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Women Discussed Debilitating Side Effects of Essure 14 Years Before FDA Released Warning

Timed to the Pending Congressional Investigation Treato Examines Timeline of Online Conversations About the Permanent Birth Control Device

NEW YORK, NY (May 18 2016) - Today <u>Treato</u> revealed that conversations in online health forums about serious, life-altering side effects from Essure, the permanent birth control device, started in 2002, the year the device was approved and 14 years before the FDA issued a product warning. In 2008 negative online conversations about Essure outweighed positive online conversations, a trend which has continued every year since. Patient advocacy groups have asked Congress to investigate the FDA's February-announced decision to mandate a black box warning for Essure; the advocacy groups want the product withdrawn from the market. <u>Essure</u> has reportedly been linked with 300 fetal deaths and the FDA has received more than 10,000 complaints about the product.

An in-depth analysis by Treato revealed that in early online conversations there was little recognition of how common the side effects were among women. Women most frequently discussed experiencing debilitating cramping, abnormal bleeding, weight gain, joint pain, migraines, ovarian cysts, hot flashes and night sweats. Women affected by Essure were wondering whether their experience was unique or if others had had similar experiences. By 2010, women are increasingly using social media forums to connect the dots and discovering there were many women experiencing the same side effects as them.

Women's attitudes about doctors shifted as more information about Essure became available. Before 2006, doctors were rarely blamed when the procedure didn't go as planned. Women reported that their doctors were telling them that their experience was unique and serious side effects hadn't been reported. By 2010 women started to blame their doctors for improperly and irresponsibly inserting the device as many doctors couldn't find the coils they implanted in the women's bodies. Women discussed filing malpractice suits because they felt their doctors didn't alert them to Essure's risks. By 2015 doctors became de-emphasized within online conversations as the blame shifts from doctors to Bayer, the manufacture, and the FDA. When now discussing doctors



online, women are discussing trying to find a doctor willing to do a hysterectomy to remove the device.

Nickel allergies became one of the most common sub-topics women were discussing related to Essure. According to Dr. Peter Schalock of Harvard Medical School, the device is 55 percent nickel and 20 percent of women are known to be nickel-allergic. Many women expressed anger at their doctors for not testing them. Women attributed the nickel in the device to the cause of the development of autoimmune disorders that didn't previously exist as well as reduction of quality of life such as an interruption to their work lives.

"The importance of social data analysis for adverse event reporting is seen through the thousands of online conversations about Essure's life-altering effects on women," says Ido Hadari, CEO of Treato. "Regulators need evolve their safety monitoring strategies with the new technologies available so they are accurately seeing the full picture of patients' experiences."

For more information about Treato's Essure data analysis.

Methodology:

TreatoVoice is a unique data asset that continuously collects and analyzes more than two and a half billion patient and caregiver conversations happening across the Internet in real-time to understand what patients are saying about their experiences with their conditions and treatments. For this data analysis Treato collected more than 17,000 online discussions about Essure from 2002 to present. Through a discourse analysis lens Treato qualitatively reviewed sample sets of posts from three distinct time frames: 2002, 2010 and 2015.

About Treato:

Treato™, the leading source of health insights from millions of real health consumers, uses patented analytics and big data technology to turn billions of disparate online conversations into meaningful social intelligence. With more than two billion posts analyzed and continuously expanding, Treato has partnered with 9 out of the world's top 10 pharma companies as well as numerous other multi-national pharmaceutical companies and healthcare organizations. Treato.com, its consumer website, helps millions of visitors each month. Treato is privately held with offices in Israel, New York and Princeton, NJ. Investors include Reed Elsevier Ventures, OrbiMed Partners and New Leaf Venture Partners, among others. For more information please visit https://treato.com/