

**LAWRENCE GOLDKIND, M.D.**  
**Goldkind Consulting, LLC**  
**9010 Marseille Drive**  
**Potomac, MD 20854-3120**  
**[LNGOLDKIND@GMAIL.COM](mailto:LNGOLDKIND@GMAIL.COM)**  
**Cell: 240-350-4928**

**Current position:**

**Assistant Professor of Medicine**  
**Department of Gastroenterology**  
**Walter Reed National Military Medical Center Bethesda**  
**Uniformed Services University of Health Sciences**  
**School of Medicine**  
**Bethesda, Maryland**

**WORK EXPERIENCE**

- 1999-present: Gastroenterology Staff Physician,  
Walter Reed National Military Medical Center Bethesda  
Bethesda, Maryland
- 2003-present: Assistant Professor of Medicine,  
Uniformed Services University of the Health Sciences  
Bethesda, Maryland
- 2001-2003: Deputy Division Director, Division of Anti-inflammatory, Analgesic  
and Ophthalmic Drug Products, Center for Drug Evaluation and  
Research,  
Food and Drug Administration  
Silver Spring, Maryland
- 1998-2000: Medical Officer, Division of Gastrointestinal and Coagulation Drug  
Products, Center for Drug Evaluation and Research,  
Food and Drug Administration  
Silver Spring, Maryland
- 1987-1998 Gastroenterology solo private practice  
Tampa, Florida
- 1994-1998 Chairman, Division of Gastroenterology,  
University Community Hospital  
Tampa, Florida
- 1993-1998 Member,  
J.A.E.B Center for Health Research, Independent I.R.B.  
Tampa, Florida

**EDUCATION**

- 1980 University of Maryland, M.D.  
1976 University of Pennsylvania, B.A. International Affairs, Summa cum laude

### **POSTGRADUATE TRAINING**

- 1986-1987 Senior Fellowship Training in Therapeutic Endoscopic Retrograde Cholangiopancreatography  
Meir Hospital, Israel
- 1984-1986 Fellowship in Gastroenterology  
Boston University Hospital and Boston City Hospital
- 1983-1984 Research and Clinical Nutrition Fellowship  
Harvard University/Massachusetts Institute of Technology

Original research project: Evaluated aspects of bioavailability of selenium when delivered via the enteral and parenteral routes. The study was conducted on inpatient volunteers at the Massachusetts Institute of Technology at the Clinical Research Center. I.R.B. approval and adherence to regulatory and safety protocols was required. Active participation in research conferences and authorship of back round section of five year multimillion dollar interventional study on dietary fat and breast cancer.

- 1980-1983 Intern, Junior Assistant Resident, Senior Assistant Resident,  
Internal Medicine  
University of Maryland Hospital

### **APPOINTMENTS**

- 2003- present Assistant professor of Medicine, Uniformed Services University of Health Sciences School of Medicine
- 1999-present Attending Staff, Division of Gastroenterology Walter Reed National Military Medical Center National Naval, Bethesda, Maryland
- 1983-1984 Nutrition Research Fellow  
Harvard University School of Medicine
- 1984 Department of Nutrition, Clinical Research Fellow  
Massachusetts Institute of Technology
- 1983-1984 Associate in Medicine  
Boston University Medical Center

### **CERTIFICATION AND LICENSURE**

- 1999-present Maryland Medical Licensure  
1986- 2011 Florida Medical License

1987 Board Certified in Gastroenterology  
1983 Board Certified in Internal Medicine  
1983-1987 Massachusetts Medical Licensure  
1981 Diplomat, National Board of Medical Examiners

### **HONORS AND AWARDS**

2003 FDA Award of Excellence  
1999 FDA Special Recognition Award FDA  
1980 Dean's Fellowship: University of Maryland School of Medicine  
1976 Phi Beta Kappa

### **PUBLICATIONS**

1. Rogers, E.L., Iseri O., Bustin, M., Goldkind, S.F., **Goldkind, L.**, *Adenocarcinoma of the Esophagogastric Junction: A Distinct Entity.* American Association for the Study of Liver Disease, Gastroenterology Research Group, May 1981.
2. Rogers, E.L., **Goldkind, L.**, Goldkind, S.F., *Increasing Frequency of Esophageal Cancer Among Black Male Veterans*, CANCER, 1982;49:610-617.
3. **Goldkind, L.**, Cave, D.R., Jaffin, B., et. al., *A New Factor in Enteric Hyperoxaluria: Oxalobacter Formigens*, American College of Gastroenterology, October 1985.
4. Rogers, E.L., Goldkind, S.F., **Goldkind, L.**, et.al., *Adenocarcinoma of the Lower Esophagus*, Journal of Clinical Gastroenterology, 1986;8:613-618.
5. **Goldkind, L.**, *Rofecoxib versus placebo ulcer rates.* Editorial, Gastroenterology, 2000;118:638-639.
6. Brinker, A., **Goldkind, L.**, Bonnel, R., Beitz, J., *Spontaneous Reports of Hypertension Leading to Hospitalization in Association with Rofecoxib, Celecoxib, Nabumetone and Oxaprozin*, Drug Aging, 2004;21(7): 479-484.
5. Rostrom A., **Goldkind, L.**, Laine L., *Nonsteroidal anti-inflammatory drugs and Hepatic Toxicity: A Systematic Review of Randomized Controlled Clinical Trials in Arthritis Patients*, Clinical Gastroenterology and Hepatology, May 2005;3(5):489-98.
6. **Goldkind L**, Laine L., *A Systematic Review of NSAIDs Withdrawn From the Market Due to Hepatotoxicity: Lessons Learned From the Bromfenac*

*Experience*, Pharmacoepidemiology and Drug Safety, April 2006;15(4):213-20.

