

**The Faculty of Medicine of Harvard University  
Curriculum Vitae**

**Date Prepared:** October 10, 2024  
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**Education:**

9/1978-6/1982	B.S. Magna cum laude	Pharmacy	Massachusetts College of Pharmacy and Allied Health Sciences
9/1996 -9/1999	Pharm.D. Summa cum laude	Pharmacy	Massachusetts College of Pharmacy and Health Sciences
1/2021- 7/2021	Certificate	Medical Writing	University of Connecticut, School of Pharmacy

**Postdoctoral Training:**

4/1996-5/1996	Fellow	Nutritional Support Preceptorship	University of Florida, College of Pharmacy, Shand's Clinic, Gainesville, FL
3/1999-6/1999	Intern	Nutrition/Alternative Medicine	Marino Center for Progressive Medicine, Cambridge, MA

**Faculty Academic Appointments:**

9/1999-8/2000	Adjunct Instructor (non-voting)	Pharmacy Practice	Massachusetts College of Pharmacy and Health Sciences, Boston, MA
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9/2002-8/2009	Adjunct Assistant Professor (non-voting)	Pharmacy Practice	Massachusetts College of Pharmacy and Health Sciences, Boston, MA
9/2007-Present	Adjunct Assistant Professor (non-voting)	Pharmacy Practice	Bouvé College of Health Sciences, Northeastern University, Boston, MA
9/2003-8/2006	Preceptor	Experiential Education	University of North Carolina College of Pharmacy at Chapel Hill, NC
9/2004- Present	Preceptor	Experiential Education	University of Washington, School of Pharmacy, Seattle, WA
9/2004- Present	Preceptor	Experiential Education	Washington State University, College of Pharmacy, Dept. of Pharmacotherapy, Spokane, WA
9/2006 -6/2022	Adjunct Assistant Professor (non-voting)	Pharmacotherapy and Experimental Therapeutics	School of Pharmacy, University of North Carolina at Chapel Hill, NC
9/2005-12/2024	Gratis Adjunct Clinical Assistant Professor (non-voting)	Pharmacy Practice	School of Pharmacy, University of Connecticut, Storrs, CT
9/2009-8/2019	Adjunct Associate Professor (non-voting)	Pharmacy Practice	Massachusetts College of Pharmacy and Health Sciences, Boston, MA
9/2019- Present	Adjunct Associate Professor (non-voting)	Pharmacy Practice	MCPHS University, Boston, MA
11/2016 – Present	Assistant Professor	Pediatrics	Harvard Medical School, Boston, MA

**Appointments at Hospitals/Affiliated Institutions:**

10/1982-3/1984	Clinical Staff Pharmacist	Department of Pharmacy	Children’s Hospital National Medical Center, Washington, DC
3/1984-9/1987	Staff Pharmacist II	Department of Pharmacy	Boston Children's Hospital
9/1987-12/2000	Clinical Pharmacist/ Sterile Products Manager	Department of Pharmacy	Boston Children's Hospital
9/1987- Present	Clinical Pharmacist	Division of Gastroenterology, Hepatology & Nutrition	Boston Children's Hospital
7/1999- Present	Clinical Pharmacist	Department of Surgery, Center for Advanced	Boston Children's Hospital

12/2000-7/2015	Team Leader	Intestinal Rehabilitation (CAIR) Department of Pharmacy	Boston Children's Hospital
9/2009-Present	Clinical Pharmacist	Division of Critical Care Medicine	Boston Children's Hospital
7/2015- Present	Manager, Clinical Research	Department of Pharmacy	Boston Children's Hospital

**Faculty Membership in Harvard Initiatives, Programs, Centers, and Institutes**

2021- Present	Faculty	Division of Nutrition	Harvard Medical School
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**Other Professional Positions:**

1996-1998	Pharmaceutical Advisory Board	Baxa Corporation
1996-1998	Pharmaceutical Advisory Board	Abbott Pharmaceuticals
2007	2007 United States Pharmacopeia, Disinfectants and Cleaning in the ISO Class 5 Environment USP <797> Ad Hoc Advisory Panel Member	United States Pharmacopeia
2008-2011	Pharmaceutical Advisory Board	Baxa Corporation
2008-2009	Professional Advisory Board	Nutrithrive
2010-2016	Pharmaceutical Advisory Board	B. Braun
2010-2020	Data and Safety Monitoring Board: Compassionate Use of an Intravenous Fat Emulsion Comprised of Fish Oil in the Treatment of Parenteral Nutrition Induced Liver Disease (PNALD)	Texas Children's Hospital, Baylor College of Medicine
2010-2015	Consultant, Global Health Primary Health Care Initiative	Bach Mai Hospital (Hanoi, Viet Nam), Abbott Fund, Boston University School of Medicine, National Institute of Nutrition and Hanoi Medical University
2012-2018	Scientific Advisory Board	Pronova Biopharma (BASF)
2013-2015	Scientific Advisory Board	Alkymos

