low output, hand held, Doppler fetoscopes so that these ingenious, useful and safe devices can be used in the privacy of the American home in circumstances chosen by American women.

Unfortunately, I am suffering from a chronic illness which has chosen to worsen significantly at this time, making my attendance and presentation to this Public Workshop just not possible. This Workshop is taking place through the thoughtful consideration and work of professionals at the FDA, and specifically is held to address many of the issues which I presented to the FDA through three Citizen Petitions, Docket Nos. 2002P-0338, 2003P-0438, and 2004-0329.

Because of my illness, I have asked a long-time friend, Mr. Dennis Newman, to read this cover letter into the record, and in so doing also place into the record a small portion of the supporting material and communication I have had with professionals at the FDA my view that certain Doppler fetoscopes should be available to American women through the OTC market. I was assured by Workshop coordinator, Domini Cassis, that Mr. Newman would be allowed to read this letter and place its supporting documents into the Workshop Record at this time.

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In brief, I am an obstetrician-gynecologist who had most of my clinical years spent as a clinician in the US Army Medical Corps. I have delivered over 4,000 babies, and was fortunate to practice obstetrics during those years of tremendous change for the good. For instance, it is realistic to opine that from the 1960s to the present the most significant advances in obstetrical care of all recorded history took place. Ultrasound, in many applications, was part of that great epoch of improvement in women's, pregnancy, and newborn health care.

I first met Dr. Lillian Yin, PhD, as a colleague in Federal Medicine in 1973, when it was my privilege to present before an oversight subcommittee of Congress what I considered to be serious dangers in the FDA's oversight of intrauterine contraceptive devices (IUDs) in general, and of the Dalkon Shield in particular. Those hearings, those chaired by Senator Ted Kennedy, and others at the FDA led inexorably to the May 28, 1976, enactment of The Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act.

With our 1973 meeting at the "Dalkon Shield Hearings" Dr. Yin and I developed both a friendship, and a professional relationship which combined my clinical observations with her strong feelings that the FDA had a distinct obligation to safeguard the pharmaceuticals and devices over which it had increasing regulatory obligations.

Our mutual interests, it seemed, came together over a seemingly small little device, generally known as the hand-held Doppler fetoscope. And the single most significant meeting of Federal minds on the subject of Doppler fetoscopes – regulatory verses clinical – just happened to take place in front of a display booth of a fledgling medical device company, IMEX Medical, at a national convention of the American College of Obstetricians and Gynecologists, held in 1986 in the new Convention Center in New Orleans.

"Lillian," I excitedly brought Dr. Yin to the IMEX booth which featured a new model of the company's expanding line of Doppler devices, "I think that every expectant mother in America should have the right to have one of these Doppler fetoscopes in her home."

"Russ," Dr. Yin responded without missing a beat, "what would happen if the woman could not hear her unborn baby's heartbeats, or thought that she heard something wrong?"

"Dr. Yin," I responded immediately, "that would be no problem as she would simply consult with her doctor."

The Doppler fetoscopes debate between Drs. Yin and Thomsen started at that moment, with Dennis Newman nervously listening in on the free-for-all.

Unfortunately, Dr. Yin – who passed away in 2000 – is not here to share here strongly held and rather unyielding views that she had an obligation to protect American women from – shall I suggest – from Dr. Thomsen and that little Doppler device.

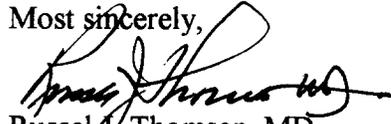
But I have never wavered in my views, actually strengthening them as time, clinical insight, and thought have led to the following conclusions:

1. In addition to the numerous studies demonstrating the amazing safety of ultrasound in obstetrical care, a virtual mountain of clinical experience refutes any lingering questions. Contrary to some historical renditions, it should be realized that portable Doppler ultrasound came to obstetrics in 1965 out of the University of Washington, commercially through Smith Kline Instruments and in 1966 with the commercial sale of the Doptone® by Smith Kline Instruments. There are a little over 4 million live births in the United States each year, or some 40 million per decade. Consider that each pregnancy has about 10 Doppler fetoscope clinical exams. That means, in the two decades (1986 to the present) since Dr. Lillian Yin and I debated the home use of Doppler fetoscopes, there have been between 750 million to 1 billion clinical exams of pregnant women. Or, in even more historical perspective, since the 1966 invention of the Doptone® there have been between 1 and 2 billion (**billion**) obstetrical examinations with Doppler fetoscopes. And in this massive use of this life saving device, no pattern of fetal or maternal risk has been observed by the FDA, in academic or in clinical medicine. That is astounding.
2. Complications of Doppler fetoscopes use have not been reported to the FDA despite an easy to use reporting system that encourages, not discourages, the reporting of potential complications of use.
3. The massive use of Doppler fetoscopes leaves, without statistical evidence to the contrary, an inescapable conclusion that Doppler fetoscopes not only have saved fetal lives because of early intervention when routine clinical visits have turned into the discovery of agonal or severely ill unborn babies.
4. If such incidental clinical encounters have resulted in the saving of innumerable fetal lives, it can only be concluded that beyond a statistical certainty, American women would (by “accidental” or intuitive timing of home Doppler use) save hundreds of lives of their unborn babies each year if OTC Doppler availability resulted in even periodic use.
5. And finally, with this possibly being the first reference to such a possibility, it is likely that OTC Doppler fetoscopes would lead to the live births of hundreds of babies each year in the United States because women have given further thought to therapeutic termination of their pregnancies after hearing (bonding with, it might be said) the heart sounds of their unborn babies. That this prevention of abortion would occur is within the findings of any study of early pregnancy acquainting of mother and fetus.
6. As this Public Workshop is being held, it is most probable that US Military

personnel are (as did my Blackhawk pilot son in Iraq and his wife in California) listening to the heartbeats of their unborn babies through the miracles of Doppler fetoscopes transmitting via the Internet to front lines in the defense of freedom.

I do wish the success of this Public Workshop as people with genuine interests in the well-being of future generations of Americans through the miracle which is OTC Doppler fetoscopes private, home use.

Most sincerely,



Russel J. Thomsen, MD
COL, MC, USA(Ret)
President
The BABYDATER® Company
Russthomsen@wavecable.com

President
The Russian American Medical Foundation
PO Box 568
Silverdale, WA 98383