7. Peura DA, **Goldkind L.**, *Balancing the gastrointestinal benefits and risks of nonselective NSAIDs*, Arthritis Res. Ther., 2005;7(Suppl 4):S7-13. Epub 2005 Sep 15.

8. **Goldkind L**, Simon, L., *Patients, their doctors: nonsteroidal anti-inflammatory drugs and the perception of risk*, Arthritis Res. Ther., 2006;8(2):105. Epub 2006 Mar 2.

9. Laine, L., **Goldkind, L.**, Curtis, S.P. Connors, L., Yanqiong, Z., Cannon C., *How common is diclofenac-associated liver injury? Analysis of 17,289 arthritis patients in a long-term prospective clinical trial*, Digestive Disease Week, 2007.

10. Moawad F.J., **Goldkind L.**, *An Unusual Case of Colonic Ischemia*, South Med J, April 2009;102(4):405-7.

11. Laine, Loren; **Goldkind, Lawrence**; Curtis, Sean P., Connors, Laurine, Yanqiong Zhang, Cannon, Christopher, *How common is diclofenac-associated liver injury? Analysis of 17, 289 arthritis patients in a long-term prospective clinical trial*, Am J Gastroenterology, 2009;104(2):356-62.

12. Moore A, Cryor B, **Goldkind L.**, et. al., *Evidence for endoscopic ulcers as meaningful surrogate endpoint for clinically significant upper gastrointestinal harm*, Clinical Gastroenterology and Hepatology, November 2009;7(11):156-63.

13. Cash BD, Young, P.E., Kikendall, J.W., Gentry, A., Itzkowitz, S.L., **Goldkind, L.**, Truesdale, M., Dykes, C., Jensen, D.W., Barlow, D.S., *Natural History of Intermediate-Sized Colon Polyps on CTC: Growth Rates Predict Histology*, Gastroenterology, May 2009;136(5): Supplement1, Page A-52.

14. Simon L, Strand V, Boers M, Brooks P, Tugwell P, Bombardier C, Fries J, Henry D, **Goldkind L**, Guyatt, Laupacis A, Lynd L, MacDonald T, Mamdani M, Moore A, Saag K, Sillman A, Stevens R, Tyndall A., *How to Ascertain Drug Safety in the Context of Benefit. Controversies and Concerns*, J Rheumatol., September 2009;36(9):2114-2121.

15. Armbruster S, **Goldkind L.**, *A 5-Year Retrospective Review of Experience With Clostridium difficile-Associated Diarrhea*, Military Medicine, April 2012;177(4):456-9.

16. Cirigliano, Vito, and **Lawrence Goldkind**, *Chronic Granulomatous Colitis Following Coffee Enema*, American Journal of Gastroenterology, Vol. 108. 75 Varik St. 9<sup>th</sup> FLR, New York, New York 10013-1917 USA: Nature Publishing Group, 2013.

## **PRESENTATIONS (oldest to most recent)**

### *Clinical trial design for outcome trials on cardiovascular risk*

International Workshop on COX-2 sponsored by the International COX-2 Study Group 1/28/-2/30/05  
Arlington Virginia

### *Pharmacovigilance*

American College of Rheumatology, Innovative Therapies in Rheumatology  
3/4/05  
Washington DC

### *Functional Dyspepsia: Regulatory insights*

World Congress of Gastroenterology  
September 2005

### *Causality Assessment in Drug Safety Assessment*

Outcome Measures in Rheumatology  
OMERACT  
University of Ottawa, Ontario Canada  
May 27, 2008

### *Case presentation: Amitiztia: Anatomy of a first cycle approval*

American Course on Drug Development and Regulatory Sciences (ACDRS5)  
University of California San Francisco, School of Pharmacy  
January 13, 2009 Washington DC

## **FDA and Health Canada Advisory Committee Meetings** **Primary Presentation**

1998: Review of Gastrointestinal safety studies of Celecoxib

1999: Review of Gastrointestinal safety studies of Rofecoxib

2000: Review of Studies for heartburn treatment/prevention: omeprazole for OTC

2001: Review of outcome studies CLASS and VIGOR for labeling changes related to Cox-2 and NSAID safety

2001: Update of Advisory committee and guidance on large outcome studies

2002: Presentation and discussion of Analgesic Drug Development

2002: Presentation Safety of NSAID and COX-2 inhibitors: Health Canada

2003: Safety review of post-marketing studies leflunomide

2010: Regulatory history of NSAID GI safety claims

- FDA primary review experience with gastrointestinal drug products including therapy for inflammatory bowel disease, proton pump inhibitors, H2 receptor antagonists for the indications of nonulcer dyspepsia, heartburn, peptic ulcer disease, ulcer prevention, analgesics (including

- NSAID, COX-2 specific inhibitors as well as non-NSAID analgesics)
- FDA supervisory review and regulatory decision making for all anti-inflammatory and analgesic drug products.

### **PAST JOURNAL REVIEW BOARD**

Gastroenterology  
Clinical Gastroenterology and Hepatology  
Pharmacoepidemiology and Drug Safety  
Arthritis and Rheumatology Research  
Biomedical Central Gastroenterology