CURRICULUM VITAE

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CAREER SUMMARY

President, BioStrategics Consulting Ltd., Marblehead, MA
January 1999-present

Responsibilities: Providing consulting services to pharmaceutical and biotechnology industry clients in four business areas: Product Development Strategy, Clinical/ Regulatory Operations, Business Strategic Analysis and Planning, and Technical Assessment and Recommendations.

Manager, Health Care/Life Sciences Consulting, KPMG Peat Marwick LLP, Boston, MA
May 1997 - December 1998

Responsibilities: Consulting on strategic and tactical issues for pharmaceutical and biotechnology company clients; business development; project and practice management; and mentoring of junior associates.

Vice President, Clinical Research, Biopure Corporation, Cambridge, MA
May 1995 - May 1997

Responsibilities: Supervision of all clinical development activities (including North America and Europe); management of contractor activities; management of strategic alliances with North American and European partners; management of an expanding Clinical Research department; contribution to corporate policies and strategies; and professional development of subordinates.

Executive Director, Clinical Research, Telor Ophthalmic Pharmaceuticals, Woburn, MA
July 1993 - May 1995

Responsibilities: Supervision of all clinical development activities (including North America and Europe); management of contractor activities; technical evaluation of preclinical compounds, developmental candidates, and strategic partnerships; management of an expanding Clinical Research department; contribution to corporate policies and strategies; and professional development of subordinates.

Director, Clinical Research, Sandoz Research Institute, East Hanover, NJ
July 1989 - July 1993

Responsibilities: Deputy Head, Immunology/Dermatology Therapeutic Area; clinical development of immunosuppressive, anti-rejection (transplant), ophthalmic, anti-rheumatic, and anti-asthma compounds; worldwide strategies and planning for immunology, ophthalmology, and human pharmacology research as well as organizational and human resource policy issues; strategic and tactical coordination with European clinical research centers; group administration; professional development of my staff.

January - July 1992: Director, Drug Registration and Regulatory Affairs; assisted the department Vice President formulate and advance new programs and initiatives aimed at improving quality and efficiency of NDA submissions; contributed to regulatory strategy in various therapeutic areas.

Clinical Project Director, Sterling-Winthrop Research Institute, Rensselaer, NY
January 1986 - June 1989:

Responsibilities: Phase 1-3 development of a quinolone antibacterial agent; Phase 1-2 development of novel anti-picornaviral agents; formulation of worldwide clinical research plans; involvement in licensure, Japanese joint-venture, and other extramural liaisons.

EDUCATION TRAINING, AND MEDICAL PRACTICE

1969	BS, University of Illinois
1973	MD, University of Chicago
1973 - 1974	Intern (Straight Medicine) University of Iowa, Iowa City, Iowa
1974 - 1976	Resident, University of Iowa, Medicine
1976 - 1978	Fellowship (Rheumatology), University of Colorado Medical Center
1978 - 1983	Solo Practice of Rheumatology, Portland, Oregon
1984 - 1985	Palm Springs Medical Center, Palm Springs, California

ACCOMPLISHMENT SUMMARY: CONSULTING

Product Development Strategy

Developed IND clinical plans and related clinical strategic frameworks for start-up pharmaceutical and biotechnology companies developing novel agents in virtually all major therapeutic areas.

For both publicly and privately held pharmaceutical, biotechnology, and medical device companies, created international clinical development plans for conventional small molecules, peptides, proteins, monoclonal antibodies, novel vaccines, and unique drug delivery technologies.

Planned and implemented clinical trials programs that align with business success, efficiently achieve value inflection points, and have (in some cases) enabled advantageous exit events.

Clinical/Regulatory Planning and Operations

Assisted numerous biotechnology companies plan and implement early-stage safety and efficacy protocols, which included protocol development, preparation of the Clinical Investigator Brochure, and site and contract research organization selection and management.

Designed, placed, and oversaw dozens of first-in-man trials at domestic and European sites for US and foreign clients.

