

# BILBAO

## SPAIN

# Almut Winterstein

## Bio



Almut Winterstein is Distinguished Professor and the Dr. Robert and Barbara Crisafi Chair for Medication Safety in the Department of Pharmaceutical Outcomes and Policy, an Affiliate Distinguished Professor in Epidemiology, and the founding Director of the Center for Drug Evaluation and Safety at the University of Florida. Since 2019, she also serves as director of the Consortium for Medical Marijuana Clinical Outcomes Research, a state-funded consortium of 9 universities in Florida. Dr. Winterstein's research interests center on the post-marketing evaluation of medications in pediatrics and pregnancy, infectious disease and psychiatry, and the evaluation of policy surrounding medication use using real-world data. As an expert in drug safety, she has

chaired the Food and Drug Administration's Drug Safety and Risk Management Advisory Committee from 2012-2018. Recognizing her contributions to pharmacoepidemiology, Dr. Winterstein was inducted as a fellow of the International Society of Pharmacoepidemiology in 2013 and served as president of the society from 2019-2020. In 2022, she was inducted into the Academy of Science, Engineering, and Medicine in Florida. She received her pharmacy degree from Friedrich Wilhelm University in Bonn, Germany, and her PhD in Pharmacoepidemiology from Humboldt University in Berlin. Dr. Winterstein has chaired more than two dozen PhD committees and received the UF-wide Dissertation Advisor/Mentoring award for her excellence in graduate training.

## Abstract

Drug exposure in pregnancy is common although data for most medications to support favorable benefit-risk for both mother and fetus are sparse. For some medications with established teratogenic risk, exposure during pregnancy remains fairly common, calling for enhanced risk management approaches. This presentation will summarize work on evaluating the effectiveness of regulatory approaches aimed at preventing prenatal exposure to teratogenic medications. It will introduce formal assessments of risk mitigation programs and introduce on ongoing study aimed at developing an explicit framework to prioritize medications for risk mitigation.

