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[redacted]

Leah E. Appel* PhD

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Education

Ph.D. in Pharmaceutics, University of Utah, Salt Lake City, UT, 1988
Dissertation: Characterization of a Self-Regulating Insulin Delivery System
Advisor: Sung Wan Kim Ph.D.

B.S. in Chemical Engineering, University of California - Los Angeles, Los Angeles, CA, 1982

Areas of Specialization

Development and application of drug delivery technology. Extensive experience in formulation and process development for oral solid dosage forms including controlled and sustained release formulations, poorly soluble compounds, fixed dose combinations and pediatric formulations for oral delivery. Strong expertise in tablets, capsules, osmotic systems, multiparticulates, and amorphous solid dispersions.

Employment

Managing Partner, 2007 - present
Green Ridge Consulting, Bend, OR
Responsible for formulation, process development, CRO/CMO management and expert witness work for >100 clients. Project areas encompass NCE development, product enhancement, fixed dose combinations. Experienced in formulation development and scale-up, transfer and troubleshooting. Specific technology expertise in oral controlled release technologies (osmotic, matrix, multiparticulates) and amorphous solid dispersions.

Director, Controlled Release, 1996 - 2006
Bend Research, Bend, OR
Responsible for formulation, process development and technology transfer for a wide range of drug delivery technologies including oral osmotics and multiparticulates. Led team to commercialize Zmax sustained release microsphere product with Pfizer. Extensive experience in formulation and process development of hot melt and spray dried dispersion-based IR and CR dosage forms.

Project Leader, 1995 - 1996
Sarcos Research Corporation, Salt Lake City, UT
Responsible for project planning management and development of electro-mechanical topical drug-delivery systems.

Research Fellow 1993 - 1995
Sr. Research Chemist 1988 - 1993
INTERx Research Corporation/Merck & Co., Lawrence, KS
Responsible for design and evaluation of erodible injectable systems for bone-growth promotion. Led electromechanical drug-delivery effort. Developed oral osmotics aqueous-based coatings.

Publications: 14 publications (see attached addendum)

Patents: 15 Patents issued, 29 pending (see attached addendum)

Presentations: 20 presentations (see attached addendum)

Scientific Appointments: Advisor for the Journal of Pharmaceutical Sciences July 2013 - 2016

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* Formerly known as Leah Appel Seminoff

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Appel, L.E. and G.M. Zentner, "Use of Modified Ethylcellulose Lattices for Microporous Coating of Osmotic Tablets," *Pharm. Res.*, 8(1991)600-604.

Appel, L.E., J.H. Clair and G.M. Zentner, "Formulation and Optimization of a Modified Microporous Cellulose Acetate Latex Coating for Osmotic Pumps," *Pharm. Res.*, 9(1992)1664-1667.

Appel, L.E., R. Balena, M. Cortese, E. Opas, G. Rodan, G. Seedor and G.M. Zentner, "In Vitro Characterization and In Vivo Efficacy of a Prostaglandin E_2/Poly (Ortho Ester) Implant for Bone Growth Promotion," *J. Controlled Rel.*, 26(1993)77-85.

Appel, L.E. and L. Witchey-Lakshamanan, "Oncologic, Endocrine & Metabolic Overview: Recent Advances in Implants for Bone Growth Promotion," *Expert Opinion on Therapeutic Patents*, 4 (1994)1461-1469.

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Thombre, A.G., L.E. Appel, M.B. Chidlaw, P.D. Daugherity, F. Dumont, L.A.F. Evans and S.C. Sutton, "Osmotic Drug Delivery Using Swellable-Core Technology," *J. Control. Release,* 94(2004)75-89.

Ray, R., L. Graham, R. Falk, J.R. Shockey, L.E. Appel, K. Dhanasekharan and L. S. Mohan, "Understanding Fluid-Bed Coating," *Fluent News,* Spring 2006, S14.

Lo, J.B., L.E. Appel, S.M. Herbig, S.B. McCray and A.G. Thombre, "Formulation Design and Pharmaceutical Development of a Novel Controlled Release Form Of Azithromycin For Single Dose Therapy," *Drug Dev Ind Pharm,* 35(2009)1522-1529.

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Appel, L.E., G.M. Zentner and G.A. Rodan, "Implant Therapy for Bone Growth Stimulation," published as World Intellectual Property Organization Publication No. WO 93/15767 A1 (1993).

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Appel, L.E., J.R. Shockey and D. C. Schelling, "Palatable Compositions Including Sodium Phenylbutyrate and Uses Thereof," U.S. Patent No. 11,154,521 (2021).

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Seminoff, L.A., and S.W. Kim, "*In Vitro* Characterization of a Self-Regulating Insulin Delivery System," paper presented to the Pharmaceutics and Drug Delivery Section, First National Meeting of the American Association of Pharmaceutical Scientists, Washington, D.C., November 2-6, 1986.

Seminoff, L.A., G. Olsen, J. Zheng, D. Wilson, and S.W. Kim, "Self-Regulated Insulin Release," paper presented to the Insulin Delivery Minisymposium at the 15th International Symposium on Controlled Release of Bioactive Materials, Basel, Switzerland, August 15-19, 1988.

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LeCluyse, E.L., J.A. Fix, L.A. Seminoff, and S. Sutton, "Relationship Between Drug Absorption Enhancing Activity and Membrane Perturbing Effects of Acylcarnitines," paper presented at the Fourth National Meeting of the American Association of Pharmaceutical Scientists, Atlanta, Georgia, October 22-26, 1989.

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Appel, L.E., and G. Zentner, "Utilization of Statistical Experimental Design in the Formulation of Modified Cellulose Acetate Latex Coating," paper presented to the Pharmaceutics and Drug Delivery Section, Sixth National Meeting of the American Association of Pharmaceutical Scientists, Washington, D.C., November 17-21, 1991.

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Appel, L.E., "Amorphous Solid Dispersions", invited presenter by Pharmatek for the Pharmatek U Seminar Series, San Diego, CA, July 30, 2009.

Appel, L.E., "Formulation Design Considerations", invited presenter by Colorcon for the webinar titled Design and Performance of Oral Osmotic Technology, November 15, 2011.

Appel, L.E., "Industry and Consulting Perspectives on Early Development," invited presenter by Patheon at the seminar titled Moving from Molecule to Clinical Trial — Overcoming Challenges in the Early Development of Small Molecules, San Diego, CA, December 13, 2011.

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