2014-2016	Scientific Advisory Board	Sancilio and Company	
2014-2020	Nutrient Specifications Working Group, Evaluating the evidence base to support guidelines for the nutritional care of preterm infants -“The Pre-B Project”	Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)/NIH	
2015-2020	Parenteral Nutrition Safety Expert Panel	United States Pharmacopeia (USP)	
2017-2020	Special Government Employee (SGE)/Consultant	Pharmacy Compounding Advisory Committee (PCAC). US Food and Drug Administration (FDA)	
2018	Consultant	Pfizer Pediatric Center of Excellence and Consumer Health and Healthy Living Work	
2018-2020	Consultant	Xellia Pharmaceuticals SA LLC	
2018-Present	Consultant	Fresenius Kabi	2 hours/month
2018- 2019	FDA Network of Experts	AASLD Experts on Cysteine Supplementation on patients with parenteral nutrition	
2018-Present	Consultant/Advisory Board	NorthSea Therapeutics	2 hours/month
2018-present	Consultant	Otsuka Pharmaceutical Factory	2 hours/month
2018-2019	Advisory Board	US Numeta Advisory Board/Baxter Pharmaceuticals	
2019	Pharmaceutical Advisory Board	Pfizer	
2021-2027	Pharmacy Compounding Advisory Committee	Food and Drug Administration	1 day/year
2021-Present	Consultant	Wolters Kluwer-Kelly (Lexicomp)	2 hours/month
2021	Visiting scholar	Takeda	
2021-Present	Consultant/Scientific Advisory Board	Alcresta	2 hours/month
2022	Pharmaceutical Advisory Board	B. Braun	3 hours (single event)

2022-2025	Dean's Advisory Board	Massachusetts College of Pharmacy and Health Sciences	4 hours/year
2022	Advisory Board	Takeda	2 hours (single event)
2023 -2024	Advisory Board	Baxter	2 hours/year
2023-2024	Advisory Board	Reckitt Benckiser Group/ Mead Johnson Nutrition	1 day/year
2024	Advisory Board	B Braun	3 hours (single event)

**Major Administrative Leadership Positions:**

**Local**

7/2015- Present	Manager, Clinical Research Program	Boston Children's Hospital, Department of Pharmacy
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**Committee Service:**

**Local**

1987- present	Nutrition Advisory Committee	Boston Children's Hospital, Member
1987-2014	Nursing Policies and Procedures Committee	Boston Children's Hospital, Member
1985-1999 2001- present	Nursing-Pharmacy Committee	Boston Children's Hospital, Member
1991-1995	Longwood Herbal Task Force	Boston Children's Hospital, Member
1991	CVC Occlusion Task Force	Boston Children's Hospital, Member
1993-2006	Infection Control Committee	Boston Children's Hospital, Member
1993	TPN Clinical Practice Guidelines Group	Boston Children's Hospital, Member
1993-1997	NICU Committee	Boston Children's Hospital, Member
1993-1997	Medication Systems Task Force	Boston Children's Hospital, Member
1993	Enteral Nutrition Task Force	Boston Children's Hospital, Member
1994-1997	Burette Use Task Force	Boston Children's Hospital, Member
1995-1999	Pharmacy Computer Implementation Committee	Boston Children's Hospital, Member
1995-2003	Pharmacy Committee	Children's Extended Care Center, Groton, MA, Member
1995-1999 2002- present	Clinical Products Evaluation Committee	Boston Children's Hospital, Member
1996	IV Therapy Task Force	Boston Children's Hospital, Member
2000- present	Pharmacy and Therapeutics Committee	Boston Children's Hospital, Member

2003	Thrombosis Management Task Force	Boston Children's Hospital, Member
2004-2010	CHAMPS (Children's Hospital Applications Maximizing Patient Safety)	Boston Children's Hospital, Member
2008-2011	Ureteral Reimplant DRG /Clinical Practice Guidelines Committee	Boston Children's Hospital, Member
2008-2022	Phlebitis Task Force	Boston Children's Hospital, Member
2008-2021	Parenteral Nutrition Safety Task Force	Boston Children's Hospital, Member
2009	Critical Care Enteral Nutrition Task Force	Boston Children's Hospital, Member
2009-present	NICU Parenteral Nutrition Task Force	Boston Children's Hospital, Member
2011-2013	Child Healthcare Corporation of America (CHCA) IV Infiltrates Collaborative	Boston Children's Hospital, Member
2012	Ethanol Lock Task Force	Boston Children's Hospital, Member
2012	HPEN Vendor Task Force	Boston Children's Hospital, Member
2015-2018	CLABSI Task Force	Boston Children's Hospital, Member
2016-2017	Data and Safety Monitoring Board Pilot Study: Safety of Chlorhexidine (CHG) Baths in Patients Less Than 2 Months of Age	Boston Children's Hospital, Chair
2018-present	Gene Therapy Scientific Review Committee	Dana Farber Boston Children's Cancer and Blood Disorders Center, Member
2019-present	Boston Children's Hospital Institutional Centers for Clinical and Translational Research (ICCTR) Education and Training Committee	Boston Children's Hospital, Member
2019-present	Experimental Therapeutics/Interventional Trials (ET/IT) Scientific Review Committee	Boston Children's Hospital, Member
2019-present	Pharmacy Policy Committee	Boston Children's Hospital, Member
2020-2022	Clinical Research Restart Group	Boston Children's Hospital, Member
2022-present	Data and Safety Monitoring Board Initial Pain Management in Pediatric Pancreatitis Opioid vs. Non-opioid	Boston Children's Hospital, Member
2022-present	Clinical Research Council	Boston Children's Hospital, Member
2022-present	Project MOSAIC/ Epic Research Advisory Council	Boston Children's Hospital, Member
<b>Regional</b>		
2020-present	Boston Inflammatory Bowel Disease Meeting Planning Committee	Boston University Chobanian & Avedisian School of Medicine, Member
2022-2025	Dean's Advisory Board	MCPHS University, Member

## National

2007	2007 United States Pharmacopoeia, Disinfectants and Cleaning in the ISO Class 5 Environment USP <797>	United States Pharmacopeia (USP), Ad Hoc Advisory Panel Member
2014-2020	Nutrient Specifications Working Group, Evaluating the evidence base to support guidelines for the nutritional care of preterm infants - "The Pre-B Project"	Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)/NIH
2015- 2020	Parenteral Nutrition Safety Expert Panel	United States Pharmacopeia
2018-2019	AASLD Experts on Cysteine Supplementation on patients with parenteral nutrition	FDA Network of Experts
2021-2027	Pharmacy Compounding Advisory Committee (PCAC)	US Food and Drug Administration (FDA)

