 **Evan B. Siegel, M.Phil., Ph.D., President and CEO –**

Dr. Siegel founded Ground Zero Pharmaceuticals, Inc. (GZP) in 1999 from his consulting firm, Ground Zero Strategics, Ltd. He currently serves as its President and CEO, and is also the Chairman of the Board. Prior to GZP Evan served as Consultant and CEO to OXO Chemie Inc., Vice President, Regulatory Affairs and Bioethics for Medical Science Systems, Inc. (now Interleukin Genetics), and Director of Regulatory Consulting Services and Principal Regulatory Scientist for Quintiles, Inc., North Carolina. Dr. Siegel has also held regulatory affairs and executive positions at Astra and Syntex, and was a Toxicology Reviewer at the US Food and Drug Administration, as well as Supervising Toxicologist and Chief of Special Services at the State of California's Food and Drug Branch, Department of Health Services. He is the author of a number of published articles in peer-reviewed journals, the editor of books on drug development and author of chapters on nonclinical development, vaccine biotechnology, and quality assurance. He has Master and Doctor of Philosophy degrees in Virology and Molecular Biology and is an Adjunct Professor in the School of Pharmacy and Centre for Integrated Preclinical Drug Development, University of Queensland, Australia. He is a member of the Lt. Governor's Biotechnology Advisory Committee to the California Economic Development Commission.

Theses:

"The Carcinogenic and Carcinotherapeutic Properties of Laser Radiation." Master's Critical Essay, Department of Environmental Sciences, Rutgers University, September 1970.

"The Nonocular Hazards of Laser Radiation," prepared for Brookhaven National Laboratories, Upton, Long Island, August 1970

"Novel Applications of Laser Light to Animal Cells in Culture: Studies of Erythrocytes; Genetic Variant, Tumor and Transformed Cells Treated with Polyene Antifungal Antibiotics, Partial and Whole Cell Irradiation," Ph.D. Dissertation, Waksman Institute of Microbiology, Rutgers University, May 1975

Presentations (Partial):

"Environmental Mutagenesis and Toxicology Screening by Flow Microfluorometry," Biochemistry Branch Seminar, Environmental Protection Agency, August 1978

Siegel, E.B., et al. "Studies of Amphotericin B Methyl Ester (AME) in Tissue Culture: II. Comparative Toxicity of AME versus Amphotericin B and Fungizone in Culture of Human Embryonic Lung and Syrian Hamster Kidney," Abstracts of the 13th Interscience Conference on Antimicrobial Agents and Chemotherapy, September 19-21, 1973.

Fisher, P.B., Siegel, E.B., et al. "Studies of Amphotericin B Methyl Ester (AME) in Tissue Culture: I. Growth Stimulatory Effect of AME on a Permanent Cell Line Derived from Normal Mouse Tissue and Toxicity to a Tumor-Derived Mouse Cell Line," Abstracts of the 13th Interscience Conference on Antimicrobial Agents and Chemotherapy, September 19-20, 1973.

Siegel, E.B. and Bryson, V. "Laser Microirradiation of Sensitized Mammalian Cells," Abstracts of the 23rd Annual Theobold Smith Society Meeting, April 5, 1974.

Siegel, E.B. "Laser Irradiation of Sensitized Mammalian Cells," invited paper at the Gordon Conference on Lasers in Medicine and Biology, Meriden, New Hampshire, June 24-28, 1974.

Siegel, E.B. "Selective Sensitization of the Mammalian Cell Plasma Membrane to Argon Laser Radiation by Two Polyene Antifungal Antibiotics," Abstracts of the 2nd Annual Meeting, American Society for Photobiology, Vancouver, B.C., July 23-26, 1974

Siegel, E.B. and Bryson, V. "Studies of Erythrocyte Susceptibility to Polyene-Induced Hemolysis: I. Use of Membrane Binding Agents as Possible Potentiators of Polyene Action," Abstracts of the 14th Interscience Conference on Antimicrobial Agents and Chemotherapy, September 11-13, 1974.

Siegel, E.B. and Bryson, V. "Studies of Erythrocyte Susceptibility to Polyene-Induced Hemolysis: II. Species - Specific Differences in Sensitivity to five Polyene Antifungal Antibiotics," Abstracts of the 14th Interscience Conference on Antimicrobial Agents and Chemotherapy, September 11.13, 1974.

