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Current positions

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

Goldkind Consulting, L.L.C.

Regulatory and scientific consultant with extensive experience in:

- FDA-regulated drug development, including design of clinical trials and concomitant drug development programs**
- Regulatory decision-making as FDA Division Director**
- Safety analysis of investigational and marketed drugs**
- FDA Guidance development**
- FDA regulatory and scientific working groups**

Professional Work Experience

- 2003- present Associate professor of Medicine
Uniformed Services University of Health Sciences School of
Medicine
Bethesda, Maryland
- 2001-2003: Acting Division Director, Division of Anti-inflammatory, Analgesic
and Ophthalmic Drug Products,
Center for Drug Evaluation and Research,
Food and Drug Administration
Silver Spring, Maryland
- 1999-present Attending Staff, Division of Gastroenterology
Walter Reed National Military Medical Center Bethesda
Bethesda, 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
- 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
- 1987-1998 Gastroenterology private practice
Tampa, Florida
- 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
Boston, Massachusetts
- 1983-1984 Clinical Research Fellow,
Department of Nutrition,
Harvard University School of Medicine
Boston, Massachusetts
- 1983-1984 Associate in Medicine
Boston University Medical Center
Boston, Massachusetts
- 1980-1983 Intern, Junior Assistant Resident, Senior Assistant Resident,
Internal Medicine
University of Maryland Hospital
Baltimore, Maryland

Education

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

Certificate 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 (oldest to newest)

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*, 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.

7. Womeldorph, C. and Goldkind, L., *Etanercept and Inflammatory Bowel Diseases: Friend or Foe* American Journal of Gastroenterology 2004;99(10):S175-176.
8. 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.
9. **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.
10. Peura DA, **Goldkind L.**, *Balancing the gastrointestinal benefits and risks of nonselective NSAIDs*, Arthritis Res. Ther. 2005;7(Suppl 4):S713. Epub 2005 Sep 15.
11. **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.
12. 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.
13. Cash, B.D., Kim, C., Jensen, D., Cullen, P., Kikendall, J.W., Scott T., Itzkowitz, S. L., Lee, D., Kurland, J.E., Goldkind, L., Barlow, D., *Accuracy of computed tomographic colonography for colorectal cancer screening in asymptomatic individuals* Gastroenterology 2007;132(4):A92.
14. Moawad F.J., **Goldkind L.**, *An Unusual Case of Colonic Ischemia* South Med J April 2009;102(4):405-7.
15. 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.

16. 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.
17. Cash B.D., 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.
18. 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.
19. Armbruster S, **Goldkind L.**, *A 5-Year Retrospective Review of Experience With Clostridium difficile-Associated Diarrhea* Military Medicine April 2012;177(4):456-9.
20. Cirigliano, Vito, and **Goldkind**, *Chronic Granulomatous Colitis Following Coffee Enema*, American Journal of Gastroenterology Vol. 108. 75 Varik St. 9th FLR, New York, New York 10013-1917 USA: Nature Publishing Group, 2013.
21. Mellor, T., Harris, N. **Goldkind, L.**, *Severe Abdominal Pain and Intestinal Edema Due to Hypoalbuminemia: 1077* American Journal of Gastroenterology 2015;110:S468.
22. Collins, J., Albert, D., Singla, M., **Goldkind, L.**, *A Tubo-Ovarian Abscess Identified via Colonoscopy: 511* American Journal of Gastroenterology 2015;110:S221-S222.
23. Albert, D., Collins, J., Singla, M., **Goldkind, L.**, *Chronic Recurrent Intestinal Pseudo-Obstruction Successfully Treated with Methylnaltrexone: Presidential Poster: 337* American Journal of Gastroenterology 2015;110:S148.
24. Zibert, K., and **Goldkind, L.**, *Isolated Jejunal Vasculitis in a Young Man* American Journal of Gastroenterology 2016;111:S1001-1002.
25. Harrison, N., and **Goldkind, L.**, *Gastric Ischemia: An Under-Recognized Cause of Upper GI Bleeding?* American Journal of Gastroenterology 2017;112:S1043.

26. Gerlach, R., **Goldkind, L.**, Ng, J., Sager, P., *Tegaserod Cardiovascular Safety Analysis: Importance of a Methodologic Approach to Drug Safety Analysis* American Journal of Gastroenterology 2018;113:S268.
27. **Goldkind, L.**, Gerlach, R., Zou, H. Howden, C.W., *Efficacy of Tegaserod in IBS-C: Original RCTs and Reanalysis in Patients with Severe Symptoms: 467* American Journal of Gastroenterology 2018;113:S269-S270.
28. Harrison, N., Davis, S., **Goldkind, L.**, *Under Pressure: Obscure Bleeding due to Small Bowel Varices: 2016* American Journal of Gastroenterology 2018;113:S1140-S1150.
29. Shumar J, Junga Z, **Goldkind L**, "Treatment Resistant Grade III Capecitabine-Induced Diarrhea Highlighting the Therapeutic Efficacy of Oral Budesonide," British Journal of Medicine Case Reports 2019;12(11).
30. Howden, C.W., Gerlach, R., Byers, A., Zou, H. **Goldkind, L.**, "Time to Onset of Tegaserod Effect on IBS-C Patients' Global Assessment of Symptom Relief" Gastroenterology 2019;Mo1546.
31. Di Bisceglie, A., Harrison, S., Gunn, N., Kohli, A., Liu, L., Flyer, A., Goldkind, L., "A Phase 2, Randomized Controlled Trial of Berberine(BUDCA) in Patients with Presumed Non-Alcoholic Steatohepatitis (NASH) and Type 2 Diabetes
<https://www.nature.com/articles/s41467-021-25701-5>

Presentations (oldest to newest)

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: Amitizia: 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 Advisory Committee Meeting Presentations (oldest to newest)

1998: Gastrointestinal safety studies of Celecoxib

1999: Gastrointestinal safety studies of Rofecoxib

2000: Studies for heartburn treatment/prevention: omeprazole for Over the Counter

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

2001: Update of Advisory Committee on large outcome studies

2002: Analgesic Drug Development

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

2003: Analysis of safety of leflunomide

2010: Regulatory history of NSAID GI safety claims

Past Journal Review Boards

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