## Professional Societies:

1979- Present	American Society of Health-Systems Pharmacists (ASHP)	Member 1991-present, Reviewer of submissions for the Annual Meetings and Clinical Midyear 1991, 1999: Served as moderator for platform presentations 1996-2001: Massachusetts representative to ASHP House of Delegates 1998-2000: Member of Council of Professional Affairs 2000: Chair of Council of Professional Affairs 2011: Reviewer, Drug Therapy Research Awards 2017-present, Member, ASHP Section of Clinical Specialists and Scientists, Section Advisory Group (SAG) on Emerging Sciences 2018-2019: Alternate Massachusetts representative to ASHP House of Delegates Member, Pharmacy Engagement in Patient Medication Education Survey Panel
1979- Present	Rho Pi Phi Pharmaceutical Fraternity	Member
1979- Present	Massachusetts Pharmacists Association	1980-1981: Secretary Member
1981- Present	Rho Chi Pharmaceutical Honor Society	Member
1982-1984	District of Columbia Society of Hospital Pharmacists	Member 1983-1984: Program Committee
1984- Present	Massachusetts Society of Health-Systems Pharmacists	Member 1991: Membership committee

1990-  
Present

American Society for Parenteral and  
Enteral Nutrition (ASPEN)

1993-2010: Annual Meeting committee  
1999: President-elect  
2000-2001: President  
2005-2010: Board of Directors  
2016-present: Nominations Committee  
2018-present: Alternate ASHP House of  
Delegates  
Member  
1999: Nominations Committee, Pharmacy  
Practice Section  
2000-2001, 2005-2006: Multivitamin Task  
Force  
2002: Reviewer submitted papers  
2004: Reviewer, A.S.P.E.N.'s Journal  
Continuing Education programs  
2003-2005: Program Committee for 2004-  
2005 Nutrition Week  
2004: Item writer, Self-Assessment Courses  
2005-2006: Clinical Practice Awards Task  
Force  
2006-2008: Clinical Guidelines Committee  
2009-2021: Selection Committee, Serlick  
Award  
2009-2020: Novel Nutrient Task Force  
2010-2015: Rhodes Research Foundation  
Mentor  
2010: Reviewer, Pediatric Nutrition  
Support Core Curriculum  
2010: Intravenous Fat Emulsion National  
Shortage Task Force  
2011: Reviewer, Adult Nutrition Support  
Core Curriculum 3rd Edition  
2011: Cysteine Shortage Task Force  
2011-2014: Research Committee  
2011-2016: Clinical Nutrition Week  
(CNW) Program Committee  
2013 Vice chairman 2014 CNW  
2014 Chair 2015 CNW  
2012-2022: Clinical Practice Committee  
2012-present: Educational and Professional  
Development (EPD) Committee  
2012-present: A.S.P.E.N. Corporate  
Scientific Council IVFE Work group  
2014: Reviewer, A.S.P.E.N Nutrition  
Support Pharmacist Standards Guidelines  
2015 - 2021 Fellows Selection Committee  
2018- 2020 Vice Chairman  
2020- 2021 Chair  
2016-2021 Parenteral Nutrition Safety  
Committee  
2016: IV Lipid Task Force



		2017-2021: Neonatal Section, leadership council 2021-2023: Board of Directors 2021- present: Public Policy Committee 2021- present: Informatics Committee 2023-2024: Vice President
1990- Present	Longwood Medical Area Nutrition Group	Member
1994- Present	Pediatric Pharmacy Association (PPA) [formerly Pediatric Pharmacy Advocacy Group (PPAG)]	Member 1994-2019: Chairman, parenteral nutrition clinical focus group 2000-2004: Board of directors 2004-2005: Vice president, finance 2006-2011: Richard A. Helms Excellence in Pharmacy Practice Award review committee 2006: Representative to the USP Stakeholders Meeting 2007: Program Committee 2008 Annual Meeting Committee 2015-present: Recertification Program Advisory Committee 2022: Executive director search committee 2023-present: Editorial board, The Journal of Pediatric Pharmacology and Therapeutics
1995- Present	Board of Pharmaceutical Specialties	Member Item writer/reviewer, nutrition support pharmacist board certification 2008: BPS Representative APhA Academy of Student Pharmacists Midyear Regional Meeting, Boston, MA 2010-2013: Specialist member, BPS Specialty Council on Nutrition Support Pharmacy
1996-1998	Pharmacy Technician Certification Board (PTCB)	Item writer/reviewer, technician certification examination
1997-1999	Council of Pharmacists, Hospital Pharmacist Report/Drug Topics	Member
1999- present	American College of Clinical Pharmacy	Member Pediatric Self-Assessment Program (PedSAP) pilot tester
2003-2005	Pharmacy Grand Rounds Steering Committee, Massachusetts College of Pharmacy and Health Sciences, Council of Boston Teaching Hospitals	Member
2005- present	European Society for Clinical Nutrition and Metabolism	Member
2014	European Academy of Paediatrics (EAP)	Member
2014- present	American Society for Nutrition (ASN)	Member

