Linda J. Scarazzini, RPh, MD

Phone: (847) 937-6395 • E-mail: linda.scarazzini@abbvie.com

Education

1990-1994	MD, Temple University School of Medicine
1984-1989	BS, Philadelphia College of Pharmacy and Science *Summa Cum Laude*
1989-1990	Graduate Course Work, Clinical Pharmacology & Toxicology, Philadelphia College of Pharmacy

Post Graduate Training

1994-1995	Internship, Internal Medicine, The Graduate Hospital of the University of Pennsylvania
1995-1997	Residency, Internal Medicine, The Graduate Hospital of the University of Pennsylvania
1997-1998	Chief Medical Resident, The Graduate Hospital of the University of Pennsylvania
1999-2000	UCLA College of Medicine, Medical Acupuncture for Physicians Program

Honors/Awards

2015	AbbVie; Chairman's Award
2014	AbbVie; R&D Presidents Award
2012	FDA; CDER Excellence Award FAERS
2011	FDA; CDER Excellence Award Compounding Pharmacy Investigation
2010	YWCA Tribute to Women and Industry
2009	Pinnacle Award Sanofi Aventis
2003	Aventis Special Achievement Award
1997	Guth Award (Clinical and Humanitarian Award) – University of Pennsylvania
1994	Alpha Omega Alpha
1994	Achievement Award in Infectious Disease – Temple University
1989	Remington Memorial Prize (Excellence in Pharmaceutics)
1989	Rho Chi Honor Society

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Professional Experience

June 2015 – Present

Vice President
Global Pharmacovigilance and Patient Safety
AbbVie
North Chicago, IL

Responsible for global pharmacovigilance and patient safety, including defining the safety strategy for all company products; Chair of AbbVie's Safety Review Board.

Industry Representative Member, FDA Drug Safety & Risk Management Advisory Committee (DSaRM). Appointment: 2015-2019.

April 2013 – June 2015

Vice President
Medical Safety Evaluation
Global Pharmacovigilance
AbbVie
North Chicago, IL

Responsibilities

Oversight and medical evaluation of clinical trial and post-marketing safety information for all AbbVie products.

- Defined the safety strategy for all company products, including drugs, biologics and medical devices
- Functioned as a recognized, senior spokesperson for drug safety at the company
- Communicated important product medical safety issues to the corporate safety governance bodies, such as the Safety Review Board and Safety Council
- Coordinated highly complex and controversial safety and policy issues that required interaction across FDA enterprise, consumers, health professionals, other federal agencies, advocacy groups, academia, professional societies, regulated industry, and the U.S. Congress
- Provided medical safety and pharmacovigilance strategy and interpretation to the leadership team of Pharmacovigilance and Patient Safety (PPS)
- Lead and developed the internal group of physicians, pharmacists, nurses and other safety scientists within PPS (i.e., Safety Science)
- Responsible for resource planning, headcount, IT and budget

May 2011 – March 2013

Director Division of Pharmacovigilance I
Acting Director Division of Pharmacovigilance II
Office of Surveillance and Epidemiology
Office of Pharmacovigilance and Pharmacoepidemiology
CDER
Food and Drug Administration
Silver Spring, MD

Responsibilities

Directed all activities related to the planning, development, administration, execution and coordination for post marketing adverse event reporting and analysis for OSE/CDER.

- Assessed emerging complex issues and advised senior level center management on potential problems

- Provided oversight, coordination and technical medical expertise and consultative services on all post-market pharmacovigilance activities, typically involving the rare, sensitive and complex subjects in large population surveillance

- Responsible for providing related clinical, medical, and/or pharmacy expertise and consultative assistance to the division staff in addressing benefit-risk assessment for individual products, as well as collaboration with other OSE and OND divisions

- Served as technical and scientific lead for the division in implementing CDER'S Safety First initiative and the Federal Adverse Event Reporting System; facilitated and monitored interactions with OND; and worked with the Office Director and staff to prioritize pre-market and post-market consultation and reviewed requests

- Coordinated highly complex and controversial safety and policy issues that required interaction across FDA enterprise, consumers, health professionals, other Federal agencies, advocacy groups, academia, professional societies, regulated industry, and U.S. Congress

- Responsible for resource planning, headcount, IT and budget for Division

June 2008 – April 2011 Associate Vice President
US Risk Identification, Surveillance and Communication
Sanofi-Aventis U.S.
Bridgewater, NJ