Siegel, E.B., Fisher, P.B., Bonner, D.P., Bryson, V., and Schaffner, C.P. "Toxicity of Polyene Antifungal Agents to Animal Cells in Tissue Culture: I. Use of a Modified 51-Cr Release Assay to quantitate Membrane Damage," Abstracts of the 14th Interscience Conference on Antimicrobial Agents and Chemotherapy, September 11-13, 1974.

Siegel, E.B., Elmore, E., and Swift, M. "Growth and Cell Cycle Abnormalities of Cultured Fibroblasts of Ataxia-Telangiectasia Patients," Abstracts of the 27th Annual Meeting of the American Society of Human Genetics, October 8-11, 1975.

"The Use of Laser Flow Microfluorometry for Cell Cycle Analysis," Automated Biochemical Systems Seminar, University of North Carolina School of Medicine, April 1, 1976.

Siegel, E.B. "The Application of Flow Microfluorometric Techniques to Cytotoxicity and Mutagenicity Studies," University of North Carolina School of Medicine, December 1977

"Frontiers of Testing: Teratogenicity, Carcinogenicity, and Mutagenicity and the Regulatory Agencies," Proceedings of the 1980 Research and Scientific Development Conference, The Proprietary Association, New York, 1980

"Drugs and the Aging," Proceedings of the 1981 Research and Scientific Conference, The Proprietary Association, New York, 1981

"Update of Present and Future Life Over-The-Counter Medications," presented at the New England Food and Drug Officials Association Conference, May 17, 1984, Portland, Maine, Vol. 48, 257-262.

Siegel, E. Presentation at the 38th Meeting of the Regional Committee of the World Health Organization for the Americas, Washington, D.C. 1986

Siegel, E. Presentation on the California State Program for Proposition 65, Williamsburg VA. 1988

Siegel, E. Presentation to The Food Retail / Wholesale Subcommittee, Los Angeles, CA. 1988

Siegel, E. Presentation on Sanitation for the Food Industry for The University of California Davis, Anaheim, CA. 1988

Siegel, E. Presentation on California proposition 65 at the National Sanitation Foundation, Ann Arbor, MI. 1988

Siegel, E. Presentation on Biotechnology at California Public Health Association. Martinez, CA. 1989

Siegel, E. Presentation to the Australian Trade Commission, Los Angeles, CA. 1989

Siegel, E. Presentation on "The New Public Health: Challenges for the 1990's." California Coalition For The Future Of Public Health, Berkeley, CA. 1989

Siegel, E. A Symposium on Regulatory Management of Carcinogenic Chemical Risks for the International Life Sciences Institution, Wrightsville Beach, NC. 1989

Siegel, E. Expanding Access to Therapies for the Institutional Review Boards and Informed Consent, Costa Mesa, CA. 1991

Siegel, E. Presentation on Women's Health Issues for Pharmaceutical Manufacturers Association, Tallahassee, FL. 1992

Siegel, E. "Why Are My Prescription Drugs So Costly?" The Art of Aging Conference, Phoenix, AZ. 1993

Siegel, E. "Planning an Effective Regulatory Strategy to Expedite Development." Third Annual Re-engineering Drug Development Through Partnerships with CROs for The Institute for International Research, Washington, D.C. 1994

Siegel, E. "OTC Pharmaceuticals and Prescribing:" Presentation to students at Howard University Washington, D.C. USA 1995

Siegel, E. "Clinical Trials, New Issues with an Old Program." The Regulatory Affairs Professionals Society, Rockville, MD. 1996

Siegel, E. "Outsourcing Regulatory Affairs and Product Development" 1996 International Biotechnology Meeting for Biotechnology Industry Organization, Philadelphia, PA. 1996

Siegel, E. "From Strategic Consulting to a Full-Service Program." Fifth Annual Partnership with CROs for The Institute for International Research, San Francisco, CA 1996

Foster, M., Porter, E., Siegel, E. "Outsourcing of Regulatory Affairs by Virtual Firms and Project Management of Virtual Teams." DIA Annual Meeting, San Diego, CA. 2000

Siegel, E. "Nuts and Bolts of the IND: A Critical Document in Drug Development." Regulatory Affairs Professional Society, Baltimore, MD. 2001

Siegel, E. "Principals & Practices of US Regulatory Affairs." Regulatory Affairs Professional Society, San Mateo, CA. 2002

Siegel, E. "Regulatory Intelligence: What It Is and It Isn't: Guidelines and Guidances vs. Hands-on Experience? The Congruence and Disconnections." Regulatory Affairs Professional Society Annual Conference & Exhibition, San Mateo, CA. 2002

