#### **CURRICULUM VITAE**

# Michael S. Epstein, M.D., F.A.C.G., A.G.A.F., A.M.E.

Investigative Clinical Research 621 Ridgely Avenue, Suite 403 Annapolis, MD 21401 Digestive Disorders Associates 621 Ridgely Avenue, Suite 201 Annapolis, MD 21401 Maryland Diagnostic & Therapeutic Endoscopy Center 621 Ridgely Avenue, Suite 101 Annapolis, MD 21401

Office: (410) 224-4887 ext. 444

Fax: (410) 266-7144 michael@icrmd.com

#### **EDUCATION AND TRAINING**

1984 - 1986Fellowship in Gastroenterology and Hepatology Washington, D.C. Veterans Administration Medical Center Director: Leonard B. Seef, M.D. 1981-1984 **Internship and Residency Program** Washington, D.C. George Washington University Hospital and School of Medicine Director: Gorge G. Rios, M.D. 1977-1981 **Doctor of Medicine** Newark, NJ Robert Wood Johnson School of Medicine, New Jersey College of Medicine and Dentistry 1973-1977 Bachelor of Arts with Distinction Boulder, CO University of Colorado

Molecular, Cellular, Developmental Biology

#### **CURRENT STATUS**

Founder and President, Investigative Clinical Research, Annapolis, MD
Member, IRB Company
Aviation Medical Examiner, FAA
Special Government Employee and Consultant, Gastrointestinal Drugs
Advisory Committee
Fellow, American Gastroenterology Association
Fellow, American College of Gastroenterology
Staff Gastroenterologist, Baltimore Washington Medical Center
Founder and President, Maryland Diagnostic & Therapeutic Endo
Center (MDTEC), Annapolis, MD
Principal Physician, Digestive Disorders Associates, Annapolis, MD
Staff Gastroenterologist, Anne Arundel Medical Center, Annapolis, MD
Assistant Professor of Medicine, Uniformed Services of Health Science,
Bethesda, MD



## **CURRENT LICENSURE**

Maryland license number D0034426, September 1986

## **BOARDS CERTIFICATION**

1987	American Board of Internal Medicine, subspecialty of Gastroenterology
1984	American Board of Internal Medicine

### PREVIOUS PROFESSIONAL POSITIONS

2006-2009	Member, Gastrointestinal Drugs Advisory Committee of the FDA
1988-2007	Member, American Gastroenterology Association
1996-2007	Vice President and Medical Director, AmeriTrial OTC Research Inc.
2003-2006	Acting Medical Director, First Circle Medical
2000-2004	Member, Board of Trustees, Anne Arundel Medical Center
2002-2004	Member, FDA Gastrointestinal and Urologic Device Panel
2000-2002	President, Medical Staff of Anne Arundel Medical Center
1999-2001	President, Medical Board Executive Committee, AAMC, Annapolis, MD
1998-2000	Vice President, Medical Board Executive Committee, Anne Arundel
	Medical Center Annapolis, MD
1998-2000	Vice President, Anne Arundel County Medical Society
1997-1999	Secretary/Treasurer, Medical Board Executive Committee, AAMC
1997-1998	Secretary, Anne Arundel County Medical Society
1995-1998	President, Maryland Ambulatory Surgery Association
1995-1999	Chairman, Anne Arundel Medical Center Institutional Review Board
1988-1995	Member, American College of Gastroenterology
1994-1995	Member at Large, Medical Executive Board, AAMC, Annapolis, MD
1990-1992	Board Member, Anne Arundel Medical Center, Annapolis, MD
1990-1992	President, Medical Staff, Anne Arundel Medical Center, Annapolis, MD
1989-1990	IRB Chair, Anne Arundel Medical Center, Annapolis, MD
1986-1990	Staff Gastroenterologist, Malcolm Grow USAF Medical Center,
	Andrews Air Force Base, Largo, MD
AWARDS	
2009	US FDA Advisory Committee Service Award
1992	Meritorious Service Medal USAF
1992	AMA Physicians Recognition Award



#### **CONSULTING CLIENTS** (Partial List)

## **Pharmaceutical Corporations**

- Proctor and Gamble Pharmaceutical
- Given Imaging
- Anesta Corporation
- McNeil Pharmaceutical
- Merck and Co. Inc.
- Roche Pharmaceutical
- Sucampo
- Allergan
- Abbott (Abbvie) Pharmacheticals
- Zx Pharmaceuticals
- Eli Lilly
- Vertice Pharmaceuticals
- Ferring Pharmaceuticals
- Otsuka America Pharmaceuticals
- Knsyl Pharmaceuticals

