

Thursday, May 6, 2004

New York State Senate Deputy Majority Leader Dean G. Skelos (R-C, Rockville Centre) announced the introduction of legislation prohibiting nonmedical ultrasounds used solely for entertainment purposes. Although private prenatal “photography” shops have appeared in shopping malls around the country, New York’s first private ultrasound studio recently appeared in Manhattan.

“The FDA has concluded that these unregulated ultrasounds ‘put a mother and her unborn baby at risk,’” said Senator Skelos. “This is high-powered equipment, and every step must be taken to ensure that mothers and their unborn children are protected from unforeseen harm. This legislation will guarantee that ultrasounds are limited to medically-necessary treatments and administered by trained professionals.”

Generally, ultrasound equipment produces a high-frequency sound wave to generate diagnostic images of developing babies. Since the 1960s, ultrasounds have offered an invaluable tool for diagnosing pregnancy and any potential abnormalities and determining the proper course of medical care. When correctly administered by trained professionals, such as sonographers, radiologists, and obstetricians, low-power ultrasounds are generally considered a safe means of gaining information about a pregnancy.

Utilizing state-of-the-art 4D technology, the most advanced ultrasound machines can provide much clearer pictures than older equipment—including facial contours, muscle definition, and hair—and combine these images into short videos. However, this modern ultrasound equipment is capable of producing intensities 8 times higher than the machines commonly used by medical professionals.

As introduced by Senator Skelos, S.6776-A would restrict the administration of any ultrasound on a pregnant woman to those performed pursuant to an order or referral by a licensed physician, nurse practitioner, or licensed midwife. In addition, the legislation prohibits the dispensation of ultrasounds for entertainment purposes or those not warranted by the condition of the patient. If enacted, a violation of this new law would be a Class A misdemeanor, with a maximum prison sentence of 1 year.

“Ultrasounds on pregnant women are used for medical purposes, to obtain information about the pregnancy,” said William B. Rosenblatt, MD, president of the Medical Society of the State of New York. “The practice of performing ultrasounds on pregnant women without a medical reason and an order from a physician, nurse practitioner, or nurse midwife should not be done. The Medical Society of the State of New York supports this bill as an effort to end this unnecessary and extremely costly practice.”

A US Food and Drug Administration (FDA) investigation concluded that nonmedical, entertainment ultrasounds are often performed without a doctor’s supervision. Moreover, the FDA warned that “ultrasound is a form of energy, and even at low levels, laboratory studies have shown it can produce physical effects in tissue, such as jarring vibrations

and a rise in temperature.” As such, the FDA concluded that “prenatal ultrasounds can’t be considered completely innocuous.” Further, the FDA noted that many of these companies use the ultrasound machines at higher energy levels and for as long as one hour to secure clear pictures and/or videos for their customers.

The FDA first became aware of the “keepsake” ultrasound industry in 1994 (Texas) and informed these providers that anyone promoting, selling or leasing ultrasound equipment for the making of “keepsake” fetal videos could be breaking the law. Although the ultrasound devices are regulated by the FDA and, as such, the FDA can take action against the “keepsake” video industry for using a prescription device without a prescription from a medical professional, the qualifications and behavior of technicians and physicians is regulated by the states.

“In the new Manhattan studio’s first month, more than 40 mothers-to-be have paid \$300 each for a procedure that could have dire consequences,” said Senator Skelos. “Even General Electric, the leading seller of 4D ultrasound machines, has joined the Medical Society, the American Institute of Ultrasound in Medicine, American College of Obstetricians and Gynecologists and the New York State Radiological Society to express its opposition to the use this equipment for nonmedical purposes. Until all the risks associated with this new technology are completely known, we must make every effort to err on the side of public safety.”