

# DEBRA GAIL SILBERG M.D., PH.D., FACG

Chestertown, MD

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## PHYSICIAN LEADER CONSULTANT

Accomplished Pharmaceutical and Academic Physician Leader and Consultant with extensive clinical, academic and industry leadership expertise. Exceptional proven experience in multiple clinical research settings. Recognized for strong mentoring skills with numerous recognitions, awards and honors.

## PROFESSIONAL EXPERIENCE

**SILBERG CONSULTING, LLC, Chestertown, MD**

**Principal and Founder**

**2020-Present**

Silberg Consulting, LLC was established to provide expertise to the pharmaceutical industry in all elements of drug development from the transition from research to human studies through to approval and post-approval studies. Over the span of Dr. Silberg's biomedical career, she has held leadership roles within both Academia and the Pharmaceutical Industry giving her a unique ability to advise on all aspects of drug development including, but not limited to trial design, protocol development, regulatory interactions and NDA submissions and their defense. Dr. Silberg consults with multiple Pharmaceutical, Biotech and adjunct companies as well as serving on a drug safety monitoring board.

**ELLODI PHARMACEUTICALS, Blue Bell, PA**

**Board of Directors Member and Scientific Advisor**

**2/2023-present**

**FINCH THERAPEUTICS, INC, Somerville, MA**

**Lead Program Physician/Senior Advisor – part time employee**

**11/2021-3/2023**

**Interim Chief Medical Officer**

**10/2021-3/2022**

**TAKEDA PHARMACEUTICAL COMPANY, LTD, (Shire was acquired by Takeda) Cambridge, MA**

**Distinguished Senior Clinical Fellow**

**10/2020-12/2020**

**Vice President, Clinical Development, Clinical Science Head PPGI**

**1/2019-10/2020**

**SHIRE PHARMACEUTICALS, Lexington, MA**

**Vice President, Clinical Development, GI and Endocrine**

**8/2018-12/2018**

**Clinical Development Therapeutic Area Lead, Lexington, MA**

**Vice President, Clinical Development, GI/Endocrine/Metabolism**

**Clinical Development Therapeutic Area Lead, Zug, Switzerland**

**1/2017-8/2018**

**Vice President, Clinical Development and Global Development Lead, Zug, Switzerland,**

**4/2016-6/2018**

**Senior Director, Clinical Medicine and Global Clinical Development**

**Lead for Gastroenterology/Hepatology, Wayne, PA**

**4/2011-4/2016**

**ASTRAZENECA, PLC, Wilmington, DE**

**Chair, Hepatotoxicity Safety Knowledge Group**

**1/2011-4/2011**

**Executive Director, Clinical Research, Medical Science Director lesogaberan**

**1/2010-4/2011**

**Senior Director, Clinical Research, Medical Science Director lesogaberan**

**1/2008-12/2009**

**Senior Director, Clinical Research, US Nexium Brand Medical Director**

**11/2006-1/2008**

**Director, Clinical Research**

**12/2003-11/2006**

## POSTDOCTORAL TRAINING AND FELLOWSHIP APPOINTMENTS

**HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA**, Philadelphia, PA 1989-1995  
**Fellowship, Gastroenterology**  
**Resident in Internal Medicine**  
**Intern in Internal Medicine**

## ACADEMIC APPOINTMENTS

**UNIVERSITY OF PENNSYLVANIA SCHOOL OF MEDICINE**, Philadelphia PA 1995-2009  
**Adjunct Assistant Professor of Medicine** Department of Medicine, Division of Gastroenterology  
**Assistant Professor of Medicine**, Department of Medicine, Division of Gastroenterology  
**Instructor in Medicine**, Department of Medicine, Division of Gastroenterology

## EDUCATION

**ALBERT EINSTEIN COLLEGE OF MEDICINE**, Bronx, NY., M.D. 1985-1989  
**WAYNE STATE UNIVERSITY SCHOOL OF MEDICINE**, Detroit, MI. (Immunology), Ph.D. 1981-1985  
**UNIVERSITY OF MICHIGAN**, Ann Arbor, MI, B.S. 1977-1981

## CLINICAL RESEARCH

**FINCH THERAPEUTICS, INC**, Somerville, MA

**Interim Chief Medical Officer**

**10/2021-3/2022**

Oversee the Clinical and PV groups at Finch Therapeutics, a microbiome company, during a time of transition to find a permanent CMO. Manage the physician team, review and sign off on IBs, review medically related regulatory documents for submissions and generally give advice on clinical stage programs within the microbiome space.

