Based on the 2016 FDA Advisory Committee recommendations, the FDA ordered the relabeling of ESSURE to include the strongest warning of risk available, which is the placement of a Black Box Warning (BBW) label, on ESSURE.

After being advised that doctors were not properly informing patients of the risks of ESSURE, the FDA ordered that a Patient Checklist be required before ESSURE could be inserted in a patient.

Doctors and their respective medical organizations to include the American College of Obstetricians and Gynecology (ACOG), the Association of Reproductive Health Professionals (ARHP) and Planned Parenthood strongly objected to the BBW and Patient Checklist and resisted their use.

Despite clear evidence of medical abuse, deception and misrepresentation of ESSURE by doctors, the ACOG, ARHP and Planned Parenthood never changed their official positions on ESSURE.

The major reasons given by these organizations for disapproval of the BBW and Patient Checklist was the perceived interference of the FDA with the Physician-Patient Relationship in obtaining Informed Consent for the placement of ESSURE.

However, these objections are fundamentally disingenuous.

The members of ACOG, ARHP and Planned Parenthood clearly had conflicts of interest motivated by financial incentives.

For example, the ability to place the ESSURE in the office or in the clinics of Planned Parenthood were a windfall "cash cow" of profits which allowed it to compete with hospitals by being able to place ESSURE in its clinics as compared to laparoscopic tubal ligation which had to be done in a hospital.

The BBW and Patient Checklist forced doctors to better inform their patients of the issues with ESSURE and, following their inception, sales of ESSURE in the United States significantly fell.

It can be said that the BBW and Patient Checklist were 2 of the 3 "death blows" in ESSURE 's demise.

The third being the multi-billion dollar tort lawsuit cases progressing through the United States courts which finally convinced Bayer to stop selling ESSURE.

In a further video, I will discuss the recent status of the $1.6 Billion dollar ESSURE settlement offer by Bayer to approximately 39,000 women included in mass tort lawsuits in the United States.