Siegel, E. "Building an Effective Sponsor-Outsource Team." DIA Annual Meeting, Chicago, IL. 2002

Siegel, E. "Impact of the New Regulatory Climate on Cellular Genetic Product Development." AFDO Annual Meeting, Portland OR. 2002

Siegel, E. ""Effective Management of Preclinical and Clinical Trials." AusBiotech Conference, Adelaide, Australia. 2003

Siegel, E. "FDA Regulation and Development of Biotechnology Products." University of New South Wales, Sydney, NSW Australia. 2003

Siegel, E. "FDA Regulation and Product Development. Use of a US Agent." Alsace Bio Valley, Colmar, Switzerland. 2003

Siegel, E. "Overview of US Regulatory Requirements for Drugs, Biologics, and Medical Devices. Overview of Drugs." RAPS Canadian Conference, Toronto, Canada. 2004

Siegel, E. "The 505(b)(2) NDA." Bio Annual Meeting, San Francisco, CA. 2004

Siegel, E. "What Makes A Successful Pre-IND Meeting?" DIA Annual Meeting, Washington, D.C. 2004

Siegel, E. "Successful Pre-IND Meetings." Translational Research, Princeton, NJ. 2004

Siegel, E. "The Strategic and Commercial Importance of the Pre-clinical Development Plan-a US Perspective." AusBiotech Annual Meeting, Brisbane, QLD Australia. 2004

Siegel, Evan. "Preparing Your Regulatory Strategy-Secrets of Success." AusBiotech Conference, Brisbane, QLD Australia. 2004

Siegel, E. "Working Effectively With Regulators: A Clinical and Commercial Imperative." ARCS Conference, Sydney, NSW Australia. 2004

Siegel, E. "Taking a Selected Candidate Drug through Successful Preclinical Development." Victorian College of Pharmacy, Melbourne, VIC Australia. 2005

Siegel. E. "Regulatory and Medical Product Development Strategy: Increasing Competitiveness." Pharma Conference, Brussels, Belgium. 2005

Siegel, E. "Successful CMC Programs. Doing the Right Things Right without Breaking the Bank." Club Bio Conference, Coolum, QLD Australia. 2005

Siegel, E. "Successful Drug Development: The Phase 1/2 and 2/3 Interfaces." DIA Annual Meeting, Philadelphia, PA. 2006

Siegel, E. "Exploratory INDs: Rapid Movement of Candidate Drugs and Biologics into Clinical Trials in Humans." University of Queensland, Brisbane, QLD Australia. 2006

Siegel, E. "Preclinical Strategies for Integrated Product Development, Session 4, Segment 10: Strategic Approaches to Compound Development." The University of Queensland, Brisbane, QLD Australia 2007.

Siegel, E. "Preclinical Strategies for Integrated Product Development, Segment 1 – 6: The US Regulatory Process and Pre-IND Drug Development." The University of Queensland, Brisbane, QLD Australia 2007

Siegel, E. "Preclinical Strategies for Integrated Product Development, Segment 2: Introduction to IND Submissions." The University of Queensland, Brisbane, QLD Australia 2007.

Siegel, E. "Preclinical Strategies for Integrated Product Development, Segment 3: Exploratory INDs and Expanded Access Programs." The University of Queensland, Brisbane, QLD Australia 2007.

Siegel, E. "Product Development in the FDA Arena; The US Regulatory Process and Drug Development." The University of Queensland, Brisbane, QLD Australia The University of UQLD 2007

Siegel, E. "Strategies for Getting to the IND; Facilitated Product Development: The US Regulatory Process." The University of Queensland, Brisbane, QLD Australia 2008

Siegel, E. "Strategies for Getting to the IND: Facilitated Product Development." Melbourne, Australia 2008

Siegel, E. "Integrated Drug and Biologic Preclinical Strategies Workshop: Getting to the IND." Malvern, Victoria, Australia 2008
Siegel, E. "Getting to the IND; Strategies for Getting to the IND: Facilitated Product Development." Sydney, Australia 2008

Siegel, E. "Strategies for Getting to YES; Facilitated Product Development The Regulatory Process." RAPS Canadian Conference, Vancouver, British Columbia, Canada 2008.

Siegel, E. "Reimbursement 101; Medtech in the USA." AusBiotech Conference, Sydney, Australia 2008

Siegel, E. "Strategies for Getting to the IND; Facilitated Product Development. AusBiotech Conference, Adelaide, Australia 2009

Siegel, E. "CMC and ADME Strategies for Preclinical Development of Drugs and Biologics; CMC and ADME Strategies for Integrated Product Development in the FDA Arena." Melbourne, Australia 2009.

