

2019.3.25-.26 FDA Panel Hearings UNITED STATES OF AMERICA DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CENTER FOR DEVICES AND RADIOLOGICAL HEALTH MEDICAL DEVICES ADVISORY COMMITTEE GENERAL AND PLASTIC SURGERY DEVICES PANEL March 26, 2019

<https://www.fda.gov/media/123746/download>

DR. CASAS: Thank you. My name is Dr. Laurie Casas. I'm a board-certified plastic surgeon in clinical academic practice for 29 years. I'm also a Clinical Professor of Surgery at the University of Chicago and a board member of the Aesthetic Society. I have no financial disclosures to report. Thank you for the opportunity to discuss how I have arrived at best practices for breast implant informed consent discussions.

Unlike many surgeries, informed consent does not end at the time of breast implant surgery. We need to share decision making with our patients to determine a path of long- term care and periodic monitoring for the lifetime of that implant.

As new patient-specific and implant-specific data are identified, we need to communicate this information to our patients in a timely manner, sometimes in person, but oftentimes electronically. Clearly, we need new technologies to collect patient-centric and implant-specific data at the time of implant surgery and longitudinally. Relying on data from industry post-approval studies has not been enough.

I applaud the creation of the FDA's National Evaluation System for health Technology, or NEST, and its goals to link and evaluate information from many sources to

Free State Reporting, Inc. 1378 Cape St. Claire Road Annapolis, MD 21409 (410) 974-0947

468

improve collection and evaluation of post-approval real-world data.

It is also vital that the Aesthetic Neural Network, or ANN, in conjunction with the Aesthetic Society, add critical data to the existing National Breast Implant Registry at the time of implant surgery and on an ongoing basis.

Our collective goal is to quickly identify, communicate, and act on implant device safety concerns. Over the past 2 days I'm hearing that we need a structured educational checklist for informed consent. I agree, and the Aesthetic Society hears you. The Aesthetic Neural Network, or ANN, will have a breast implant informed consent checklist that will be updated as new safety information becomes available.

First and foremost, I'm an advocate for breast implant patients. My goal will always be patient safety and a better informed patient, through transparent and informed dialogue at the time of implant surgery and throughout the lifetime of each implanted device. Inadequate data collection must stop today.

Thank you.