**Lead Physician Autism Spectrum Disorder Program/Senior Advisor**

**11/2021-3/2023**

**TAKEDA PHARMACEUTICAL COMPANY, LTD**,

**2019-2020**

**Senior Distinguished Clinical Fellow**

**10/2020 to 12/2020**

Strategic advisor to the clinical teams and to R&D in general

**Global VP Clinical Development, Clinical Science Head of GI**

**1/2019-10/2020**

- Provide leadership, oversight and expertise to the program teams in Clinical Development within the GI therapeutic area comprising of approximately 30 physicians and clinical scientists (US, Europe, China and Japan).
- Manage the Clinical Science Leaders of the programs within the therapeutic area (IBD, EoE, CIC, Celiac, Liver, Motility, Microbiome and Acid Peptic).
- Oversee the clinical aspects or lead discussions with Regulatory Authorities (EMA and FDA) to facilitate advancement of programs.
- Chair the Synopsis/Protocol Review Board and Development Review Forum.
- Work cross-functionally within R&D and the business units (commercial).
- Clinical representative to the Business Development team (acquisitions or partnership) to make recommendations to the team for new opportunities from a strategic and scientific perspective. As Clinical Science TA head for GI, member of the GI Therapeutic Leadership team, GI labeling team, Business Development team.
- Member of three Joint Steering Committees in partnerships with Takeda

**SHIRE PHARMACEUTICALS**

**2011-2018**

**Therapeutic Clinical Development Lead for GI/Endocrine and Metabolism (GEM)**

**1/2017-1/2019**

- Provided leadership and expertise to the program teams in Clinical Development within the therapeutic area. Managed the Global Development Leaders of the programs within the therapeutic area (IBD, EoE, CIC, Hypoparathyroidism, Short Bowel Syndrome, NASH, pediatric cholestatic diseases, and lysosomal storage disease)
- Led discussions with Regulatory Authorities (EMA and FDA) to facilitate advancement of programs

- Work cross-functionally within R&D and the business units (commercial).
- As GEM TA lead, member of the Clinical Development Leadership team, Protocol Review team and Development Steering Committee.
- Led the Shire team in the defense of prucalopride (Motegrity) at the FDA Advisory Committee leading to NDA approval (October 2018)

### **Global Development Team Lead**

**6/2014-1/2017**

Eosinophilic Esophagitis (SHP621) program 2/2015 to 6/2018,  
SHP626 in NASH 6/2014 to 1/2017

Prucalopride for CIC 9/2016 -1/2017

- Oversaw the R&D cross-functional team for the programs including Clinical Development, Regulatory and Commercial strategy and development plans
- Supervised and managed the medical leads for each of the programs

### **Medical Lead**

**4/2011 to 8/2013**

- Prucalopride: Oversaw the medical aspects of the program, supervising two physicians working globally.
- SPD557 (5HT4 – pro-kinetic): Provided medical leadership to the team and PRO expertise, designed the Phase 2b protocol for proof of concept. Provided Go No/Go criteria leading to the decision to discontinue the program
- Internal Medicine leadership team – member of the IM business unit leadership team to discuss strategic plans for the IM business
- Business Development - Evaluate new opportunities in gastroenterology and make recommendations for investment
- Due Diligence and Pre-due diligence – Medical lead for (pre and) due diligence in GI to make recommendations for investment based on the scientific and clinical attractiveness of the program

### **C-Path representative**

- Shire representative (among three companies) to C-Path initiative (FDA/Industry) to develop PROs in GI, in particular dyspepsia (2011-2015).