2016-2021	Academy of Nutrition and Dietetics Evidence Analysis Workgroup for the Evidence Analysis Library (EAL)	Member
2017- present	Oley Foundation	Member, Oley Advisory Council
2019- present	The North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN)	Member. NASPGHAN Council for Pediatric Nutrition Professionals (CPNP) Member, Nutrition Committee (10/22- 10/25) Member, Intestinal Failure, Special Interest Group
2021- present	Society of Neonatal Nutrition Gut & Growth	Founding member
2021	The Institute for Safe Medication Practices (ISMP)	Expert Advisory Panel, Sterile Compounding Technology Safety Summit

### **Grant Review Activities:**

2009-2016	ASHP Research Foundation	Reviewer
2010	Health Research Board, An Bord Taighde Sláinte, Dublin, Ireland	Reviewer
2011-2014	ASPEN Rhoads Research Foundation	Reviewer
2016- present	Swiss National Science Foundation	Reviewer

### **Editorial Activities:**

#### **Ad hoc Reviewer**

American Journal of Health-System Pharmacy  
Nutrition in Clinical Care  
Best Practices for Hospital & Health-System Pharmacy  
Practice Standards Division, American Society of Health-System Pharmacists  
JPEN Journal of Parenteral and Enteral Nutrition  
NCP, Nutrition in Clinical Practice  
JPPT Journal of Pediatric Pharmacology and Therapeutics  
The Annals of Pharmacotherapy  
A.S.P.E.N. Core Curriculum  
Clinical Orthopaedics and Related Research  
Journal of Perinatology  
Nutrition  
Clinical Nutrition  
Pediatrics  
The Journal of Pediatrics  
American Journal of Infection Control  
A.S.P.E.N. Pediatric Nutrition Support Core Curriculum 1st edition  
Acta Paediatrica  
British Journal of Nutrition

Journal of the American Dietetic Association  
A.S.P.E.N. Adult Nutrition Support Core Curriculum  
European Journal of Clinical Nutrition  
The Journal of the Academy of Nutrition and Dietetics  
Nutrients  
International Journal of Medical Sciences  
Applied Physiology, Nutrition, and Metabolism  
Neonatology  
British Journal of Pharmaceutical Research  
European Journal of Pediatrics  
Expert Review of Gastroenterology & Hepatology  
Journal of Medical Case Reports  
A.S.P.E.N. Pediatric Nutrition Support Core Curriculum 2nd edition  
BMC Research Notes  
The Journal of Thrombosis and Haemostasis  
Postgraduate Medicine  
Lifeline Newsletter, Oley Foundation  
Journal of Nutrition and Health  
Jornal de Pediatria (Brazil)  
Expert Opinion on Drug Delivery  
Journal of Infection and Public Health  
International Journal of Drug Safety and Discovery  
Journal of Cardiovascular Pharmacology and Therapeutics  
Nutrition Research  
Clinical Biochemistry  
Hospital Practice  
Pharmaceutics  
Clinical Nutrition ESPEN  
Pharmacy  
Journal of Nutrition & Intermediary Metabolism  
Annals of the New York Academy of Sciences  
Hospital Pharmacist's Letter and Hospital Prescriber's Letter  
Early Human Development  
Journal of Colloid and Interface Science  
Therapeutics and Clinical Risk Management  
Journal of Pediatric Intensive Care  
The Journal of Nutrition  
Scientific Reviews  
EBioMedicine  
BMC Pediatrics  
Frontiers in Pharmacology  
PLOS One  
Frontiers in Pediatrics  
Journal of Pediatric Gastroenterology and Nutrition (JPGN)

Expert Review of Gastroenterology & Hepatology  
 JPGN Reports  
 Pediatric Transplantation  
 Journal of International Medical Research  
 Evidence-Based Complementary and Alternative Medicine  
 European Journal of Pharmaceutical Sciences for Nutrition and Cancer: An International Journal  
 BMC Medicine  
 Clinical Nutrition Open Science  
 Nutrition: The International Journal of Applied and Basic Nutritional Sciences  
 New England Journal of Medicine

**Other Editorial Roles**

2008-2016	Editorial Board	ICAN: Infant, Child, & Adolescent Nutrition
2012-2019	Editorial Board	JPEN: Journal of Parenteral and Enteral Nutrition
2013-Present	Editorial Board	AJIC American Journal of Infection Control
2019-2021	Associate Editor	JPEN: Journal of Parenteral and Enteral Nutrition
2023-Present	Editorial Board	JPPT: Journal of Pediatric Pharmacology and Therapeutics

**Honors and Prizes:**

1979	Rho Chi First Year Award	Massachusetts College of Pharmacy (MCP)	National Pharmaceutical Academic Honor Society
1979	Rho Pi Phi First Year Award	MCP	Pharmaceutical Fraternal Society
1980	1 <sup>st</sup> Year Award	Massachusetts Society of Hospital Pharmacists	
1981	Rho Chi Honor Society	MCP	National Pharmaceutical Academic Honor Society
1981	Rho Chi Third Year Award	MCP	National Pharmaceutical Academic Honor Society
1994	Practitioner Excellence Award	Massachusetts Society of Health System Pharmacists	
2001	Fellowship appointment	American Society of Health-System Pharmacists	
2007	Innovative Pharmacy Practice Award	Massachusetts Pharmaceutical Association	Research

