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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

Drug Information Association (DIA)

International Society of Pharmacoepidemiology (ISPE)

International Society of Pharmacovigilance (ISoP)

Royal Society of Medicine

Publications

Dahlberg S, Chang ET, Weiss SR, Dopart P, Gould E, Ritchey ME. Use of Contrave, Naltrexone with Bupropion, Bupropion, or Naltrexone and Major Adverse Cardiovascular Events: A Systematic Literature Review. Diabetes Metab Syndr Obes. 20022;15:3049-3067.

Weiss SR. Myocarditis Cases After mRNA-Based COVID-19 Vaccination in the US. JAMA. 2022;327:2019-2020.

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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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Bennet CL, Spiegel DM, Macdougall IC, Norris L, Qureshi ZP, Sartor O, Lai SY, Tallman MS, Raisch DW, Weiss Smith S, Silver S, Murday AS, Armitage JO, Goldsmith D. A review of the safety, efficacy, and

utilization of erythropoietin, darbepoetin, and peginesatide for patients with cancer or chronic kidney disease: A report from the Southern Network on Adverse Reactions (SONAR). Semin Thromb Hemost. 2012;38:783-796.

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.

Santos-Oliveira R, Antunes LJ, Albernaz MdS, Bordim JA, Weiss Smith S. Survey on radiopharmaceutical in Brazil: Trend and Analysis. Current Radiopharmaceuticals. 2010;3:304-307.

Deshpande G, Gogolak V, Weiss Smith SR. Data Mining in Drug Safety Review of Published Threshold Criteria for Defining Signals of Disproportionate Reporting. Pharmaceutical Medicine. 2010;24:37-43.

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.

Boyer R, McPherson ML, Deshpande G, Weiss Smith S. Improving medication error reporting in hospice care. The American journal of hospice & palliative care. 2009;26:361-7.

St. Charles M, Weiss Smith S, Beardsley R, Fedder D, Carter-Pokras O, Cross R. Gastroenterologists' Prescribing of Infliximab for Crohn's Disease: A National Survey. Inflammatory bowel diseases 2009;15:1467-75.

Santos-Oliveira R, Carneiro-Leão AMA, Weiss Smith S Radiopharmaceuticals drug interactions: a critical review. An Acad Bras Cienc. 2008;80:665-75.

McPherson ML, Weiss Smith SR, Powers A, Zuckerman IH. Patient's knowledge about medications is associated with diabetes control. J Res Soc Admin Pharmacy. 2008;4:37-45.

Santos-Oliveria R, Weiss Smith S. Radiopharmacy in Brazil after Amendment 49. Intern J Nuclear Law. 2008;2:115-119.

Weiss Smith S. Sidelining safety - The FDA's inadequate response to the IOM report. New Engl J Med. 2007;357:960-963.

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.

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and Protecting the Health of the Public. Editors: Baciu A, Stratton K, Burke SP: National Academies Press. 2006. Available at: http://www.nap.edu/catalog/11750.html

Lee E, Maneno MK, Smith L, Weiss SR, Zuckerman IH, Wutoh AK. National Patterns of Medication Use during Pregnancy. Pharmacoepidemiol Drug Safety. 2006;15:537-545.

Hirshorn JM. Weiss SR, LoCasale R, Levine E, Blaisdell CJ. Looking beyond urban/rural differences: Emergency department utilization by asthmatic children. J. Asthma. 2006;43:301-6.

Koro CE, Bowlin SJ, Weiss SR. Antidiabetic therapy and the risk of heart failure in type 2 diabetic patients: an independent effect or confounding by indication. Pharmacoepidemiol Drug Safety. 2005;14:1-7.

Cluxton RJ, Li A, Heaton PC, Weiss SR, Zuckerman IH, Moomaw CJ, Hsu VD, Rodriguez EM. Impact of labeled hepatic enzyme monitoring for troglitazone and rosiglitazone: Findings from the Ohio State Medicaid program. Pharmacoepidemiol Drug Safety. 2005;14:1-9.

Zuckerman IH, Weiss SR, McNally D, Layne B, Mullins CD, Wang J. Impact of an educational intervention for secondary prevention of myocardial infarction on Medicaid drug use and cost. Am J Managed Care. 2004;10:493-500.

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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Weiss S. Evaluation of markers for early detection of pregnancy in an automated database. Am J Epidemiol. 2001;Jul 15;154:180-7.

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Brambilla DJ, McKinlay SM, McKinlay JB, Weiss, SR, Johannes CB, Crawford SL and Longcope C. Does collecting repeated blood samples from each subject improve the precision of estimating steroid hormone levels? J Clin Epidemiol. 1996;49:345-350.

Washburn RA, Smith KW, Goldfield (Weiss) SRW, and McKinlay JB. Reliability and physiologic correlates of the Harvard Alumni Activity Survey in a general population. J Clin Epidemiol. 1991;44:1319-26.

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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

Fedder D and Weiss Smith S. Overview of the History and Profession of Public Health. In: A Pharmacist's Guide to Public Health. American Pharmacists Association Press. September 2010

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)