### **ASTRAZENECA LP**

**2003-2011**

#### **Hepatotoxicity Safety Knowledge Group**

**2005-2011**

- Hepatotoxicity Advisor Panel Provided clinical gastroenterology expertise to all therapeutic areas regarding hepatotoxicity related to drug exposure through the Hepatotoxicity Advisory Panel
- Assumed the Chair of the Hepatotoxicity Safety Knowledge Group 2011

### **Senior Director and Executive Director, Clinical development of lesogaberan (reflux inhibitor)**

**2007-2011**

Responsible for all medical aspects of global development (Phase 1-2).

- Primary clinical presenter to the FDA (pre-IND meetings, all safety and PRO discussions), EMEA and Icelandic authorities
- Led the medical and safety teams supporting lesogaberan. Responsible for medical input to the study design concepts
- Promoted to Executive Director in 2010
- Co-rewrote guidance on the collection and interpretation of clinical liver data for AstraZeneca trials to align with the FDA guidance
- Review potential in-licensing opportunities for gastrointestinal products

### **Lead Study Team Physician on Phase IV clinical trials in gastroesophageal reflux disease**

**2003-2008**

- US Nexium Medical Director and member of the Nexium Development Leadership team, responsible for medical input into Phase IV proposals and presentation to the US AZ leadership team
- Reviewed medical content of health care professional and consumer promotional and non-promotional material
- Medical input into labeling changes and FDA submissions
- Managed the professional development and assign responsibilities to the physicians within the GI therapeutic area

### **Chair of the Investigator Sponsored Studies (ISS) program for the GI therapeutic area in the US**

**2004-2007**

- Led team meetings to review proposals/protocols, giving scientific/clinical evaluations and discussing projects with the global Nexium team, RSMs and investigators

**Lead Study Team Physician** on a Phase II clinical trial in irritable bowel syndrome (IBS)

**2005**

**UNIVERSITY OF PENNSYLVANIA**

**2001-2003**

- Principal investigator for a translation research study (clinical/basic science) in patients with Barrett's esophagus
- Obtained demographic and clinical information from patients with Barrett's esophagus prior to and after upper endoscopy. During endoscopy, obtained tissue samples then isolated RNA and performed gene arrays to investigate the molecular mechanism involved in the transdifferentiation to Barrett's esophagus.
- Authored the protocol and grant application, and successfully obtained IRB approval and NIH funding for this study

**HOSPITAL, UNIVERSITY AND ADMINISTRATIVE APPOINTMENTS**

**UNIVERSITY OF PENNSYLVANIA, Philadelphia PA**

**Director, Morphology Core for the Center for Molecular Studies in Digestive and Liver Disease and Program**

Project: Molecular Programs that Differentiate Prestructural Tissues

Projects, Differentiation of tissues involved in nutrition and metabolism and mechanisms of Esophageal Carcinogenesis

**Director, GI Fellows Clinical Outpatient Program Gastroenterology Fellowship**

**Associate Director, Combined Degree (MD-PhD) and Physician Scholar Programs**

**MEDICAL SPECIALTY CERTIFICATION**

American Board of Internal Medicine, Gastroenterology

**1997 and 2007**

American Board of Internal Medicine, Internal Medicine

**1993 and 2003**

**MEDICAL LICENSURE**

Pennsylvania

**1991-Present**

**PROCESS IMPROVEMENT OR SPECIAL COMMITTEES**

Columbia University Alliance, Joint Steering Committee member

**2020-2020**

Theravance, Joint Steering Committee member

**2019-2020**

Cour Therapeutics, Joint Steering Committee member

**2019-2020**

Shire, Develop standards for Safety Assessment in Programs

**2012**

AZ, Clinical Study Protocol Simplification Project

**2006-2008**

AZ, Hepatotoxicity Advisory Panel

**2005-2011**

**AWARDS, HONORS AND MEMBERSHIP IN HONORARY SOCIETIES**

ACG Presidential Poster Award

ADHF-Robert and Sally Funderburg Research Scholar Award in Gastric Biology Related to Cancer

(An Experimental Model of Intestinal Metaplasia)

Sidney Cohen Teaching Award for Faculty (University of Pennsylvania)