2007	Best of the New Award	Boston Globe	Research
2008	Stanley Serlick Award	American Society for Parenteral and Enteral Nutrition	For significant contributions to improving safe practices for parenteral nutrition
2009	The 2009 Drug Therapy Research Award	American Society of Health Systems Pharmacists	For an Outstanding Contribution to the Research Literature Related to Drug Therapy in Health Systems (For the manuscript, "Safety and efficacy of a fish oil-based fat emulsion in the treatment of parenteral nutrition-associated Liver Disease," reference #14)
2010	2009 Top 5 Papers of the Year	Journal of Parenteral and Enteral Nutrition	For the manuscript, "Fish oil-based lipid emulsions prevent and reverse parenteral nutrition-associated liver disease: The Boston experience." (reference #16)
2010	MSHP Outstanding Service Award	Massachusetts Society of Health System Pharmacists	
2011	2010 Top Cited Papers of the Year	Metabolism: Clinical and Experimental	For the manuscript, "Effects of glucose or fat calories in TPN on systemic inflammation and fat metabolism in rats." (reference #24)
2011	Fellowship appointment	Pediatric Pharmacy Association (formerly Pediatric Pharmacy Advocacy Group)	
2012	Distinguished Nutrition Support Pharmacist Award	American Society for Parenteral and Enteral Nutrition	Contributions to the practice of nutrition support pharmacy
2013	Fellowship appointment	American Society for Parenteral and Enteral Nutrition	
2018	2018 Clinical Nutrition Team of Distinction Award	American Society for Parenteral and Enteral Nutrition	
2019	2019 Best in Care Award (nominee, CAIR program)	Boston Children's Hospital	Recognizes the significant contributions made team members. Our patients and

			families recognize staff members and volunteers who embody the following principles of patient- and family-centered care: respect, information sharing, compassion and participation.
2019	Fellowship appointment	Massachusetts Society of Health System Pharmacists	
2020	ASPEN Champion	American Society for Parenteral and Enteral Nutrition	In recognition of her significant and sustained contributions to the association.
2020	HPN Research Prize	Oley Foundation	For the manuscript, "Intravenous Fish Oil Monotherapy as a Source of Calories and Fatty Acids Promotes Age-Appropriate Growth in Pediatric Patients with Intestinal Failure-Associated Liver Disease"
2020	The Richard A. Helms Award of Excellence in Pediatric Pharmacy Practice	Pediatric Pharmacy Association	For exemplary pediatric patient care, sustained and meritorious contributions to pediatric pharmacy practice, sustained and meritorious contributions to PPA, contributions to education, precepting, and/or mentorship, and contributions of new knowledge (scholarship)
2022	HPN Research Prize	Oley Foundation	For the manuscript, "Fish Oil Emulsion Reduces Liver Injury and Liver Transplantation in Children with Intestinal Failure-Associated Liver Disease: A Multicenter Integrated Study"
2023	HPN Research Prize	Oley Foundation	For the manuscript, "4% Tetrasodium-EDTA and Catheter Complication Rates in a High-Risk Population of Pediatric Intestinal Failure Patients"

2024	Bowl of Hygeia	Massachusetts Pharmacists Association	Recognizes pharmacists who possess outstanding records of civic leadership in their communities and encourages pharmacists to take active roles in their communities. It is considered one of the profession's most prestigious awards
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**Report of Funded and Unfunded Projects**

**Past**

2006-2009	<p>Efficacy of Omega-3 enriched fat emulsions in the prevention of parenteral nutrition induced liver injury in infants (Prospective randomized trial)  March of Dimes (Puder, PI)  Co-PI (\$256,086/total directs)  Efficacy of Omega-3 enriched fat emulsion in the prevention of PNALD in infants.  The goals of this project were: 1) To determine whether the parenteral administration of an omega-3 fatty acid-based fat emulsion reduces the proportion of cholestasis in infants. 2) Describe biochemical tests of liver function profiles over time in the two treatment groups. 3.) To assess the safety and tolerability of an omega-3 fatty acid-based fat emulsion (Omegaven) as opposed to a conventional fat emulsion (Intralipid®).</p>
2008-2012	<p>Cholestasis Prevention: Efficacy of IV Fish Oil  FDA, R01 FD003436  Co-PI (\$262,745/total direct) (Puder, PI)  The goals of this project were to determine the safety and efficacy of preventing parenteral nutrition associated liver disease with a fish oil-based emulsion.</p>
2010-2012	<p>An initial trial of enteral fish oil supplementation in the treatment of intestinal failure-associated liver disease.  Harvard Catalyst   The Harvard Clinical and Translational Science Center (NIH Award #UL1 RR025758)  Co-PI (\$50,000/total direct)</p> <p style="text-align: right;">The</p> <p>goal was to determine whether oral omega-3 fatty acids would reverse continued liver injury after patients are weaned from parenteral nutrition.</p>
2008-2013	<p>Cholestasis Reversal: Efficacy of IV Fish Oil  FDA R01 FD003460  Co-PI (\$462,053/total direct) (Puder, PI)  The goals of this project were to determine the safety and efficacy of treating parenteral nutrition associated liver disease with a fish oil-based emulsion.</p>
2014-2015	<p>Co-investigator, Abbott Fund facilitated by BU, USA, Nutrition status of children with congenital heart disease (CHD) before and after corrective cardiac surgery in Children’s Hospital 1, Viet Nam (Lenders/Tang)</p>
2015-2016	<p>Safety and tolerability of intravenous fish oil lipid emulsion during hematopoietic cell transplantation in children.  Inquiry Investment Drives Evidence into Action Grant Program  PI (\$49,500 total direct)  The goal of this project is to determine the safety of a fish oil lipid emulsion in children undergoing hematopoietic cell transplantation. This is a randomized, controlled pilot study</p>

