Joseph B. Bogardus, Ph.D

SUMMARY

Sr. Advisor specializing in pharmaceutical drug product development for small molecules as well as peptides and proteins. Over thirty years experience in industry and academia covering all phases of pharmaceutical R&D, including discovery compound evaluation, drug substance form selection, preformulation, formulation development, technology transfer, and formal stability studies.

PROFESSIONAL EXPERIENCE

Executive Director, Pharmaceutics R&D, Bristol-Myers Squibb*:* 2001-2005; retired 2005

- Responsible for department of over sixty scientists conducting formulation and process development of new drug candidates and line extensions, including technology transfer to manufacturing sites.
- Drug candidates encompass small molecule oral and injectable products from a variety of therapeutic areas, as well as injectable proteins and peptides.

Executive Director, Early Candidate Development and Stability, Bristol-Myers Squibb: 1998-2001

- Created a streamlined approach in which the early candidate development group was responsible for discovery support, form selection, preformulation, and formulation development for first-in-human studies.
- Reduced timelines and API requirements, while resulting in stable and bioavailable formulations for Phase I and early Phase II studies.
- Supervised the stability group responsible for preparing stability reports for all types of regulatory submissions.

Executive Director, Pharmaceutics R&D, Bristol-Myers Squibb Company: 1993-1998

- Directed pharmaceutics departments at the following sites for development of oral, injectable, and topical drug products covering all phases of development:
  - Syracuse, NY (1993-1996),
  - Evansville, IN (1993-1994)
  - Buffalo, NY (1993-1995)
  - New Brunswick, NJ (1994-1998)
- Supervised the stability group responsible for preparing stability reports for all types of regulatory submissions

Director, Pharmaceutical Product Development, Bristol-Myers Squibb: 1989 1993

- Directed pharmaceutics development including preformulation, formulation, and formal stability groups.

Associate Director, Basic Pharmaceutics Research, Bristol-Myers Squibb: 1984 1989

- Supervised a group conducting preformulation and exploratory formulation development studies for new drug candidates.

Assistant Professor, College of Pharmacy, University of Kentucky: 1979-1984

- Conducted research in pharmaceutics, supervised post-docs and graduate students, and taught graduate and undergraduate courses

Senior Research Scientist, Pharmaceutical Research and Development, Pfizer: 1977-1979

- Developed injectable drug products for new drug candidates and line extensions.

Research Scientist, Pharmaceutical Research and Development, Pfizer, Inc. 1973-1976

- Developed solid oral drug products for new drug candidates and line extensions.

EDUCATION

Ph.D., University of Kansas, Lawrence, KS, 1973
Major: Pharmaceutical Chemistry

M. S., University of Kansas, Lawrence KS, 1972
Major: Pharmaceutical Chemistry

B.S., University of Kentucky, Lexington, KY: 1970
Major: Chemistry (with distinction)

HONORS, AWARDS, and GRANTS

American Association of Pharmaceutical Sciences

American Chemical Society Analytical Chemistry Award University of Kentucky, 1970

National Science Foundation Graduate Traineeship University of Kansas, 1970 -1973

NIH Grant, "Mechanism of Interaction of Cholesterol and Monoglycerides", University of Kentucky, 1982 - 1984

SCIENTIFIC PUBLICATIONS

J. B. Bogardus and R. K. Blackwood, Jr., "Solubility of Doxycycline in Aqueous Solutions", *J. Pharm. Sci.*, *68*, 188 (1979).

J. B. Bogardus and R. K. Blackwood, Jr., "Dissolution Rates of Doxycycline Free Base and Hydrochloride Salts", J. Pharm. Sci., 68, 1183 (1979).

J. B. Bogardus and N. R. Palepu, "Ionization and Solubility of an Amphoteric β-Lactam Antibiotic", *Int. J. Pharmaceutics*, *4*, 159 (1979).