ADHF-Robert and Sally Funderburg Research Scholar Award in Gastric Biology Related to Cancer –

Secondary Recipient Award

Center for Molecular Studies in Digestive and Liver Disease Pilot and Feasibility Grant

Measey Foundation Fellowship

Center for Molecular Studies in Digestive and Liver Disease Pilot and Feasibility Grant

Glaxo Fellow's Award

AGA Foundation/Merck Senior Fellow Research Award

Alpha Omega Alpha Medical Honor Society

Ben Gurion University Exchange Fellowship

## GRANTS

1995-2000	NIH/NIDDK K08-DK02375 <u>CDX-1 and CDX-2 in development</u>
1997-2003	NIH/NIDDK P30-DK50306 <u>Center for Digestive and Liver Disease-Morphology Core</u>
1999-2000	NIH/NIDDK R03-DK56082-01 <u>Cdx expression in the gastrointestinal tract</u>
2001-06	NIH/NIDDK R01-DK59539 <u>Cdx in GI Differentiation and Transdifferentiation</u>
2001-03	NIH/NIDDK PO1-DK49210 <u>Subproject: Role of Cdx in Gut Differentiation and Nutrition</u>
2001-03	NIH/NIDDK PO1-DK49210 <u>Differentiation of Tissues Involved in Nutrition and Metabolism</u> (Morphology Core)
2002-04	NIH/NIDDK R21-DK63623 <u>Molecular Mechanisms Underlying Barrett's Esophagus</u>

## PROFESSIONAL AND SCIENTIFIC SOCIETIES

### National Societies

1993-Present	American Gastroenterological Association (Member)
2003-Present	Fellow, American College of Gastroenterology
2014-18	Member, Executive Board, AGA Center for Diagnostics and Therapeutics
2014-17	Member, AGA Research Awards Panel
2011-13	Member, AGA Ethics Committee
2008-10	AGA Women's Committee
2009	Member, AGA Task-force on Mentoring
2007-09	Corporate Council Trustee – American Society of Gastrointestinal Endoscopy Foundation Board of Trustees
2006-09	Member, AGA Institute Research Policy Committee

### National Scientific Committees

2016-18	Member of the Liver Forum Pediatric Working Group (Academia, Industry, Agency alliance)
2011-17	C-Path PRO consortium, representative to the Functional Dyspepsia working group
2008-11	Industry Representative to the Gastrointestinal Drug Advisory Committee (FDA)
2003	Study Section member, NIH/NIDDK Special Emphasis Panel, ZDK1 GRB-9 O4, Small Clinical Grants in Digestive Diseases and Nutrition.
2002-03	Member Scientific External Advisory Committee for GRASP, New England Medical Center
2002	Study Section member, NIH/NIDDK Special Emphasis Review Committee ZDK1 GRB-1
2002	NCI Stomach and Esophageal Cancers Progress Review Group Roundtable Meeting
2001	Delegate to the Growth, Development and Aging Section of AGA
2001	Study Section member, NIH/NIDDK RFA-01-023
2001	Ad hoc Reviewer, NIH/NCI Subcommittee E
2001	Study Section member, NIH/NCI PO1 NCI-E GRB-B
2000-01	External Reviewer, The Cancer Research Campaign, United Kingdom
2000	Study Section member, NIH/NIDDK PO1 ZDK1 GRB-3 (J1)
2000	Reviewer, NIH/NIDDK ZDK1 GRB-4 Digestive Diseases Research Core Study Section
2000	Ad hoc Reviewer, NIH/NIDDK DDK-C Study Section
2000	External Reviewer, American Cancer Society, Research Scholar Grant
1999	Ad Hoc Committee, Veterans Administration Hospital, Competitive Pilot Project Fund
1999	External reviewer, Center for Gastroenterology Research on Absorptive and Secretory Processes, Pilot Project

## EDITORIAL POSITIONS

Reviewer for peer-reviewed journal: American Journal of Physiology, Gastroenterology, DNA and Cell Biology, Journal of Clinical Investigation, Molecular Diagnostics, FEBS letters, Scandinavian Journal of Gastroenterology, American Journal of Gastroenterology, International Journal of Cancer, Nature Reviews Cancer and Gut  
**1997-2005**