Responsibilities

- Led a team of safety experts to develop and communicate risk management strategies, as well as the tactical minimization strategies, in support of all Sanofi-Aventis products
- Directed cross functional teams providing collaboration and support for risk management initiatives and development of risk communication strategies, leveraging informational and educational needs of customers into evidence-based strategies and programs
- Ensured state-of-the-art identification, collection and reporting of adverse drug events/ reactions/experiences in close collaboration with Case Management by creating a cohesive team focused on accentuating synergies, inter-dependencies and cross functional interactions
- Established state-of-the art signal detection through early active surveillance of aggregate postmarketing safety data to ensure accurate and robust product safety information
- Collaborated with Evidence-Based Medicine and Medical Units in the development, analysis and interpretation of study data to optimize the effective and safe use of Sanofi-Aventis products
- Coordinated the feasibility, cost estimates, and implementation of the RMP/REMS, through direct involvement or leverage with key stakeholders
- Responsible for maintaining state-of-the-art knowledge regarding risk management methods and US and EU safety regulations
- Represented Sanofi-Aventis on Pharma Benchmarking and PhRMA subcommittees
- Responsible for U.S. Drug Safety resource planning, headcount, and budget

Jan 2005 – May 2008

Senior Director
Therapeutic Area Leader
Global Marketed Products Pharmacovigilance Unit (MPPU)
Endocrine/Metabolism/Rheum/Anti-Infective/Respiratory
Global Pharmacovigilance and Epidemiology
Sanofi-Aventis, Pharmaceuticals, member of Sanofi-Aventis, Inc.
Bridgewater, NJ

Responsibilities

- Developed, proposed and monitored strategy and objectives of Marketed Product Phamacovigilance Therapeutic Area and Medical Device Group in agreement with corporate Sanofi- Aventis objectives
- Responsible for Therapeutic Area resource planning, headcount and budget
- Provided senior clinical safety expertise. Integrated strategic principles into clinical safety reviews and medical device risk assessment reports
- Participated in the design and implementation of risk management plans (postmarketing data / surveillance) to support marketed drugs and devices
- Represented Sanofi-Aventis on Pharma Benchmarking and PhRMA subcommittees

Feb 2001-Dec 2004

Director
Clinical Safety Analysis
Metabolism/Allergy/Respiratory/CNS Therapeutic Area
Global Pharmacovigilance and Epidemiology
Aventis, Pharmaceuticals
Bridgewater, NJ

Responsibilities

- Supported IND and NDA preparation and interacted with regulatory authorities worldwide
- Reviewed study protocols and investigator drug brochures for appropriate presentation and handling of safety issues
- Liaised with the Clinical Team/Monitors/CROs/DSMB/Investigators/and support staff to conduct ongoing global safety overview of products through Phase I-IV
- Liaised with the Data Management and Statistics group for preparation, review and evaluation of data listings and summary tables for safety data
- Communicated safety data to all areas within the company and to investigators, external consultants, DSMBs, and worldwide regulatory authorities
- Provided Qualitative and Quantitative assessment of postmarketing safety data from all relevant sources
- Provided interpretation and assessment of safety data for use in benefit/risk analysis of products
- Collaborated with Global Epidemiology to design, analyze, and interpret studies to evaluate postmarketing safety signals and natural history of disease
- Collaborated with Global Epidemiology and Labeling to develop and implement risk management strategies
- Developed and analyzed detailed clinical analyses presented in PSURs (Periodic Safety Update Reports)
- Participated in FDA Advisory Committee and EMA Hearings

Aug 2000-Jan 2001 Associate Director, Clinical Safety Analysis
Oncology Therapeutic Area
Global Pharmacovigilance and Epidemiology
Aventis Pharmaceuticals
Bridgewater, NJ

Responsibilities

- Reviewed study protocols and investigator drug brochures for appropriate presentation and handling of safety issues
- Presented safety data at investigator meetings
- Liaised with the Clinical Team/Monitors/CRO's/Investigators and their support staff to generate and resolve data queries relating to AEs and SAEs
- Assessed post-marketing safety data on a case-by-case basis for medical accuracy and clinical content
- Responded to safety queries from health professionals, consumers, and regulatory agencies
- Participated in professional meetings (DIA, ACR)