J. B. Bogardus, "Phase Equilibria of Nafcillin Sodium:Water", *J. Pharm. Sci.*, *71*, 105 (1982). Presented at the APhA Academy of Pharmaceutical Sciences 29th National Meeting, San Antonio, Texas, November, 1980.

J. B. Bogardus, "Unusual Cholesterol Solubility in Water/Glyceryl-1-monooctanoate Solutions", *J. Pharm. Sci., 71*, 370 (1982). Presented at the APhA Academy of Pharmaceutical Sciences 31st National Meeting, Orlando, Florida, November, 1981.

J. B. Bogardus, "Common Ion Equilibria of Hydrochloride Salts and the Setschenow Equation", *J. Pharm. Sci., 71*, 588 (1982).

J. B. Bogardus and T. Higuchi, "Kinetics and Mechanism of Hydrolysis of Labile Quaternary Ammonium Derivatives of Tertiary Amines", *J. Pharm. Sci., 71*, 729 (1982).

J. B. Bogardus, "Liquid Crystal Solubilization of Cholesterol: A Potential Method for Gallstone Dissolution", *J. Pharm. Sci, 72*, 338 (1983). Presented at the APhA Academy of Pharmaceutical Sciences 31st National

Meeting, Orlando, Florida, November, 1981.

P. J. McNamara and J. B. Bogardus, "Effect of Initial Conditions and Drug-Protein Binding on the Time to Equilibrium in Dialysis Systems", *J. Pharm. Sci., 71,* 1066 (1982).

J. B. Bogardus, "Crystalline Anhydrous/Hydrate Phase Changes of Caffeine and Theophylline in Solvent/Water Mixtures", *J. Pharm. Sci., 72*, 837 (1983).

J. B. Bogardus, "Importance of Viscosity in the Dissolution Rate of Cholesterol in Monooctanoin Solutions", *J. Pharm. Sci., 73*, 906 (1984). Presented at the APhA Academy of Pharmaceutical Sciences 35th National Meeting, Miami Beach, Florida, November, 1983.

M. Jay, N. Ogawa, J. B. Bogardus, A. R. Mlodozeniec and G. A. Digenis, "Anisotropy of Indium111 in Cetyltrimethylammonium Bromide Solutions", *Int. J. Pharmaceutics, 19,* 97 (1984).

J. B. Bogardus, "Dissolution Rate of Cholesterol in Monooctanoin", *Hepatology, 4,* 166S (1984). Proceedings of the Kroc Foundation Research Conference, "Physical Chemistry of Bile in Health and Disease," Santa Ynez, California, December, 1983.

J. B. Bogardus, "Liquid Crystalline Phase Formation by Cholesterol in Aqueous Fatty Acid Salt Solutions", *Hepatology, 4,* 148S (1984). Proceedings of the Kroc Foundation Research Conferences, "Physical Chemistry of Bile in Health and Disease," Santa Ynez, California, December, 1983.

C.-M. Chen, W. P. Coppola, W. H. Johns, J. B. Bogardus, and R. A. Lipper, "Degradation Kinetics and Mechanism of N-6-[(Dimethylamino]methylene]mitomycin C in Aqueous Solutions", *J. Pharm. Sci., 75,* 208 (1986).

H. Dannan, M. N. Khawam, J. B. Bogardus, A. A. Hussain and P. A. Crooks, "S-Acylation of Cysteine by O-Acetylsalicylic Anhydride: A Possible Mechanism for Aspirin Hypersensitivity?", *J. Pharm. Sci., 75,* 1081 (1986).

R. K. Perrone, M. A. Kaplan, and J. B. Bogardus, "Extent of Cisplatin Formation in Carboplatin Admixtures", *Amer. J. Hosp. Pharm., 46,* 258 (1989).

J. B. Bogardus, M. A. Kaplan, and J. P. Carpenter, "Precipitation of Teniposide during Infusion", *Amer. J. Hosp. Pharm., 47,* 518 (1990).