## LECTURES BY INVITATION

- February 12, 1998 "Regulation of Intestine Specific Genes" Department of Oncology, Montefiore Medical Center, University Hospital for the Albert Einstein College of Medicine, Bronx, NY
- June 17, 1999 "Gastric Cancer" Gastroenterology and Hepatology Update Course, Park Hyatt Hotel, Philadelphia, PA
- April 27, 2000 "Cdx in gastrointestinal development and differentiation" Digestive Disease Research Core Center Directors Meeting, University of Pennsylvania Philadelphia, PA
- May 23, 2000 "Cdx and Intestinal Development" NIDDK 50th Anniversary Symposium, Digestive Disease Week, San Diego, CA
- June 16, 2000 "Intestinal metaplasia: integrating human data with experimental models", Upper Gastrointestinal Tract: Biology and Genetics, Penn Tower Hotel, PA
- November 15, 2000 "Cdx in Intestinal Differentiation and Metaplasia", Physiology Department, University of Michigan Medical School, Ann Arbor, MI
- April 3, 2001 "A model of Intestinal Metaplasia" Molecular Basis for Neoplasia in the Digestive Tract Conference and Retreat, Center for Molecular Studies in Digestive and Liver Disease, Gregg Conference Center, Bryn Mawr, PA
- July 7, 2001 "Animal models of metaplasia" FASEB Summer Research Conference. Gastrointestinal Tract IX: Mechanisms of Disease and Protection, Whitefish, MT
- October 15, 2001 "The Genetic Basis of GI Cancers: Approach to Diagnosis" Bethlehem Speakers Program, Astra-Zeneca, Bethlehem, PA
- October 16, 2001 "The Genetics of GI Diseases-How Can We Use Our Knowledge for Patient Care" Department of Medicine Grand Rounds, St. Luke's Hospital, Bethlehem, PA
- July 9, 2002 "Barrett's Esophagus from Bench to Bedside" Department of Medicine Grand Rounds, Hospital of the University of Pennsylvania, Philadelphia, PA
- October 10, 2002 "Intestinal Metaplasia: Of Mice and Men" Gastroenterology Medical Science for Physicians Lecture, University of Texas Southwestern Medical Center, Dallas, TX
- November 13, 2002 "Intestinal Metaplasia: Of Mice and Men" Frontiers of GI Research Conference, University of Illinois at Chicago, Chicago, IL
- February 28, 2003 "Intestinal Metaplasia: At Tale of Two Species" Gastroenterology Research Seminar" Emory University School of Medicine, Atlanta, GA
- April 3, 2003 "Combined Degree Programs: Is this in your future?" Haverford College, Haverford, PA
- November 11, 2005 "Pharmaceutical funding opportunities for research" for the GRG "Methodologies in Healthcare Outcomes in Gastroenterology" course. Meza, AZ
- November 10, 2006 "Pharmaceutical funding opportunities for research" for the GRG "Methodologies in Healthcare Outcomes in Gastroenterology" course. Denver, CO
- November 9, 2007 "Pharmaceutical funding opportunities for research" for the GRG "Methodologies in Healthcare Outcomes in Gastroenterology" course. Fort Lauderdale, FL
- May 18, 2008 "Cooperative Agreements: Industry, Academia and the NIH" Digestive Disease Week, San Diego, CA