For domestic and overseas pharmaceutical, biotechnology, and medical device clients, prepared Clinical Investigator Brochure, other IND documentation, and clinical protocols for novel products; placed domestic and overseas clinical trials; and presented to FDA meetings.

For Phase 2, Phase 3, and supplemental NDA projects, developed clinical protocols; managed expert consultant panels and integrated their input; qualified and managed contractors and related external resources; created clinical-regulatory documentation (including NDA submissions), acted as clinical lead in meetings, calls, and other interactions with multiple US FDA review divisions as well as European authorities, and prepared responses to regulatory questions.

Business Strategic Analysis and Planning

As an acting member of senior management teams, assisted numerous early-stage biotechnology companies with corporate strategic planning, market assessment and modeling, and strategic partnering/merger/acquisition efforts.

Participated in a CEO-level strategic planning effort to assist a commodity medical supplier leverage its specialized knowledge and embryonic therapeutic assets into an aggressive, opportunistic, development-oriented pharmaceutical unit.

Technical Assessment and Recommendations

Led the due diligence team and performed extensive scientific, clinical, and regulatory research for an effort that resulted in acquisition of a novel product that progressed directly into Phase 3 clinical trials under an FDA-agreed Special Protocol Assessment.

For a securities analyst client for a $12BB private asset management fund, performed assessments of clinical trial data, clinical/regulatory dossiers, and market intelligence for development-stage and newly launched products in multiple therapeutic areas.

OTHER PROFESSIONAL HISTORY AND AFFILIATIONS

Certifications:	Subspecialty Certification in Rheumatology, 1978 American Board of Internal Medicine, 1976
Licensure:	New Jersey (MA53834) New York (165291-1) Illinois (036-070273) Massachusetts (78382)
Memberships:	American College of Physicians (Fellow) American College of Rheumatology (Fellow) Massachusetts Medical Society Faculty of Pharmaceutical Medicine of the Royal College of Physicians of the United Kingdom
Honors:	Fellow, American College of Physicians, 1983 Phi Kappa Phi, Phi Beta Kappa, Bronze Tablet, 1966 – 1969

Governance/Volunteer Service:

University of Chicago Medical & Biological Sciences Division Alumni Association: Member, Alumni Council: 2008 – present; Executive Committee Member and Chair, Chicago Partners Program, 2011 – 2015; Vice President, 2013-2015; President, 2015-2017

University of Chicago Biological Sciences Division and Pritzker School of Medicine: Member, Council (formerly Visiting Committee), 2009-present; Member, Nominations Subcommittee, 2014-present

Massachusetts Institute of Technology Venture Mentoring Service (www.mitvms.com): Mentor, 2017-present

Bridgewell (www.bridgewell.org): Member, Board of Directors, 2009 – 2014; Chair, Patient Care Assessment Committee; Member, Executive Committee

Temple Sinai of Swampscott and Marblehead: President, 2009 – 2011

University of Illinois School of Molecular and Cellular Biology: Mentor, 2018-present