- to test the safety and tolerability of FOLE, compared to soybean oil lipid emulsion, in 20 children requiring PN during hospitalization for HCT.
- 2015-2016 Safety and tolerability of intravenous fish oil lipid emulsion during hematopoietic cell transplantation in children.  
American Society for Parenteral and Enteral Nutrition  
Co-PI (\$30,000 /total direct) (Carey PI)
- 2016-2018 The Safety and Tolerability of Intravenous Fish Oil Lipid Emulsion in Children Undergoing Hematopoietic Cell Transplantation.  
Gateway for Cancer Research  
Co-PI (\$256,745/ total direct) (Carey PI)
- 2017-2018 Production and Evaluation of a New Intravenous Lipid Emulsion  
Otsuka Pharmaceutical Group  
Role: Co-investigator (\$165,227/total direct) (Puder PI)
- 2018-2020 A 90 day, Phase 3, Open Labeled Exploratory Study of RELiZORB to Evaluate Safety, Tolerability, and Nutrient Absorption in Children with Short Bowel Syndrome who are Dependent on Parenteral Nutrition  
Alcresta  
Role: Co-investigator (\$673,000/total direct) (Puder PI)
- 2018 The role of GPR120 signaling and treatment with a modified fatty acid molecule in high fat diet-induced murine model of insulin-resistance and hepatic steatosis.  
Northsea Therapeutics  
Role: Co-investigator (\$104,184/total direct) (Puder PI)
- 2018 Structurally engineered fatty acid, PRB-06179 in a murine model of parenteral nutrition associated liver injury.  
Northsea Therapeutics  
Role: Co-investigator (38,225/total direct) (Puder PI)

## Current

- 2015 Safety and tolerability of intravenous fish oil lipid emulsion during hematopoietic cell transplantation in children (STARFISH).  
Role: Co-Investigator (Carey PI)
- 2020 Variables associated with central line occlusions  
IDEA grant  
Role: Co-investigator (DeGrazia, PI)
- 2021-2025 A 90-day, Phase 3, open labeled exploratory study of RELiZORB to evaluate safety, tolerability, and nutrient absorption in children with short bowel syndrome who are dependent on parenteral nutrition.  
FDA, R01 FD006349-01A2  
Role: Co-investigator (\$660,139/total direct) (Puder PI)  
The goal of this study is to test the lipase enzymatic cartridge for safety and the enhancement of nutrient absorption in patients with short bowel syndrome.
- 2022-2026 A 90 Day Observational Study as an Extension to the Phase 3, Open Labeled, Exploratory Study of RELiZORB to Evaluate Safety, Tolerability, and Nutrient Absorption in Children with Short Bowel Syndrome who are Dependent on Parenteral Nutrition  
Alcresta Therapeutics  
Role: Co-investigator (\$1,260,111 direct) (Puder PI)  
The goal of this study is to test the lipase enzymatic cartridge for safety and the



enhancement of nutrient absorption in patients with short bowel syndrome. This adds 90 days to the FDA funded study.

### **Unfunded Current Projects**

2020            Use of tetrasodium EDTA catheter lock solution (Kitelock 4% Sterile Catheter Lock Solution) to prevent central line-associated bloodstream infection (CLABSI) in infants and children.  
 SterileCare  
 Role: Co-investigator (Puder PI)  
 This is a compassionate use protocol for the use of an alternative locking solution to prevent central line associated bloodstream infections in at risk patients with intestinal failure.

### **Report of Local Teaching and Training**

#### **Formal Teaching of Residents, Clinical Fellows and Research Fellows (post-docs):**

1997	Drug-Nutrient Interactions Interns-Fellows	Boston Children's Hospital One-hour lecture
1997	Overview of Incompatibilities Interns-Fellows	Boston Children's Hospital One-hour lecture
1999	Gastroesophageal Reflux Disease Interns	Marino Center for Progressive Health, Cambridge, MA One-hour lecture
2001	Aminoglycosides Pharmacokinetics in Cystic Fibrosis Patients Interns-Fellows	Boston Children's Hospital One-hour lecture
2002	Essential Fatty Acid Deficiency Interns-Fellows	Boston Children's Hospital One-hour lecture
2003	Patient Compliance Interns-Fellows	Boston Children's Hospital One-hour lecture
2003	Secondary Dyslipidemia Interns-Fellows	Boston Children's Hospital One-hour lecture
2003	Aluminum Toxicity Interns-Fellows	Boston Children's Hospital One-hour lecture
2004	Metabolic Bone Disease in the NICU Interns-Fellows	Boston Children's Hospital One-hour lecture
2005	Overview of Commonly Medications Used to Treat GERD Interns-Fellows	Boston Children's Hospital Two 1-hour lectures
2006	Reversal of Parenteral Nutrition Associated Cholestasis in Two Infants Using Parenteral Fish Oil Interns-Fellows	Boston Children's Hospital One-hour lecture
2008	IBD Drug Review Interns- Fellows	Boston Children's Hospital One 2-hour lecture
2009	Medication Review: Gastroesophageal Reflux Disease Fellows	Boston Children's Hospital One-hour lecture

2009	Management of Catheter Occlusions Interns-Fellows	Boston Children's Hospital One-hour lecture
2010	Omegaven Interns-Fellows	Boston Children's Hospital One-hour lecture
2012	Overview of Amino Acid Products Interns-Fellows	Boston Children's Hospital One-hour lecture
2013	Vitamins and Nutritional Supplements Interns-Fellows	Boston Children's Hospital One-hour lecture
Ongoing	Introduction to Parenteral Nutrition Interns-Fellows	Boston Children's Hospital One-hour lecture

### **Clinical Supervisory and Training Responsibilities:**

7/1999- present	Clinic preceptor/ pharmacy practice Boston Children's Hospital	Twenty-four weeks per year with doctor of pharmacy students, PGY2 pharmacy residents, and international pharmacists and physicians participating in nutrition fellowships. Direct contact and interactions at minimum 20 hours per week.
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### **Research Supervisory and Training Responsibilities:**