Siegel, E. "CMC and ADME Strategies for Integrated Product Development in the FDA Arena.; The US Regulatory Process and Drug Development. The University of Queensland, Brisbane, QLD Australia 2009.

Siegel, E. "CMC and ADME Strategies for Preclinical Development of Drugs and Biologics." The University of Queensland, Brisbane, QLD Australia 2009.

Siegel, E. "Optimizing Early Phase Development to Move the Program Forward; You Have a Promising Lead Candidate – What Next?" AusBiotech Conference Brisbane, Australia 2010.

Siegel, E. "Regulatory Strategy – Therapeutic Antibodies for Cancer." Beijing, China 2010.

Siegel, E. "You Have an IND-What's Next" The University of Queensland, Brisbane, QLD Australia 2010.

Siegel, E. "What's Hot at the FDA-Safety" Brisbane, Australia 2011.

Siegel, E. " Mechanics of US New Product Submissions: INDs, NDAs, CTDs, 505(b)(2) (j)." San Francisco, CA November 2011.

Siegel, E. "Preclinical and Nonclinical Data Requirements for INDs, NDAs and BLAs" Kuala Lumpur, Malaysia 2011.

Siegel, E. "Better Translation of Your IP Into Rapid Development and Clinical Trials" Adelaide, Australia 2012.

White Papers (Partial):

WHO Monographs on Food Additives, Food and Drug Administration, 1978-1980

Siegel, E. Substances Abuse and Misuse Among the Elderly (alcohol, prescription drugs, over-the-counter drugs) New York State Assembly Standing Committee on Aging Public Hearing, Albany, New York 1980 October 24.

Siegel, E. White Paper: Update on Pregnancy Testing - The State of the Art and Regulatory Considerations The Proprietary Association, Washington D.C. 1985 September 25.

Books and Book Chapters:

Siegel, E. Chemistry, Manufacturing, and Control Requirements of the NDA and ANDA. Marcel Dekker, Inc. New York, NY. Guarino: New Drug Approval Process, Fourth Edition, Revised and Expanded. 2002 July; 361-401

Siegel, E., (Chapter) The QA System, Pharmaceutical Manufacturing Handbook, John Wiley & Sons, 2007.

Siegel, E. Development and Approval of Combination Products: A Regulatory Perspective (by Evan B. Siegel), John Wiley & Sons, 2008.

Siegel, E, (Chapter) Preclinical Development Handbook: Toxicology, John Wiley & Sons, 2008.

Siegel, E. (Chapter) New Drug Approval Process, 5th Edition, Accelerating Global Registrations, Marcel Dekker, Inc., 2010.

Siegel, E., (Chapter) Recombinant Vaccines: Development, Production, and Application, in Pharmaceutical Biotechnology: Drug Discovery and Clinical Applications, Second Edition, Wiley-VCH Verlag GmbH & Co., 2012.

Publications:

Siegel, E. Measurement of Polyene Antibiotic-Mediated Erythrocyte Damage by Release of a Hemoglobin and Radioactive Chromium. American Society for Microbiology USA. 1977 April; 675-8.

Campbell, J.A., Stack, H.F., Williams, M.R., Tillery, D., Custer, N., Russell, B.F., King, S.W., Siegel, E.B., and Garrett, N.E. "Cellular Toxicity of Four Liquid Effluent Samples from Textile Mills: Studies on the Rabbit Alveolar Macrophage, WI-38 Human Fibroblast, and Chinese Hamster Ovary Cell in Vitro," Environmental Protection Agency, Washington, DC, February 1978.

Campbell, J.A., Stack, H.F., Williams, M.R., Custer, N., Russell, B.F., King, S.W., Siegel, E.B., and Garrett, N.E. "Cellular Toxicity of Stainless Steel and Rhodium Samples: Studies on the Rabbit Alveolar Macrophage in Vitro," Environmental Protection Agency, Washington, DC, February 1978.

Pflug, G, Siegel, E. OTCs in the 1980s. Research and Scientific Development Conference Proceedings USA. 1980; 47-58.

Siegel, E. Drugs and the Aging. Regulatory Toxicology and Pharmacology 2 USA. September 1982; 287-295.

Siegel, E. The Use of Flow Microfluorometry for Pharmaceutical Testing. Regulatory Toxicology and Pharmacology USA. 1984 April; 287-304.