- May 2, 2010 “Doing it Right: Principled Collaboration Between Industry and Gastroenterology” Digestive Disease Week, New Orleans, LA
- January 24, 2011 “Hepatic System: Drug Induced Liver Injury”, symposium entitled “Safety Pharmacology in Drug Discovery & Development: Nonclinical & Clinical Strategies to Identify & Address Key Safety Risks” presented by AstraZeneca to the FDA. White Oak, MD
- April 4, 2012 “PRO development: Context of Use Examples from GI” Third Annual Patient Reported Outcome (PRO) Consortium Workshop, Silver Spring, MD
- June 24, 2013 “Patient Reported Outcomes as Endpoints for Clinical Studies” Annual DIA meeting, Boston MA
- September 10, 2013 “Clinical Outcome Assessments as Endpoints for Clinical Studies:” ERT Proficiency Conference, Princeton NJ
- March 18, 2014 “Addressing Study Endpoints for Clinical Relevance” DIA Conference entitled: Beginning with the End in Mind-Study Endpoints: Targeting Patient-Centered Outcomes, Bethesda MD
- March 19, 2014 “Context of Use: Industry Perspective” DIA Conference entitled: Beginning with the End in Mind-Study Endpoints: Targeting Patient-Centered Outcomes, Bethesda MD
- April 9, 2014 “Patient Centric Concepts: Does the Right Instrument Exist? ERT Proficiency Conference, Naples, FL
- May 6, 2014 “Guidance on PRO Endpoints and Label Regulations” CBI PRO/COA Summit Philadelphia, PA
- June 12, 2014 “Planning Ahead for Children – How Does Industry Work With Investigators and Regulators” ESPGHAN, Jerusalem, Israel
- July 16, 2014 “Enhancing the Development and Use of Patient-Reported Outcomes in Drug Development” Panel member and discussant “Experiences with the FDA Guidance on PROs: Standardizing Communication Process” Brookings Institution Conference, Washington, DC
- June 3, 2018 “Challenges in Pharma Sponsored Research” DDW, Washington DC
- June 19, 2020 APFED (American Partnership for Eosinophilic Disorders) Panel discussion – Pharma Roundtable, Web based presentation for APFED
- June 25, 2020 “Resuming clinical trials amidst COVID-19”, Web based presentation for the AGA University

### **ORGANIZING ROLES IN SCIENTIFIC MEETINGS**

- May 22, 2001 PPARS and Differentiation Research Forum, Moderator, American Gastroenterological Association, Digestive Disease Week, Atlanta, GA.
- Abstract Reviewer for the American Gastroenterological Association Sections Digestive Disease Week: Growth, Development and Aging; Intestinal Disorders; and Barrett's Esophagus and Esophageal Cancer (Chair of Session)
- May 20, 2002 Molecular Mechanisms of Intestinal Differentiation, Moderator, American Gastroenterological Association, Digestive Disease Week, San Francisco, CA
- May 21, 2002 Pathways of Esophageal and Gastric Cancer, Moderator, American Gastroenterological Association, Digestive Disease Week, San Francisco, CA
- Abstract Reviewer for the American Gastroenterological Association Section Digestive Disease Week: Growth, Development and Aging (Chair of Session); Intestinal Disorders.
- May 22, 2012 Navigating Common Ethical Dilemmas in the Practice of Gastroenterology, Moderator, American Gastroenterological Association, Digestive Disease Week, San Diego, CA
- May 7, 2017 Clinical Trials in Special Populations, Moderator, American Gastroenterological Association, Digestive Disease Week, Chicago, IL