7/2002- present	Research Collaborator/ Boston Children's Hospital	Collaborated with research fellows in both basic and clinical research. Direct contact and interactions 4 hours per week.
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### **Formally Mentored Harvard Students (Medical, Dental, Graduate, and Undergraduate):**

2001-2002	Jenna Garza M.D. / Pediatric Surgeon, McAllen TX Published 2 manuscripts
2002-2003	Patrick Javid, M.D./ Pediatric Surgeon, Associate Professor University of Washington, Seattle Published 4 manuscripts
2003-2004	Ian Alwayn M.D., Ph.D. / Transplant Surgeon/Research Associate, Professor Transplant Surgery, LUMC - Medische Faculteit Leiden and received 3 Dutch government research grants. Queen Elizabeth II Foundation Chair. Professor and Chief of Transplant Surgery Leiden University Published 5 manuscripts
2005-2007	Sendia Kim, M.D. / Plastic Surgeon, MD Anderson Cancer Center, Houston TX Published 5 manuscripts
2005-2007	Sang Lee, M.D. / Pediatric Surgeon, Assistant Professor, University of North Carolina, Chapel Hill Published 8 manuscripts and received the Daland Fellowship Grant from the American Philosophical Society. (7 research awards)
2007-2010	Hau Le, M.D. / Assistant Professor Biomedical Engineering and Pediatric Surgery, University of Wisconsin, Madison WI

- Published 16 manuscripts, received the Rappaport Research Fellowship Grant from the Department of Surgery, and a NIH (NICHD) Loan Repayment Program Grant (4 research awards). Assistant Professor of Surgery, Research Associate University of Wisconsin
- 2007-2009 Jonathan Meisel, M.D./ Surgery Resident, Beth Israel Deaconess Medical Center  
Published 11 manuscripts  
Currently Assistant Professor Emory University (1 research award)
- 2007-2009 Vincent de Meijer, M.D., Ph.D./Surgery Resident Erasmus MC, Netherlands  
Published 13 manuscripts; received 3 grants from the Netherlands and received his PhD 6/2011 (2 research awards). Division of Hepatobiliary Surgery and Liver Transplantation, Research Associate University of Groningen
- 2008-2010 Alpin Malkan, M.D./ Surgery Resident Danbury Hospital, CT  
Published 2 manuscripts
- 2009-2012 Erica Fallon, M.D. / Pediatric Surgery Fellow, Toronto Sick Kids  
Published 14 manuscripts. Received the Rappaport Research Fellowship Grant from the Department of Surgery, and a NIH (NIDDK) NRSA grant (9 research awards)  
Assistant Professor Surgery, Columbia University, NY
- 2010-2012 Deepika Nehra, M.D./ General Surgery Resident, Massachusetts General Hospital  
Published 7 manuscripts, Received NIH T-32 Training grant, and NIH (NCI) Loan Repayment Program Grant (4 research awards)  
Assistant Professor Surgery, Harvard Medical School. Brigham and Women's Hospital  
Assistant Professor Surgery, University of Washington Department of Surgery
- 2011-2013 Brian Kalish/ Harvard Medical Student  
Published 5 manuscripts  
Neonatology and Research Fellow, Boston Children's Hospital  
Received Howard Hughes Medical Institute Grant  
Instructor Pediatrics, Research Associate, Boston Children's Hospital  
Assistant Professor Pediatrics and Molecular Genetics, Toronto Sick Kids
- 2011-2014 Sarah Carlson, M.D./General Surgery Resident, Beth Israel Deaconess Hospital  
Published 11 manuscripts  
Assistant Professor of Surgery, Boston University School of Medicine
- 2012-2015 Prathima Nandivada M.D./Research Fellow/Surgery Resident Beth Israel Deaconess Hospital  
Published 16 manuscripts  
Pediatric Surgery Fellow, Boston Children's Hospital  
Received NIH (NICHD) LRP Grant. Rappaport Fellowship  
Assistant Professor Surgery Harvard Medical School, Boston Children's
- 2012-2014 Melissa Chang, M.D./General Surgery Resident Mount Sinai Hospital, New York, NY.  
Published 8 manuscripts
- 2012-2014 Eileen Cowan, M.D./Neonatologist Assist. Professor University of Wisconsin, Madison  
Published 7 manuscripts
- 2014-2017 Gillian Fell, M.D., Ph.D./ Research Fellow, Boston Children's Hospital and General Surgery Resident, Brigham and Women's Hospital, Boston MA  
Pediatric Surgery Fellow, Los Angeles Children's Hospital  
Research Associate, Pediatric Surgeon, Stanford University  
Published 20 manuscripts

- 2015-2017 Meredith Baker, M.D./ Research Fellow  
Resident Beth Israel Deaconess Hospital  
Pediatric Surgery Fellow, Columbia University  
Pediatric Surgeon, Maine Medical Center  
Published 17 manuscripts
- 2015-2019 Duy Dao, M.D./ Research Fellow, Boston Children's Hospital and General Surgery  
Resident, NYU Langone Medical Center, New York, NY  
Pediatric Surgery Fellow, Children's Hospital of Philadelphia  
Published 18 manuscripts
- 2015-2018 Lorenzo Anez-Bustillos, M.D./Research Fellow  
General Surgery Resident Beth Israel Deaconess Hospital  
Pediatric Surgery Fellow, Toronto Sick Kids  
Published 18 manuscripts
- 2016-2019 Bennet Cho/Harvard Medical School  
Surgical Research Fellow, Boston Children's Hospital  
General Surgery Resident, Massachusetts General Hospital  
Published 9 manuscripts
- 2016 Zhiling Li PhD  
Visiting pediatrician, Shanghai Children's Hospital, Shanghai Jiao Tong University  
Published 1 manuscript
- 2018-2020 Victoria Ko, M.D./Research Fellow  
General Surgery Resident, Rutgers  
Pediatric Surgery Fellow, Nicklaus Children's (Miami Children's)  
Published 2 manuscripts
- 2018 Paul Anthony McGreggor Crowley, MD  
Instructor in Pediatrics, Boston Children's Hospital  
Published 1 manuscript
- 2018-2022 Jenny Yu, M.D.  
Research Fellow Sandra and Richard Cumming Research Fellowship (BIDMC)  
Published 5 manuscripts
- 2019-2021 Jordan Secor, MD/Research Fellow  
General Surgery/Thoracic Surgery Resident Massachusetts General Hospital  
Published 5 manuscripts
- 2020-2023 Savas Tsikis, M.D./Research Fellow  
Surgical Research Fellow, Boston Children's Hospital  
Published 10 manuscripts