Siegel, E. Update of Present and Future Life of Over the Counter Medication. Association of Food and Drug Officials, Quarterly Bulletin Washington, D.C. 1984 May; 257-2.

Siegel, E. Response to letter regarding labeling of bupivacaine solutions. Regional Anesthesia USA, Volume 17. No. 4. 1992; 241-2.

Porter, E, Siegel, E. Regulating the Outsource Provider. Contract Pharma USA. 2001 September; 54-2

Barquest, J, Porter, E, Siegel, E. Points to Consider in GO/NO-GO Decision Making for Pharmaceutical Product Development. Decision Resources, Inc. Waltham, Massachusetts, 2001 December; 1-18.

Siegel, E. New Approaches to Old Partnership Strategies. Wall Street Reporter Magazine, Inc. New York, NY, 2004 May; 1-7

Siegel, E. The Strategic Preclinical Plan - An Integral Element in the FDA Pre-IND Consultation Process. Regulatory Affairs Focus. Washington, D.C. 2004 July; 7-12

Siegel, E. Drug and Device Marriage Changes Medical Development and Approval Process. Wall Street Reporter Magazine, Inc. New York, NY, 2004 August; 1-7

Siegel, E. Make the Pre-IND Meeting Work for You. Annual Meeting. Geneseq USA. 2004; 1

Siegel, E. The Pre-Pre-IND FDA Consultation Process for Preclinical Studies: Opportunities for Launching a Rapid Drug or Biologic Development Program. Preclinica, 2005 May-June

Siegel, E. Focus on the USA - Winning on the battlefield: The Phase I/II and II/III interfaces in drug development in the USA. The Organisation for Professionals in Regulatory Affairs. The Regulatory Rapporteur, Washington, D.C. 2005 October; 10-12

Siegel, E., et al., "Examination of Regulatory Frameworks Applicable to Biologic Drugs (Including Stem Cells and Their Progeny) in Europe, the U.S., and Australia: Part 1-A method of Manual Documentary Analysis." Stem Cells Translational Medicine, 2012.

Teaching:

Siegel, E. "Flow Microflourometry in Automated Cell Cycle Analysis," University of north Carolina School of medicine, Chapel hill, NC, 1974-1977.

Siegel, E. Course on Toxicology of Drugs and Pesticides, Graduate Course at University of California, Davis, 1988.

Siegel, E. Workshop - Issues of Special Populations in Drug Development for Schering-Plough Research Institute, Kenilworth, NJ. 1992

Siegel, E. The Regulatory Process for Drug Development PERI, Washington, DC. 2003

Siegel, E. The Regulatory Affairs Process, RAPS course, Washington, DC 2004

Siegel, E. Regulatory Advisor and Member, San Diego State University and San Diego Institute for Palliative Care Institutional Review Board, 2000-2009.

Siegel, E., Several graduate students and Honors Undergraduates, UQ School of Pharmacy (per Prof. Maree Smith) and Biotechnology Program (per Prof. Ross Barnard), 2006-Present. Multiple in-person meetings in Brisbane, emails, and telephone conferences. Member of Doctoral and other committees for these students.

Membership in Professional Societies (Partial):

American Society for Microbiology 1970-Present

New York Academy of Sciences, 1971-Present

Regulatory Affairs Professional Society 1982-Present

Drug Information Association 1988-Present

Biotechnology Industry Organization 1999-Present

Southern California Biotechnology Conferences 1999-Present

Genetics Society of America 1999-Present

Member, Editorial Board, Regulatory Affairs Journal, 2000-2002

International Society for Pharmacoepidemiology 2000-Present

AusBiotech 2003 – Present

American Society of Clinical Oncology 2012-

Honors and Awards (Partial):

Radiological Health Training Grants 1969-1970

NIH Graduate Fellowships, 1970-1975

Cancer Research Training Grants 1972-1975

Busch Equipment Grants, Waksman Institute of Microbiology, 1972-1975

Howard Hughes Training Grants, Cancer Research, 1970-1975

NIH Postdoctoral Fellowships, Medical Genetics, 1974-1977

University of North Carolina School of Medicine Postdoctoral Medical Genetics Training Grants, 1974-1977

1984 Outstanding Young Men of America

Who's Who in the World. 7th Edition 1984-1985

Certificate of Commission (Commissioned Officer), U.S. Department of Health and Human Services, Public Health Service, FDA, CA 1992 March