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EXECUTIVE SUMMARY

Over 35 years of experience in parenteral product design and development. Broad training and detailed technical knowledge in organic chemistry, physical chemistry, and pharmaceutical sciences. Notable accomplishments include:

- As expert witness in patent litigation concerning formulation of injectable pharmaceuticals (2012-present), I have consulted in ten cases for several pharmaceutical companies, represented by major law firms. These included:
  - Trade secret misappropriation (2012):
    - Tekmira Pharm. Corp. v. Alnylam Pharm., Inc., et. al., Civil Action No. 11-1010-BLS2 (Mass.).
  - Hatch-Waxman litigation (2013-present)
    - Cadence Pharmaceuticals Inc. et al. v. Sandoz, Inc., Civil Action No. 13-cv-00278
    - Helsinn Healthcare SA et al. v. Cipla Ltd. et al., Civil Action No. 13-cv-00688
    - Merck, Sharp & Dohme Corp. v. Fresenius Kabi USA, LLC, Civil Action No. 14-cv-03917
    - Millennium Pharmaceuticals, Inc. v. Apotex Corp. et al., Civil Action No. 13-CV-01874-GMS (D. Del.) (Consolidated)
    - Pfizer Inc. et al. v. Mylan Inc. et al., Civil Action No. 15-cv-00026
    - AMAG Pharmaceuticals, Inc. v. Sandoz Inc., Civil Action No. 16-cv-01508
    - Hospira, Inc. v. Fresenius-Kabi, USA, LLC, Civil Action No. 16-cv-00651
  - Inter partes review declaration (Jan 2017)
    - Mylan Institutional Inc. v. Fresenius Kabi USA, LLC, Cases IPR2017-00643 through -00645

- I have testified at deposition five times in four cases, and once at trial (July 2018). In that case, we won a critical decision based on my testimony, and the judge referenced my direct and cross-examination testimony 55 times in her favorable decision.

- Technical leader at Baxter in formulation of marketed pharmaceutical products, including premix IV infusion formulations of the phosphate ester prodrug, clindamycin phosphate, and premixed IV infusion formulations of vancomycin, fluconazole, and nitroglycerin.

- While at Baxter, worked on well over 100 injectable formulation projects. Expert in all phases of injectable pharmaceutical product development in flexible plastic containers, as well as rigid containers, including glass.

- A technical leader, led formulation development of pharmaceuticals for respiratory therapy (Baxter co-development of inhaled tobramycin for cystic fibrosis – TOBI® in conjunction with the pharmaceutical company, PathoGenesis).

- Scientific consultant in development of a nitrogen mustard oncology drug (2013-2015). As a consulting member of regulatory submission team, worked with Spectrum Pharmaceuticals and its corporate partner, CyDex, in the preparation of the 505(b)(2) filing for Spectrum Pharmaceutical's Evomela®, a propylene glycol-free vial product of melphalan, a nitrogen-mustard oncolytic used to treat multiple myeloma. Product contains the solubilizer/stabilizer, Captisol® (sulfobutylether(7m)-beta-cyclodextrin).

- Served as formulation leader on product development teams focused on the development of new containers for injectable pharmaceuticals products:

    - Development of Baxter's first sterile-fill, no freeze plastic container, Galaxy PL-2501. This involved years of testing various plastic film materials as well as identifying extractables and their degradation products from bonded laminates.
    - Minimization and eventual elimination of PVC, latex and DEHP from plastic parenteral containers. This involved at least five years of work through development of intermediate prototypes.
    - Developed glass container system for Baxter's nitroglycerin injection. This involved the testing of many elastomeric closures including EPDM, butyl rubber, and Teflon-coated stoppers such as Daikyo and West Fluorotec, Helvoet Omniflex, etc.
    - Studied the migration of drug into plastic containers and elastomeric closures (e.g., nitroglycerin, bupivacaine) and developed mathematical models for container sorption.

- Work on development and troubleshooting teams for numerous parenteral products. Examples: anti-"blooming" project for haze prevention in autoclaved plastic containers, particularly PVC; identification of container extractables, minimization of water-vapor transmission through plastics, modeling of formulation changes (e.g., pH) caused by container leachables.
- Developed mathematical models and computer simulations for predicting the effect of plastic container parameters (e.g., film thickness, plastic type and blend, volume and configuration of inner bag and overpouch, overwrap material and thickness, etc.) on formulation stability. Example: PHYSIONEAL container modification and effects on formulation such as pH and pCO_2.

- Expertise in physical chemistry of colloidal dispersions.

  - While at Baxter, I led the development of nanoparticulate pharmaceutical dispersions, in particular itraconazole, and was a key scientist in the development of paclitaxel/albumin microspheres and antiretroviral agents for HIV (HAART). Many patents were generated from my work on nanosuspensions.
  - Designed custom coatings for colloid stabilization, including poloxamer butanesulfonate (US Patent 7,776,360).
  - Developed concepts for novel iron oxide sols in iron supplementation for renal therapy.

