

“Hot Flashes and Cool Revelations: Dispelling Myths about Hormone Replacement Therapy and Breast Cancer”

Program Summary: In this “mock” podcast (JALBCA Health podcast), legal and medical experts will explore a new perspective on Hormone Replacement Therapy (HRT) and breast cancer risk. Legal experts Caroline Brancatella, Esq., and Danielle Tangorre, Esq., will analyze a fictional scenario involving a social media influencer working in conjunction with a NY licensed physician to sell and promote “Serenity Now,” a product that is not FDA approved and is advertised and sold to all 50 states. Pierette claims that her product treats the symptoms of menopause and peri-menopause without increasing the risk of breast cancer. The legal experts will explain both the civil and criminal consequences for Pierrette and the physician under NY law. This includes a framework for understanding how NY defines and regulates the unauthorized practice of law, professional misconduct, as well as FDA labeling, communications and off label use, regulation of advertising and exemplary social media posts, corporate practice, and the Federal Trade Commission’s role. The medical experts will explain the use of HRT for menopause and peri-menopause, symptom management, treatment options and the latest data on the breast cancer risk relating to HRT.

- 6:00-6:05** Introduction & Legal Fact Pattern: JALBCA Health podcast, legal and medical experts, and presentation of the legal fact pattern. *Hosts*
- 6:05-6:30** Legal framework for the licensed practice of medicine, jurisdictional issues, and state and federal regulatory oversight, and interplay with limited availability of remedies and relief for menopause and peri-menopause symptoms, compounded by myths about HRT. *Caroline Brancatella, Esq., Danielle Tangorre, Esq., Dr. Yael Zack and Melissa Ferrara, MS, FNP-BC*
- 6:30-6:50** Criminal civil and professional misconduct consequences and policy rationale for the unauthorized practice of medicine and aiding or abetting same; understanding the policy rationale in conjunction with the benefits and risks of HRT including increased cancer risk, factors that increase cancer risk and considerations for prescribing HRT to the general female population. *Caroline Brancatella, Esq. and Dr. Yael Zack*
- 6:50-7:15** Off-label drug use and the practice of medicine, state and federal regulatory guidance and considerations including labeling, safety, approval and FDA communication restrictions, as relevant in particular to HRT for breast cancer survivors, with discussion of breast cancer epidemiology, endocrine therapy for breast cancer and how it works, treatment side effects, interventions and clinical trials/findings. *Danielle Tangorre, Esq. and Dr. Ruth Oratz*
- 7:15-7:35** The business of medicine and professional services, FTC-permitted marketing and advertising of medicine, penalties and enforcement actions, and best practices for providers; health considerations for HRT use, alternative treatments and management strategies. *Danielle Tangorre, Esq., Dr. Oratz, Dr. Zak and Ms. Ferrara*
- 7:35-7:40** Audience Questions [legal/medical 5 minutes]