Reproductive Genetics, IVF & Endocrinology

Carlsbad, Monday 12th October 2015

Rep. Darrell E. Issa
1800 Thibodo Road, #310
Vista, CA 92081

Dear Congressman Issa,

As a physician, I am writing to express my concern regarding a type of female birth control known as "Essure®". This is a relatively new method of contraception for women which became available in the United States in November 2002. As you may know, the FDA has received more than 5,000 complaints about this device to date.

Curiously, this non-emergency medical device entered the U.S. marketplace under somewhat unusual regulatory circumstances. It received pre-market approval (PMA) as a Class III medical device, even though its therapeutic niche was for "elective contraception." While birth control is an important area in women's health, it is certainly not the type of urgent medical condition for which the PMA process was originally intended.

Where did the approval process go wrong with Essure®? First, the FDA did not consider that these coils contain a nickel alloy. Because a substantial number of individuals have an allergic or hypersensitivity reaction to this metal, some women with Essure® suffer from an inflammatory reaction which variably manifests in many negative ways.

But perhaps more crucially, patient safety data reported on Essure® and submitted to the FDA were from unregistered clinical trials, suffered from inadequate follow-up, and were discontinued far too early for a device designed for lifetime use. By any measure, this is slipshod research and had the effect of underestimating the true complication rate.

Even more troubling is the fact that at least one participant in an early Essure® clinical trial has claimed that her records were fraudulently "adjusted" to make it look like the device was safer than it actually was. Thus, among many women here in California there is now a perception that the FDA remains more interested in helping keep this deeply flawed product on the market, than it is in safeguarding the general health of American women.

E. Scott Sills, MD PhD
Medical Director

California License #G88985
New York License #195607
United Kingdom Reg. #7056747

Center for Advanced Genetics 3144 El Camino Real, Suite 106 Carlsbad, California 92008 USA
TEL +1 760.994.0156 FAX +1 760.994.0159 ✉ info@CAGivf.com

Against this background, as someone quite familiar with this particular medical device based on years of clinical practice, and given the level of harm and the dubious safety record associated with Essure®, I would respectfully ask that you contact FDA leadership and begin the process to reconsider the PMA protection for Essure®. Although more data on this device are absolutely needed, continued PMA protection in the meantime is not.

It may be useful to coordinate such an effort with your House colleague Rep. Mike Fitzpatrick (R-PA), as the date for a Congressional hearing on medical device safety and women's health approaches. According to my patients who are following this issue closely, legislation is being drafted to revoke the PMA protection currently afforded to Essure®. If you can accomplish this, you will rightly be viewed as a true champion for women's health in the United States.

I appreciate your work on my behalf in Congress and would be happy to provide any additional information that you believe would be useful concerning the points discussed here.

Kind regards,

E. Scott Sills, MD PhD
FACOG, FACS, FRCPI

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