## PUBLICATIONS

### Research Publications, peer reviewed

1. Holda, J.H., **D. Silberg**, and R.H. Swanborg. Autoimmune effector cells. IV. Induction of experimental allergic encephalomyelitis in Lewis rats without adjuvant. *J. Immunol.* 130:732.1983.
2. **Silberg, D.G.** and R.H. Swanborg. Autoimmune effector cells. VII. Cellular requirements for the induction of autoreactive T cells of experimental allergic encephalomyelitis in healthy nonimmune rats. *J. Immunol.* 136:2432.1986.
3. Hayosh, N.S., **D.G. Silberg** and R.H. Swanborg. Autoimmune effector cells. Part 10. Effector cells of autoimmune encephalomyelitis in healthy nonimmune rats. *J. Neuroimmunol.* 18:315.1988.
4. **Silberg, D.G.**, W.Wang, R.H. Moseley, and P.G. Traber. The down regulated in adenoma (dra) gene encodes an intestine-specific membrane sulfate transport protein. *J Biol. Chem.* 270:11897. 1995.
5. Diamond, R.H., C.Peters, S.P.Jung, L.E. Greenbaum, B.A. Haber, **D.G.Silberg**, P.G.Traber and R.Taub. Expression of PRL-1 nuclear PTPase is associated with proliferation in liver but with differentiation in intestine. *Amer. J. Physiol* 34:G121. 1996.
6. Tung, J., A.J. Markowitz, **D.G. Silberg**, and P.G. Traber. Developmental expression of the sucrase-isomaltase gene in transgenic mice is regulated by an evolutionarily conserved promoter. *Amer. J. Physiol.* 36:G83 (273: G83-92). 1997.
7. **Silberg, D.G.**, E.E. Furth, J.K. Taylor, T. Schuck, T. Chiou, and P.G. Traber. Cdx1 protein expression in normal, metaplastic and neoplastic human alimentary tract epithelium. *Gastroenterology* 113:478. 1997.
8. Kaestner, K.H., **D.G. Silberg**, P.G. Traber, and G. Schutz. The mesenchymal winged helix transcription factor *Fkh6* is required for the control of gastrointestinal proliferation and differentiation. *Genes & Dev* 11:1583-1595. 1997.
9. Yang, H., W. Jiang, E.E. Furth, X. Wen, J.P. Katz, R.K. Sellon, **D.G. Silberg**, T.M. Antalis, C.W. Schweinfest, and G.D. Wu. Intestinal inflammation reduces expression of DRA, a transporter responsible for congenital chloride diarrhea. *Am.J.Physiol.* 275: G1445-G1453. 1998.
10. Moseley, R.H., P. Hoglund, G.D. Wu, **D.G. Silberg**, S. Haila, A. de la Chapelle, C. Holmberg, and J. Kere. The *down regulated in adenoma* gene encodes a chloride transporter defective in congenital chloride diarrhea. *Amer. J. Physiol.* 276: G185-G192. 1999.
11. Canete-Soler, R., **D.G. Silberg**, M.D. Gershon, W.W. Schlaepfer. Mutation in neurofilament transgene implicates RNA processing in the pathogenesis of neurodegenerative disease. *J Neurosci* 19:1273-1283. 1999.
12. Ren, P., **D.G. Silberg**, A.E. Sirica. Expression of an intestine-specific transcription factor (Cdx1) in intestinal metaplasia and in subsequently developed intestinal-type of cholangiocarcinoma in rat liver. *Amer. J. Path.* 156:621-627.2000.
13. Lynch, J., E.R. Suh, **D.G. Silberg**, S. Rulyak, N. Blanchard, P.G. Traber.. The caudal-related homeodomain protein Cdx1 inhibits proliferation of intestinal epithelial cells by downregulation of D-type cyclins.*J. Biol. Chem.* 275:4499-4506. 2000.
14. **Silberg, D.G.**, G.P. Swain, E.R. Suh, P.G. Traber. Cdx1 and Cdx2 expression during intestinal development. *Gastroenterology.* 119:961-971.2000.
15. Steppan, C.M., E.J. Brown, C.M. Wright, S. Bhat, R.R. Banerjee, C.Y. Dai, G.D. Enders, **D.G. Silberg**, X. Wen, G.W. Wu, M.A. Lazar. A novel family of tissue-specific resistin-like molecules. *PNAS* 98:502-506.2001.
16. **Silberg, D.G.**, J. Sullivan, E. Kang, G.P. Swain, J. Moffett, N.J. Sund, S.D. Sackett, K.H. Kaestner. Cdx2 ectopic expression induces gastric intestinal metaplasia in transgenic mice. *Gastroenterology* 122: 689-696. 2002
17. Boudreau, F., E.H.H.M. Rings, G.P. Swain, A.M.S. Sinclair, E.R. Suh, **D.G. Silberg**, R.H. Scheuermann, P.G. Traber. A novel colonic repressor element regulates intestinal gene expression by interacting with Cux/CDP. *Mol. Cell Bio.* 22:5467-5478.2002.
18. Almeida R., E. Silva, F. Silva, **D.G. Silberg**, J. Wand, C. de Bolós, L. David. Expression of intestine-specific transcription factors, CDX1 and CDX2, in intestinal metaplasia and gastric carcinomas. *J. Pathol.*, 199(1):36-40. 2003.