M. Paborji, N. L. Pochopin, W. P. Coppola and J. B. Bogardus, "Chemical and Physical Stability of Chimeric L6, a Mouse-Human Monoclonal Antibody", *Pharm. Res., 11,* 764 (1994). Presented at the Sixth National AAPS meeting, Washington, DC, November, 1991. N

P. Barbour, M. Paborji, T. C. Alexander, W. P. Coppola and J. B. Bogardus, "Stabilization of Chimeric BR96-Doxorubicin Immunoconjugate", *Pharm. Res., 12,* 215 (1995).

B. Gandhi, J. B. Bogardus, D. E. Bugay, R. K. Perrone, and M. A. Kaplan, "Pharmaceutical Relationships of Three Solid State Forms of Stavudine", *Int. J. Pharmaceutics, 201,* 221 (2000).

PRESENTATIONS

"Quasielastic Light Scattering of Sodium Dodecyl Sulfate Micelles containing C-6 to C-16 Alcohols, Acids, or Esters", J. B. Bogardus and Z. J. Kokot, ACS 59th Colloid and Surface Science Symposium, Potsdam, New York, June 1985.

"Oxidative Degradation of a New Cephalosporin", M. W. Lovell, P. A. Ziemba, and J. B. Bogardus, AAPS National Meeting, Washington, DC, November 1986.

"Aqueous Solution Stability of Etoposide", M. K. Park and J. B. Bogardus, AAPS National Meeting, Washington, DC, November 1986.

"Comparison of Alkyl-Oxygen and Carbonyl –Oxygen Bond Cleavage During Hydrolysis of HMG-CoA Reductase Inhibitors", M. Paborji, D. W. Dodsworth, and J. B. Bogardus, AAPS National Meeting, Orlando, Florida, October 1988.

"Preformulation Study on Pemirolast (BMY-26517), A Novel Antiallergy Agent", AAPS National Meeting, Atlanta, Georgia, October 1989.

"Intramolecular Rearrangement of Mitomycin C in Aqueous Solutions", M. Paborji, W. P. Coppola, and J. B. Bogardus, AAPS National Meeting, Las Vegas, Nevada, November 1990.

"Investigation of the Mechanism of Aggregation of Chimeric BR96, a Mouse-Human Monoclonal Antibody", AAPS National Meeting, Orlando, Florida, November 1993.

INVITED PRESENTATIONS

"Amphiphilic Liquid Crystalline Forms of Pharmaceutical Substances", Symposium, APhA Academy of Pharmaceutical Sciences, National Meeting, Philadelphia, Pennsylvania, November 1983.

"Dissolution Processes: A Micro Point of View", Symposium, APhA Academy of Pharmaceutical Sciences, National Meeting, San Antonio, Texas, November, 1984.

"Principles and Methods for Studying Drug Solubility", Symposium, APhA Academy of Pharmaceutical Sciences Midwest Regional Meeting, Chicago, Illinois, May 1985.

"Formulation Aspects of New Drug Delivery", Symposium, AAPS Eastern Regional Meeting, Atlantic City, New Jersey, September 1987.

"Physical Chemical Properties of Molecules in Solution", University of Wisconsin Land O' Lakes Conference, Lake Delton, Wisconsin, June 1988.

"Preformulation Studies in the 1990's: What should we be doing?, Symposium, AAPS Eastern Regional Meeting, New Brunswick, New Jersey, June 1993.
"Philosophy of Drug Substance Form Selection and Case History of a New Antibiotic",
Symposium, AAPS National Meeting, Seattle, Washington, November 1996.

"Impact of ICH/FDA Guidelines on Formulation Development and Stability", Symposium, AAPS Congress of the Americas", Orlando, Florida, March 2001.

"Development Strategies to Control Drug Substance Phase Changes in the Drug Product", International Workshop on Physical Chemical Properties of Solids -2, Lancaster, Pennsylvania, September 2001.
"Principles of Form Selection for Acids and Bases vs. their Salts", Symposium, AAPS Annual Meeting, Denver, Colorado, October 2001.

