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Professional Profile

Dr. Weiss is an epidemiologist with 25 years of experience in Pharmacoepidemiology and Regulatory Sciences. She specializes in the safety of FDA-regulated medical products; drugs, biologics, vaccines, devices, and combination products. Dr. Weiss works with Pharmaceutical companies to develop, articulate, and optimize safety strategies at all phases of a product lifecycle, from pre-approval through post-marketing. In addition to conducting epidemiological studies, she works on the design and evaluation of registries, risk evaluation and mitigation strategies (REMS), and pharmacovigilance signal detection strategies/enhanced pharmacovigilance of adverse events. Dr. Weiss has served as a consultant and expert witness on litigation involving the safety of regulated medical products.

Academic Credentials & Professional Honors

Ph.D., Epidemiology, Johns Hopkins University, 1996

M.S., Exercise Science, Northeastern University, 1986

B.S., Biology, University of Maine, Orono, 1981

Fellow, International Society of Pharmacoepidemiology

Prior Experience

President & Consulting Epidemiologist, Avigilan LLC, 2013-2017, 2018-2020

Senior Research Leader, Evidera-PPD, 2017-2018

Professor & Director of the Center for Drug Safety, University of Maryland, 1997-2013

Visiting Professor, Johns Hopkins Bloomberg School of Public Health, 2005-2015

Visiting Scientist, National Cancer Institute, NIH, 2008-2012

Epidemiologist, US Food & Drug Administration, 1994-1997

Professional Affiliations

International Society of Pharmacoepidemiology (ISPE)

Drug Information Association (DIA)

Editorial Board, Research in Social and Administrative Pharmacy

Publications

Tave A, Goehring E, Desai V, Wu C, Bohn RL, Tamayo SG, Sicignano N, Juhaeri J, Jones JK, Weiss SR. Risk of interstitial lung disease in patients treated for atrial fibrillation with dronedarone versus other antiarrhythmics. Pharmacoepidemiol Drug Saf. 2021 Mar 17. doi: 10.1002/pds.5233. Epub ahead of print. PMID: 33730412.

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Zandberg DP, Huang TY, Ke X, Baer MR, Gore SD, Weiss Smith S, Davidoff AJ. Treatment and outcomes for chronic myelomonocytic leukemia compared to myelodysplastic syndromes in older adults. Haematologica. 2013;98:584-90.

Shamloo BK, Chhabra P, Freedman A, Potosky A, Malin J, Weiss Smith S. Novel adverse effects of bevacizumab in the US FDA Adverse Event Reporting System database: A disproportionality analysis. Drug Safety. 2012;35:507-518.

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Weiss Smith S, Deshpande G, Chung C, Gogolak V. FDA's Drug Safety Surveillance Program: Adverse Event Reporting Trends. Arch Internal Med. 2011;171:591-593.

Charneski L, Deshpande G, Weiss Smith S. The impact of an antimicrobial allergy label in the medical record on patient's clinical course. Pharmacotherapy. 2011;31:L742-7.

Santos-Oliveira R, Weiss Smith S, Albernaz MdS, Bordim JA, Antunes LJ. Surveillance of

radiopharmaceuticals in Latin America: An Alert. Rev Esp Med Nucl. 2011;30:134- 6.

Freedman AN, Sansbury LB, Figg WD, Potosky AL, Weiss Smith SR, Khoury MJ, Nelson S, Weinshilboum RW, Ratain MJ, McLeod H, Epstein RS, Ginsburg GS, Schilsky RL, Liu G, Flockhart DA, Ulrich CM, Davis RL, Lesko LJ, IZineh I, Randhawa G, Ambrosone CB, Relling RV, Rothman N, Xie H, Spitz M, Ballard--- Barbash R, Doroshow JH, Minasian L. Cancer Pharmacogenomics and Pharmacoepidemiology: Setting a Research Agenda to Accelerate Translation. J National Cancer Instit. 2010;102:1-8.

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Kaplan S, Weiss Smith SR, Zuckerman IH. Blood Pressure and Bone Mineral Density in Pre- and Post-menopausal Women. J Women's Health. 2010;19:1209- 1215.

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Bollinger ME, Weiss Smith S, LoCasale R, Blaisdell C. Transition to Managed Care Impacts Healthcare Service Utilization by Children Insured by Medicaid. Journal of Asthma. 2007;44:717-22.

Blaisdell CJ, Weiss SR, LoCasale R, Gu A. Risk Areas for Pediatric Acute Care. Health in Place. 2007;13:404-416.

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patients: an independent effect or confounding by indication. Pharmacoepidemiol Drug Safety. 2005;14:1- 7.

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Kimes D, Ullah A, Levine E, Nelson R, Timmins S, Weiss SR, Bollinger ME, Blaisdell C. Relationships between pediatric asthma and socioeconomic/urban variables in Baltimore, Maryland. Health & Place. 2004;10:141-152.

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Koro CE, Fedder D, L'Italien GJ, Weiss SR, Magder LS, Kreyenbuhl, J, Revicki, D, Buchanan, RW. Assessment of the independent effect of Olanzapine and Risperidone exposure on the risk of hyperlipidemia in schizophrenia patients. Arch Gen Psychiatry. 2002;59:1021-1026.

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Longcope C, Herbert PN, McKinlay SM and Goldfield (Weiss) SRW. The relationship of total and free estrogens and sex hormone-binding globulin with lipoproteins in women. J Clin Endocrinol Metab. 1990;71:67-72.

Washburn RA, Goldfield (Weiss) SRW, Smith KW and McKinlay JB. The validity of self-reported exercise-induced sweating as a measure of physical activity. Am J Epidemiol. 1990;132:107- 13.

BOOK CHAPTERS

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Weiss Smith S, Sellers J. Drug Safety. In: A Pharmacist's Guide to Public Health. American Pharmacists Association Press. September 2010

Weiss Smith S. Pharmacoepidemiology. In: Encyclopedia of Epidemiology. Editor: Boslaugh S. Sage Publications Inc. October 2007.

Additional Education & Training

Postdoctoral Fellowship in Pharmacoepidemiology & Regulatory Sciences (FDA)