19. Brembeck F.H., F.S.Schreiber, T.B. Deramaudt, L. Craig, B.Rhoades, G. Swain, P. Grippo, D.A. Stoffers, **D.G. Silberg**, A.K. Rustgi The mutant K-ras oncogene causes pancreatic periductal lymphocytic infiltration and gastric mucous neck cell hyperplasia in transgenic mice. *Cancer Research*. 63 (9): 2005-2009.2003.
20. Mesquita P., N. Jonckheere, R. Almeida, M.P. Ducourouble, J. Serpa, E. Silva, P. Pigny, F.S. Silva, C. Resi, **D. Silberg**, I. Van Seuningen, L. David. Human MUCS mucin gene is transcriptionally regulated by Cdx homeodomain proteins in gastrointestinal carcinoma cell lines. *J Biol Chem*. 278 (51):51549-51556.2003.
21. Rankin E.B, W. Xu, **D.G. Silberg**, E. Suh. Putative intestine specific enhancers located in the 5' sequence of the CDX1 gene regulate CDX1 expression in the intestine. *Am J. Physiol Gastrointes Liver Physiol*.286:G872-G880.2004.
22. Wang, M.L., M.E. Shin, P.A. Knight, D. Artis, **D.G. Silberg**, E. Suh, G.D. Wu. Regulation of RELM/FIZZ isoform expression by Cdx2 in response to innate and adaptive immune stimulation in the intestine. *Am J. Physiol Gastrointest Liver Physiol*. 288(5):G1074-83.2005.
23. Katz J.P., N. Perreault, B.G. Goldstein, L. Actman, S.R. McNally, **D.G. Silberg**, E.E. Furth, K.H. Kaestner. Loss of Klf4 in mice causes altered proliferation and differentiation and precancerous changes in the adult stomach. *Gastroenterology* 128(4):935-945.2005.
24. Goldstein J.L., P.B Miner Jr, P.K. Schlesinger, S. Liu, **D.G. Silberg**: Intragastric acid control in non-steroidal anti-inflammatory drug users: comparison of esomeprazole, lansoprazole, and pantoprazole. *Aliment Pharmacol Ther* 23:1189-1196.2006
25. Katz P.O., G.G. Ginsberg, P.E. Hoyle, M.B. Sostek, J.T. Monyak, **D.G. Silberg**. Relationship between intragastric acid control and healing status in the treatment of moderate to severe erosive oesophagitis. *Aliment Pharmacol Ther* 25:617-28.2007
26. Crissey M.A., R.J. Guo, F. Fogt, H. Li, J.P. Katz, **D.G. Silberg**, E.R. Suh, J.P. Lynch. The homeodomain transcription factor Cdx1 does not behave as an oncogene in normal mouse intestine. *Neoplasia* 10:8-19.2008
27. Drossman DA, Danilewitz M, Næsdal J, Hwang C, Adler J, **Silberg DG**. Randomized, Double-Blind, Placebo-Controlled Trial of the 5-HT Receptor Antagonist AZD7371 Tartrate Monohydrate (Robalzotan Tartrate Monohydrate) in Patients With Irritable Bowel Syndrome. *Am J Gastroenterol*. 103(10):2562-2569. 2008
28. Stairs DB, Nakagawa H, Klein-Szanto A, Mitchell SD, **Silberg DG**, Tobias JW, Lynch JP, Rustgi AK. Cdx1 and c-Myc foster the initiation of transdifferentiation of the normal esophageal squamous epithelium toward Barrett's esophagus. *PLoS ONE*. 3(10):e3534. 2008
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30. Spechler SK, Barker PN, **Silberg DG**. Intragastric acid control in patients who have Barrett's esophagus: comparison of once-and twice-daily regimens of esomeprazole and lansoprazole. *Aliment Pharmacol Ther*. 30 (2):138-45. 2009
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## EDITORIALS, REVIEWS, CHAPTERS, PARTICIPATION IN COMMITTEE REPORTS

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