"Salt Forms or Free Species: Making the Right Decision", AAPS Workshop on Chemical and Physical Form Selection of Drug Candidates, Arlington, Virginia, April 2002.

"Choosing Pharmaceutical Solid State Forms", Keynote Speaker, University of Kentucky Postgraduate Conference, Lexington, Kentucky, April 2005.

BOOK CHAPTER

H. Kostenbauder and J. B. Bogardus, "Reaction Kinetics", in Remington: The Science and Practice of Pharmacy, A. R. Gennaro (Editor), 17th, 18th, and 19th Editions, Mack Publishing Co.

U. S. PATENTS

M. A. Kaplan, J. B. Bogardus, and R. A. Lipper, "Temperature Stable Crystalline di(1-methyl-2pyrrolidinone) and di(N-formylpyrrolidine) Adducts of Cephalosporin Derivatives", U.S. 4,680,389; July 14, 1987 (Assignee: Bristol-Myers Company).

M. A. Kaplan, M. W. Lovell, and J. B. Bogardus, "3-Propenyl Cephalosporin Isomer Separation Process and Derivative", U.S. 4,727,070; February 23, 1988 (Assignee: Bristol-Myers Company).

M. A. Kaplan, R. K. Perrone, and J. B. Bogardus, "Etoposide Solution in NMP", U.S. 4,772,589; September 20, 1988 (Assignee: Bristol-Myers Company).

M. A. Kaplan, N. R. Palepu, and J. B. Bogardus, "Lyophilized or Precipitated Cephalosporin Zwitterion and Salt Combination", U.S. 4,808,617; February 28, 1989 (Assignee: Bristol-Myers Company).

M. N. Nassar, S. N. Agharkar, and J. B. Bogardus, "Stable Injectable Antiemetic Compositions", U. S. 4,882,356; November 21, 1989 (Assignee: Bristol-Myers Company).

M. A. Kaplan, R. K. Perrone, J. B. Bogardus, and K. W. Douglas, Sr., "Concentrated, Stabilized Cis-Diamminedinitratoplatinum Solutions for Conversion to Cisplatin", U.S. 4,94,689; August 7, 1990 (Assignee: Bristol-Myers Company).

M. A. Kaplan, R. K. Perrone, J. B. Bogardus, and K. J. Wilcox, "Water and Solvent Soluble Axial Hydroxy and Mono-and Di-carboxylic Acid Derivatives Having High Tumor Activity", U.S. 5,196,555; March 23, 1993 (Assignee: Bristol-Myers Squibb Company).

M. Paborji, J. B. Bogardus, S. N. Agharkar, and W. P. Coppola, "Stable Solutions of Mitomycin C", U.S. 5,216,011; June 1, 1993 (Assignee: Bristol-Myers Squibb Company).

M. A. Kaplan, L. Phusanti, R. K. Perrone, S. R. Stenberg, S. Agharkar, and J. B. Bogardus, "Stabilized Solutions of Platinum(II) Antitumor Agents", U.S. 5,455,270; October 3, 1995 (Assignee: Bristol-Myers Squibb Company).

U. V. Venkataram, M. K. Franchini, and J. B. Bogardus, "Stable Solutions of Rebeccamycin Analog", U.S. 5,496,809; March 5, 1996 (Assignee: Bristol-Myers Squibb Company).

R. B. Gandhi, J. B. Bogardus, P. M. Garofalo, T. R. Marr, R. K. Perrone, and M. A. Kaplan, "D4T, Polymorphic Form 1 Process", U.S. 5,608,048; March 4, 1997 (Assignee: Bristol-Myers Squibb Company).

J. B. Bogardus, M. A. Kaplan, and R. K. Perrone, "Antiviral, Highly Water Soluble, Stable, Crystalline Salts of 2', 3'-dideoxyinosine, 2', 3'-dideoxy-2',3'-didehydrothymidine and 2',3'dideoxy-2',3'-dideoxy-2'-fluoroinosine, U.S. 6,027,650; March 27, 2001 (Assignee: Bristol-Myers Squibb Company).