#### **Device Manufacturers**

- Proteus Biomedical
- Ethicon Endosurgical
- Medigus
- Betastim Ltd. Life Sciences
- GI View Ltd.
- EVASC Medical Systems
- Precision Endoscopic Therapeutics

#### **Legal Firms**

- Baker, Donelson, Bearman, Caldwell, & Berkowitz, PC, *Jackson, MS*
- Nutter, McClennen, & Fish, LLP, Boston, MA
- Lisa S. Levine, P.A., Weston, FL
- Frommer Lawrence & Huang, LLP, New York, NY
- Dickstein Shapiro, New York, NY
- Hogan & Harston, Washington, D.C.
- Keating Jones Hughes, PA, Portland, OR
- Latham Watkins, LLP, Washington D.C. & San Francisco, CA



#### PERSONAL DATA

Born: December 30, 1955, Ft. Meade, Maryland

Children: Lauren J. Epstein, October 17, 1986

Stephen D. Epstein, October 1, 1989 Rachelle A. Epstein, August, 9, 1991

Hobbies: Water skiing, skiing, aviation

#### **PUBLICATIONS**

1. Cash, B.D., Moncrief, M.B.C., **Epstein, M.S**. *et al.* Patient experience with NER1006 as a bowel preparation for colonoscopy: a prospective, multicenter US survey. *BMC Gastroenterol* **21**, 70 (2021).

- 2. **Epstein, M.**, Johnson, D., Hawes, R., Schmulewitz, N., Vanagunas, A., Gossen, R., Eaton, S., Robieson, W., Dubow, J., Chatamra, K., & Benesh, J. Gastrointestinal safety of levodopa-carbidopa intestinal gel system in advanced Parkinson's Disease. *Movement Disorders*. (in press)
- 3. Cash, B. D., **Epstein, M. S.,** & Shah, S. M. (2016). A novel delivery system of peppermint oil is an effective therapy for irritable bowel syndrome symptoms. *Digestive Diseases and Sciences*, 61(2), 560-571.
- 4. Cash, B. D., **Epstein, M. S.**, & Shah, S. M. (2016). Patient Satisfaction with IBS Symptom Relief Using a Novel Peppermint Oil Delivery System in a Randomized Clinical Trial and in the General Population. *International Journal of Digestive Diseases*, 2(2), 227.
- 5. **Epstein, M.,** Johnson, D. A., Hawes, R., Schmulewitz, N., Vanagunas, A. D., Gossen, E. R., Robieson, W.Z., Eaton, S., Dubow, J., Chatamra, K., & Benesh, J. (2016). Long-term PEG-J Tube safety in patients with advanced Parkinson's disease. *Clinical and Translational Gastroenterology*, 7(3), e159.
- 6. **Epstein, M.S.**, Ehrenpreis, E.D., & Kulkarni, P.M. (2014). Biosimilars: the need, the challenge, the future: the FDA perspective. *The American Journal of Gastroenterology*, 109(12), 1856-1859.
- 7. McLemore, E.C., Rai, R., Siddiqui, J., Basu, P., Tabbba, M., & **Epstein M.S.** (2012). Novel endoscopic delivery modality of infrared coagulation therapy for internal hemorrhoids. *Surgical Endoscopy*, 26(11), 3082-3087.
- 8. Au-Yeung, K.Y., Moon, G.D., Robertson, T., DiCarlo, L.A., **Epstein, M.S.**, Weis, S.E., Reves, R.R., & Engel, G. (2011). Early clinical experience with networked system for promoting patient self-management. *American Journal of Managed Care*, 17(7), e277-e287.
- 9. Jacobson, I. M., Brown, R. S., Freilich, B., Afdhal, N., Kwo, P. Y., Santoro, J., Becker, S., Wakil, A.E., Pound, D., Godofsky, E. Strauss, R., Bernstein, D., Flamm, S., Pauly, M.P., Mukhopadhyay, P., Griffel, L.H., & Brass, C.A. (2007). Peginterferon alfa-2b and weight-based or flat-dose ribavirin in chronic hepatitis C patients: A randomized trial. *Hepatology*, 46(4), 971-981.
- 10. **Epstein, M.S.** (1995). Munchausen syndrome: Case reports and literature overview. *Maryland Medical Journal*, *44*(1), 39-43.