Jan 2000-July 2000 Physician Advisor
Executive Health Resources
Havertown, PA

Responsibilities

- Partner, small business start-up
- Evaluated quality of care and medical utilization issues
- Educated physicians about the efficient and coordinated delivery of patient care
- Communicated appropriate information to payers to assure certification and reimbursement for delivered medical care
- Coordinated clinical, utilization management, discharge planning and social work efforts for inpatient care
- Developed plans for continuous improvement of coordinated inpatient healthcare delivery processes, and delivery of inpatient and outpatient medical care

Aug 98-Aug 99	Clinical Associate Internal Medicine Associates of Delaware County
July 95-June 98	Junior Associate Internal Medicine Associates University of Pennsylvania Hospital Philadelphia, PA
July 95-June 98	Assistant Instructor of Medicine The University of Pennsylvania Philadelphia, PA
June 89-Aug 94	Clinical Pharmacist Internship Crozer Chester Hospital Burn Treatment Center Chester, PA

Research Activities

1994-1996	Blood transfusion and Immunosuppression in HIV Disease The University of Pennsylvania Philadelphia, PA
1989-1990	Reperfusion Injury Philadelphia College of Pharmacy and Science Philadelphia, PA
1987-1988	Leukotriene Antagonist Dosage Formulation Glaxo Smith Kline Division of Pharmaceutics

Instructional Activities

Aug 98-Aug 99	Instructor in Ambulatory Medicine Clinic *MCMC Thomas Jefferson University*
July 97-July 99	Attending Physician on Medicine In-Patient Service Attending Physician in Ambulatory Medicine Clinic Moderator of Resident Morning Report Preceptor for Physical Diagnosis Course *The University of Pennsylvania*

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Certification	August, 1998 American Board of Internal Medicine Maintenance of Certification ABIM 2008 August, 1989 American Board of Pharmacy
Licensure	Active Medical License in the state of Pennsylvania- MD063424L Pharmacy License in the state of Pennsylvania
Professional Memberships	American College of Physicians American Medical Association Drug Information Association International Society of Pharmacovigilance International Society of Pharmacoepidemiology

Presentations

"Patient advocacy space in the pharmaceutical sector"
Presented at Leadership in Healthcare: Focusing on the Oncology Patient Women in Science (WIS) affinity group to gather at HBA (Businesswomen's Association) Healthcare Annual Conference. Philadelphia, PA, November 6-8, 2017

"Learning Leadership"
Presented at the AbbVie Emerging Leader Program (ELP), Wheeling, IL, April 19, 2016

"Post Authorization Efficacy and Safety Studies: Challenges and Opportunities"
Presented at the 28th Annual EuroMeeting, Hamburg, Germany, April 7, 2016

Centre for Innovation in Regulatory Science, "Building Quality into Companies, Benefit-Risk Decision Making", Philadelphia, PA, December 5, 2014

Centre for Innovation in Regulatory Science, Annual Benefit-Risk Workshop "Assessment in the Post-Approval Period: How to ensure a life cycle approach to evaluating benefits and risks", Washington, DC, June 12-13, 2014

MedWatch Reporting, Industry Perspective," Safety and Social Media a Unique Perspective", September 2013

Drug Information Association: "Pharmacovigilance and Risk Management Strategies", January 2013

Integration of Safety information into EMR's
Presented at Health Information Management and Systems Society Meeting, February 2012

Practical Issues for FDA Meetings in the New Era of Regulation
Presented at the 45th Annual DIA Meeting, San Diego, California, June 2009

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Professional Meetings/Training

2016: "Diversity, Inclusion, & Life Sciences Symposium: Understanding Obstacles to Access", Chicago, IL, June 22, 2016

Drug Information Association, "28th Annual EuroMeeting", Hamburg, Germany, April 6-8, 2016

2014: Drug Information Association, "Benefit-Risk Assessment from Inception to Maturation: Aligning Regulatory and Industry Goals", Bethesda, MD, January, 2014

2013: Drug Information Association, "Pharmacovigilance and Risk Management Strategies 2013", Washington, DC, January 14-16, 2013

Drug Information Association, "Safety and Social Media: Is this the Question or the Answer", Webinar, September 2013

2012: EHR Initiative Launched to Empower Drug Safety and Medication Adherence. Las Vegas, NV, February 21, 2012