- Worked in organic synthesis (1983-84) at Baxter Travenol R&D in Morton Grove, Illinois; synthesized potential drug degradation products for identification of unknowns in pharmaceutical formulations.

- Developed a stable frozen formulation of the carbapenem antibiotic, meropenem, using 2-hydroxypropyl beta-cyclodextrin, which served a dual function as an inclusion complexation host and glass-transition modifier (high Tg' vitrification agent). We were able to demonstrate at least one year of stability in the frozen state (Wong J, Kipp JE, Miller RL, Nair LM, Ray GJ. Mechanism of 2-hydroxypropyl-beta-cyclodextrin in the stabilization of frozen formulations. Eur. J. Pharm. Sci., 2014, 62:281-292).

- Use of 2-hydroxypropyl beta-cyclodextrin in stabilizing meropenem in the frozen state was patented (US Patent 8,183,233. Stable pharmaceutical formulations. Kipp, James E..; Wong, Joseph C-T; Nair, Lakshmy; Miller, Reagan; Rabinow, Barrett E. Issued May 22, 2012).

- Formulation and delivery of poorly soluble drugs in solution, particularly by use of inclusion complexation with cyclodextrins

- Research and development of injectables containing cyclodextrins (e.g., sulfobutylether-beta-cyclodextrin).
- Developed zileuton/cyclodextrin formulation at Baxter (for Critical Therapeutics, Inc.), and submitted patent application (US2007 0111965A1. COMPOSITIONS COMPRISING LIPOXYGENASE INHIBITORS AND CYCLODEXTRIN. Kipp; James E.; Gupta; Pramod. May 17, 2007.

- Inventor of two lyophilization processes: “Preparation of submicron sized nanoparticles via dispersion lyophilization”, 2014, US Patent 8,722,091; “Preparation of submicron sized nanoparticles via dispersion lyophilization”, 2004, US Patent 6,835,396.

- Expertise in drug delivery platform development

  - Lead formulator for in-line, low gravity reconstitution systems for National Aeronautics and Space Administration (NASA). Co-inventor in two patents; received several U.S. government awards.
  - Developed computational models for assessment of drug binding to beta-cyclodextrin based on molecular structure. Results were presented at several national scientific meetings.
  - Lead scientist and inventor of Baxter’s nanoparticulate drug delivery platform (NANOEDGE^{TM}) – led research and development of nanoparticulate suspensions. Wrote review articles, taught AAPS short course (Baltimore, 2004) on nanosuspension formulation.
  - Nanoparticle engineering by rapid solvent-antisolvent precipitation and homogenization, as well as dispersion lyophilization.
  - Lead development of nanosuspension formulations of poorly water soluble drugs, such as itraconazole and prednisolone.

- Led exploratory formulation of cell expansion media in conjunction with the Immunotherapy group at Baxter. This entailed the application of iron dextran (colloidal iron oxide in dextran) as a nutrient iron source. This therapy incorporated use of Baxter’s cell isolation technology, the ISOLEX 300i Magnetic Cell Selection System. The ISOLEX system used superparamagnetic iron microbeads coated with murine anti IgG to effect separation of hematopoietic stem cells.

- Innovative creativity in the development of new drug delivery technology and intellectual property (22 issued patents, and over 35 patent applications).

- Market surveillance and evaluation of new technology opportunities for Baxter. Continued this work as a consultant for other pharmaceutical companies.

- Expert in modeling physical and chemical processes

- Developed computational modeling techniques to predict properties of drugs in solution, solid state and interfacial phenomena (QSPR/QSAR). Chemometric modeling and data mining, research presented at AAPS meetings.
- Developed QSPR neural network modeling (US Patent Application US2008 0104001A1) for prediction of cyclodextrin complexation, solubility, and drug receptor binding (QSAR).
- Developed models and computer programs to predict chemical kinetics under non-isothermal conditions. This enabled rapid assessment of thermal stability.
- As part of inventing a magnetic filtration device, I modeled magnetic flux, a priori, in 2D cross-sections of potential magnetic arrays using conventional software (VIZIMAG). Results were verified using magnetometry.

- Taught courses at University of Illinois, Chicago, on chemical kinetics, and ionic equilibria.

- Presented seminar on non-isothermal kinetics (Univ. of Texas at Austin)

- Conducted site inspection of an analytical laboratory used in a regulatory submission for a pharmaceutical firm under contract with a contract research company in San Diego, CA.

EMPLOYMENT HISTORY

Kipp Pharmaceutical Consulting, Inc.

President, Founder *January 2014 – Present*

- As consultant, served as expert witness in patent litigation.
- Provided support in writing the CMC/PD section of 505(b)(2) application for an anticancer injectable (the nitrogen mustard, melphalan) for an oncology pharmaceutical firm (Evomela®, by Spectrum); this application for an alkylating agent was approved. Evomela utilizes the modified beta-cyclodextrin, Captisol®, as a stabilizer.

- Consulted for various pharmaceutical companies on research and development of diverse pharmaceutical technologies and delivery systems. Developed new product concepts and research plans.

- Worked on new product ideas for oncology drugs (Spectrum Pharmaceuticals, Inc.)

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