- 11. Devaney, K., Goodman, Z.D., **Epstein, M.S.**, Zimmerman, H.J, & Ishak, K.G. (1993). Hepatic sarcoidosis: clinicopathologic features in 100 patients. *The American Journal of Surgical Pathology*, 17(12), 1272-1280.
- 12. **Epstein, M.S.**, Ingram, C.W., Borts, F.W., Korman, L.Y., & Seef, L.B. (1986). Retrospective and prospective analysis of focal defects demonstrated by computerized tomography. *Gastroenterology*, *90*(5), 1724.

#### **ABSTRACTS**

- 1. Bertiger, G., **Epstein, M.,** Marshall, D., & Dahdal, D. (2016). A low-volume sodium picosulfate and magnesium citrate bowel preparation has no effect on cardiovascular parameters in patients preparing for colonoscopy. Seattle, WA.
- 2. Draganov, P., **Epstein, M.**, Hawes, R. Johnson, D., Vanagunas, A., Robieson, W.Z., Chatamra, K., Benesh, J.A., & Eaton, S. (2016). Short- and long-term safety of PEG-J used for continuous infusions of levodopa-carbidopa intestinal gel. Vancouver, BC, Canada.
- 3. **Epstein, M.S.**, Clayton, L., Ng, R., & DeMicco, M. (2016). Efficacy and safety of the novel 1L PEG and ascorbate bowel preparation NER1006 versus standard 2L PEG with ascorbate in overnight or morning split-dosing administration: results from the phase 3 study. San Diego, CA.
- 4. **Epstein, M.**, Willey, R., Almansa, C., & Dahdal, D. Efficacy, safety and patient-reported tolerability of sodium picosulfate plus magnesium citrate in patients with previous bowel preparation experience. San Antonio, TX.
- 5. **Epstein, M.S.**, Clayton, L., Ng, R., & DeMicco, M. (2016). Efficacy and safety of the novel 1L PEG and ascorbate bowel prearation NER1006 versus trisulfate solution in overnight split-dosing administration: results from the phase 3 study NOCT. Vienna, Austria.
- 6. Poordad, F., Sedghi, S., Pockros, P.J., Ravendrhan, N., Reindollar, R, Lucey, M.R., **Epstein, M.**, Bank, L., Bernstein, D., Trinh, R., Krishnan, P., Piolot-Matias, T., Polepally, A.R., Pothacamury, R.K., Rajvineeth, K., Martinez, M., & Nelson, D.R. (2016). GEODE-II: Efficacy and safety of ombitasvir/paritaprevir/ritonavir and dasabuvir with low-dose ribavirin QD in patient with genotype 1a chronic hepatitis C virus infection without cirrhosis. Paris, France.
- 7. Poordad, F., Sedghi, S., Pockros, P.J., Ravendrhan, N., Reindollar, R, Lucey, M.R., **Epstein, M.**, Bank, L., Bernstein, D., Trinh, R., Krishnan, P., Piolot-Matias, T., Polepally, A.R., Pothacamury, R.K., Rajvineeth, K., Martinez, M., & Nelson, D.R. (2016). GEODE-II: Efficacy and safety of ombitasvir/paritaprevir/ritonavir and dasabuvir with low-dose ribavirin QD in patient with genotype 1a chronic hepatitis C virus infection without cirrhosis. Boston, MA.
- 8. Bertiger, G., **Epstein, M.,** Hutson-Walker, A., Almansa, C., & Dahdal, D.N. (2016). Comparison of bowel preparation quality scales used in randomized controlled trials of patients undergoing colonoscopy. Las Vegas, NV.
- 9. Vanagunas, A., Draganov, P., Schmulewitz, N., **Epstein, M.**, Hawes, R., Johnson, D., Benesh, J.A., Chatamra, K., Easton, S., Facheris, M.F., Hall, C.M., & Robieson, W.Z. (2016). Multi-year safety and durability of PEG-J used for continuous infusion of



# DOCKET

# Explore Litigation Insights



Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

# **Real-Time Litigation Alerts**



Keep your litigation team up-to-date with **real-time** alerts and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

# **Advanced Docket Research**



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

# **Analytics At Your Fingertips**



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

#### API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

#### **LAW FIRMS**

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

#### **FINANCIAL INSTITUTIONS**

Litigation and bankruptcy checks for companies and debtors.

### **E-DISCOVERY AND LEGAL VENDORS**

Sync your system to PACER to automate legal marketing.