Celebrity Series of Boston: Member, Board of Overseers, 2019-present

Epstein Hillel School, Marblehead MA: Director, 2019-present

APPENDIX: BIBLIOGRAPHY

ORIGINAL PUBLICATIONS

1) Kovalchik, M.T., Guggenheim, S.J., Silverman, M.H., Robertson, J.S., Steigerwald, J.C. The kidney in progressive systemic sclerosis -- a prospective study. Ann Int Med. 1978; 89:881-887.A
2) Silverman, M., Lubeck, M.J., Briney, W.C. Central retinal vein occlusion complicating systemic lupus erythematosus. Arthritis Rheum. 1979;21:839-843.
3) Silverman, M.H. Polyarteritis nodosa complicating ulcerative colitis. J. Rheumatology 1984;11:337-379.
4) Cook, J.A., Silverman, M.H., Schelling, D.J., Nix, D.E., Schentag, J.J., Brown, R.R. and Stroshane, R.M. Multiple dose pharmacokinetics and safety of oral amifloxacin in healthy volunteers. Antimicrob Agents Chemother. 1990;34:974-979.
5) Stroshane, R.M., Silverman, M.H., Sauerschell, R., Brown, R.R., Boddy, A.W. and Cook, J.A. Preliminary study of the pharmacokinetics of oral amifloxacin in elderly subjects. Antimicrob Agents Chemother. 1990;34:751-754.
6) Boyko, E.J., Iravani, A., Silverman, M.H., Schelling, D.J. and the Amifloxacin Multi-Center Trial Group. A randomized controlled trial of a 10 day course of amifloxacin versus trimethoprim-sulfamethoxazole in the treatment of acute, uncomplicated urinary tract infection. Antimicrob Agents Chemother. 1990;34:665-667.
7) Solch, S., Nadler, P.I. and Silverman, M.H. Safety and tolerability of 2% cyclosporine ophthalmic ointment (Sandimmune®) in normal volunteers. J Ocular Pharmacol. 1991;7:301-312.
8) Laibovitz, R., Solch, S., Andriano, K., O'Connell, M. and Silverman, M.H. Pilot trial of cyclosporine 1% ophthalmic ointment in keratoconjunctivitis sicca. Cornea 1993;12:315-323.
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10) Ujhelyi M, Hoyt RH, Burns K, Fishman RF, Musley S, and Silverman MH. Nitrous oxide sedation reduces discomfort caused by atrial defibrillation shocks. Pacing Clin Electrophysiol 2004;27:485-491.
11) Garcia F, Petry KU, Mudersapch L, Gold MA, Braly P, Crum CP, Magill M, Silverman M, Urban RG, Hedley ML, and Beach KJ. ZYC101a for treatment of high-grade cervical intraepithelial neoplasia: a randomized controlled trial. Obstet Gynecol 2004;103:317-326.
12) Van Troostenburg AR, Lee D, Jones TR, Dyck-Jones JA, Silverman MH, Lam GN, Warrington SJ. Safety, tolerability, and pharmacokinetics of subcutaneous Å6, an 8-amino acid peptide with anti-angiogenic properties, in healthy men. Int J Clin Pharmacol Ther 2004;42:253-259.
13) Van Troostenburg A-R, Clark EV, Carey WDH, Warrington SJ, Kerns WD, Cohn I, Silverman MH, Bar-Yehuda S, Fong K-LL, Fishman P. Tolerability, pharmacokinetics, and concentration-dependent hemodynamic effects of oral CF101, an A3 adenosine receptor agonist, in healthy young men. Int J Clin Pharmacol Ther 2004; 42:534-542.

14) Berkenblit A, Matulonis UA, Kroener JF, Dezube BJ, Lam GN, Cuasay LC, Brünner N, Jones TR, Silverman MH, Gold MA. Å6, a urokinase plasminogen activator (uPA)-derived peptide in patients with advanced gynecologic cancer: A phase I trial. Gynecol Oncol 2005;99:50-57.
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16) Bar-Yehuda S, Silverman MH, Kerns WD, Ochaion A, Cohen S, Fishman P. The anti-inflammatory effect of A_3 adenosine receptor agonists: a novel targeted therapy for rheumatoid arthritis. Expert Opin Investig Drugs 2007;16:1-13.
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1) Steigerwald, J.C., Assini, J.F., Silverman, M.H.: Lupus erythematosus. In: Conn, H.F., ed. Current Therapy. Philadelphia, WB Saunders, 1979.
2) Steigerwald, J.C., Lewis, T.T., Silverman, M.H.: Rheumatology. In: Reller, L.B., Sahn, S.A., Schrier, R.W., eds. Clinical Internal Medicine. Boston, Little, Brown and Co., 1979.