2011: YWCA "32st Annual Tribute to Women & Industry Awards", Somerset, NJ, March 31, 2011

2010: Drug Information Association, "Facilitating Innovation for Better Health Outcomes", Washington, DC, June 12-17, 2010

YWCA "31st Annual Tribute to Women & Industry Awards", Parsippany, NY, May 26, 2010

2009: Drug Information Association, "Better Medicines: Improving Safety with Every Step", San Diego, CA, June 21-25, 2009

2007: Women Unlimited Leadership Program

2004: International Society of Pharmacoepidemiology, Annual Scientific Meeting, Bordeaux, France August 2003; *Workshop Presentation*

2003: International Society of Pharmacoepidemiology, Annual Scientific Meeting, Philadelphia, PA, August 2003

2002: Drug Information Association, "Contemporary Pharmacovigilance and Risk Management Strategies", Washington, DC, January 14-17, 2002

Aventis-sponsored, "Quantitative Methods in Benefit Risk Assessment", April 16, 2002 International Society of Pharmacovigilance 2002 Congress, Amsterdam, Netherlands, October 16-19, 2002 American College of Rheumatology 66th Annual Scientific Meeting, New Orleans, LA, October 24-29, 2002

2001: Drug Information Association, "Safety Information and Labeling" New Orleans, May 24-25, 2001

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Publications

Thao Doan, Fabio Lievano, Mondira Bhattacharya, Linda Scarazzini, Cheryl Renz. Pharmacovigilance: A Practical Approach. ELSEVIER 1st Edition. Aug. 2018.

Rebecca J Mullen, James Duhig, Andrea Russell, Linda Scarazzini, Fabio Lievano, Michael S. Wolf. Best-practices for the design and development of prescription medication information: A systematic review. Patient Education and Counseling. 2018; 1351-1367.

Fabio Lievano, Linda Scarazzini, Frank Shen, James Duhig, Jeremy Jokinen. The future of safety-science is happening now: The modernization of the benefit-risk paradigm Pharmacoepidemiol Drug Saf. 2017;1-6.

Chen M-C, Iyasu S, Sorbello A, Scarazzini L. Spontaneous reporting and pharmacovigilance practice: USA. In: Andrews EB, Moore N, eds. Mann's Pharmacovigilance. Oxford, UK: John Wiley & Sons, Ltd; 2014: 229-239.

Fine AJ, Sorbello A, Kortepeter C, Scarazzini L. Progressive multifocal leukoencephalopathy after natalizumab discontinuation. Ann Neurol. 2014;75(1):108-115.

Cannon GW, Strand V, Oed C, Scarazzini L, Holden WL. Adverse events during clinical trials in rheumatoid arthritis (RA) comparing leflunomide, methotrexate, sulfasalazine and placebo: meta-analysis of data from phase II & III clinical trials. Ann Rheum Dis 2004;63(suppl):252.

Cannon GW, Holden WL, Juhaeri J, Dai W, Scarazzini L, Stang P. Adverse events with disease-modifying antirheumatic drugs: a cohort study of leflunomide compared with other DMARDs. *J Rheumatology* 2004;31:1906-11.

Holden WL, Scarazzini L, Faich G. Epidemiologic vs post-marketing spontaneous report data: vive la difference. Pharmacoepidemiol Drug Saf 2004;13 (suppl 1):S244.

Cannon GW, Strand V, Simon LS, Kavanaugh AF, Hochberg MC, Scarazzini L, Holden WL. Interstitial lung disease in rheumatoid arthritis patients receiving leflunomide. *Arthritis Rheum* 2004;50 (suppl):S561.

Cannon GW, Strand V, Scarazzini L, Holden WL. Comparison of adverse event reporting rates for etanercept, infliximab, leflunomide, and methotrexate between September 1998 and June 2003. *Arthritis Rheum* 2004;50 (suppl):S561.

Cannon GW, Strand V, Scarazzini L, Holden WL. Comparison of adverse event reporting rates for etanercept, infliximab, leflunomide and methotrexate. Arthritis Rheum 2003;48 (suppl):S242.

Cannon GW, Strand V, Scarazzini L, Holden WL. Proportional reporting ratios as a method to develop signals for post-marketing surveillance of leflunomide. Arthritis Rheum 003;48 (suppl):S331.