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5) "Distribution of Rheumatologists in Oregon, 1981" (map) Data on file, American Rheumatism Association, 1982.
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PRESENTATIONS

1) Silverman M.H. Coagulation profiles in progressive systemic sclerosis. Western Regional Meeting of the American Rheumatism Association, Scottsdale, Arizona, November 1977.
2) Silverman M.H. Coagulation abnormalities and possible relationship to renal disease in progressive systemic sclerosis. Annual Scientific Meeting of the American Rheumatism Association, New York, New York, June 1978.

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5) "Introduction of New Biologic Agents: Blocking Peptides to MHC/Antigen Recognition as a Model for Regulatory Review." Early Decisions in DMARD Development II: Biologic Agents in Autoimmune Disease, San Francisco, September 1990.
6) "Issues in Ethical Pharmaceutical Development in the United States." The Second Japan-United States Health Care Symposium, Atlanta, Georgia, October 1990.
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11) Wahr, J.A., et.al. “Hemodynamic effects of a bovine hemoglobin-based oxygen carrying solution in surgical patients.” American Society of Anesthesiologists, New Orleans, 21-23 October, 1996.
12) “The Clinical Development Process in a Virtual Environment.” Drug Information Association 37th Annual Meeting, Denver, 11 July, 2001.
13) “Clinical Perspectives on Therapeutic Vaccine Development.” Drug Information Association 10th Annual Workshop on Biotechnology, Irvine CA, 26 March, 2002.
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adenosine A3 receptor agonist, in healthy young men." Annual Meeting of the British Pharmacological Society, Guildford, UK, 26 June, 2003.

16) Dezube B.J., Silverman M., Proper J.A., Weeden W., Morrissey J., Tsengaye K., Choy V.J., Williams L.A., Wilson D., Geurson A., Gelder F.B. "A passive immunotherapy, PEHRG214, in patients infected with HIV-1: A multidose study. XV International AIDS Conference, Bangkok, Thailand, 11-16 July, 2004.

17) Berkenblit A., Gold M.A., Matulonis U.A., Kroener J.F., Dezube B.J., Lam G.N., Cuasay L.C., Brunner N., Jones T.R., Silverman M.H. "Å6, a urokinase plasminogen activator (uPA)-derived peptide: A phase 1 trial in patients with advanced gynecologic cancer. 16th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics, Geneva, Switzerland, 28 September-1 October, 2004.

18) Chan T.C., Czarniecki C., Burrows W., Bittker R., Stough D.B., Lam G.N., Silverman M.H. "EcoNail™ (5% econazole plus 18% SEPA®) nail lacquer in patients with onychomycosis: safety, local tolerability, and systemic exposure." 66th Annual Meeting of the Society for Investigative Dermatology, St Louis, 3-7 May, 2005.

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20) Chan T., Dobs A., McMurray J., Pino J., Silverman M., Swerdloff R. "A topical testosterone replacement therapy formulated with a chemical skin penetration enhancer – SEPA®." 8th International Congress of Andrology, Seoul, Korea, 12-16 June, 2005.

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European Society of Gynaecologic Oncology (ESGO), Berlin, Germany, 28 October-1 November 2007.

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27) Pardanani A.D., Gotlib J., Jamieson C., Cortes J., Talpaz M., Stone R.M., Shorr J., Silverman M.H., Gilliland D.G., Tefferi A. "A Phase I Study of TG101348, An Orally Bioavailable JAK2-Selective Inhibitor, in Patients with Myelofibrosis." 50th American Society of Hematology Meeting, San Francisco CA, 6-9 December 2008.

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31) Lin C, Ghamande SA, Dezube BJ, Silverman MH, Fong K-L, Kuo M, Mach W, Tseng Y, Hsu S, Goel S. TLC388, a novel topoisomerase-1 inhibitor with antihypoxia inducible factor-1 alpha activity: A phase I and pharmacokinetic study in patients with advanced solid malignancies. American Society of Clinical Oncology Annual Meeting, Chicago, 4-8 June 2010. (J Clin Oncol 28, 2010 (suppl; abstr e13020)).

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