- 2020-2023 Scott Fligor, M.D.  
Surgical Research Fellow, Boston Children’s Hospital  
Published 10 manuscripts
- 2020-2022 Kristin Leone, M.D./Research  
Harvard Neonatal-Perinatal Medicine Fellowship Program, Scholarship Oversight  
Committee
- 2021-  
present Thomas Hirsch, M.D.  
Surgical Research Fellow, Boston Children’s Hospital  
Published 5 manuscripts

**Formal Teaching of Peers (e.g., CME and other continuing education courses):**

- No presentations below were sponsored by 3<sup>rd</sup> parties/outside entities*
- Those presentations below sponsored by outside entities are so noted and the sponsor(s) is (are) identified.*

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|------------------|--|-----------------------------|
| 2007             | Enhancing the Safety of Parenteral and Enteral Nutrition “Home Parenteral Nutrition in the Pediatric Patient: Special Considerations” and “Calcium- Phosphate Compatibility” Harvard Medical School Continuing Education | 2 lectures<br>Cambridge, MA |
| 2008             | Enhancing the Safety of Parenteral and Enteral Nutrition, “Is there a Role for Peripheral Parenteral Nutrition?” and “Issues in Calcium-Phosphate Compatibility” Harvard Medical School Continuing Education             | 2 lectures<br>Cambridge, MA |
| 2020-<br>present | “Parenteral Nutrition,” OPENPediatrics: Online Medical Education, Boston Children’s Hospital/Harvard Medical School  | Online course<br>Boston, MA |

**Local Invited Presentations:**

- No presentations below were sponsored by 3<sup>rd</sup> parties/outside entities*
- Those presentations below sponsored by outside entities are so noted and the sponsor(s) is (are) identified.*

- 1991 “Variations in Compounding Practices Among Home Care Companies,” Longwood Nutrition Rounds, Boston, MA
- 1993 “Incidence of Cholestasis in Infants Receiving Parenteral Nutrition: Comparison of Aminosyn PF and TrophAmine.” Deaconess Home Health Care, Boston, MA
- 1996 “Management of Catheter Occlusions,” Massachusetts Society of Health Systems Pharmacists Annual Meeting in Boxborough, MA

- 1997 “Medication Errors,” presented to nursing staff in conjunction with Risk Management staff of Children's Hospital, Children's Extended Care Center, Groton, MA
- 1998 “Minimizing Incompatibilities,” presented to the pharmacy staff, Children's Hospital, Boston, MA
- 1998 “Issues with Parenteral Drug Therapy,” presented to the pharmacy staff, Beverly Hospital, Beverly, MA and the staff of Children's Hospital, Boston, MA
- 1998 “Update on Extravasations,” presented to the pharmacy staff, Brigham & Women’s Hospital, Boston, MA
- 2000 “2000: An Antimicrobial Odyssey: New uses for Old Therapies and Review of New Agents,” with Roger Dionne, presented at the 1st Annual Cardiology Nursing Educational Day, Children’s Hospital, Boston, MA
- 2003 “Essential Fatty Acid Deficiency,” Longwood Nutrition Conference, Division of Nutrition at Harvard, Harvard Medical School, Boston, MA
- 2003 “Secondary Dyslipidemia in the ICU,” Longwood Nutrition Conference, Division of Nutrition at Harvard, Harvard Medical School, Boston, MA
- 2016 “Fluids, Electrolytes and Acid-Base,” Department of Clinical Nutrition, Boston Medical Center, Boston, MA
- 2020 “How to Survive an FDA Site Visit (and live to tell about it),” Clinical Research Regulatory Education Series, Boston Children’s Hospital, Boston, MA
- 2020 “Medication Compatibility and Lipid Emulsions,” Clinical Nutrition Service, Boston Children’s Hospital, Boston, MA
- 2020 “Hypertriglyceridemia, Essential Fatty Acid and Lipid Infusion: Case and discussion,” Clinical Nutrition Service, Boston Children’s Hospital, Boston, MA
- 2021 “Are you interested in learning about the electronic research orders safety system (ROSS)?” Boston Children’s Hospital, Boston, MA
- 2021 “The Role of Premedications in Managing Infliximab Reactions,” IBD Conference, Division of Gastroenterology, Hepatology and Nutrition, Boston Children’s Hospital, Boston MA
- 2022 “How Not to Conduct a Drug Trial: Lessons Learned from Omegaven Approval,” Institutional Centers for Clinical and Translational Research, Boston Children’s Hospital, Boston MA
- 2023 “Pharmacologic Management of Intestinal Failure Associated Complications,” Nursing Surgical Programs, Boston Children's Hospital, Boston, MA

## **Report of Regional, National and International Invited Teaching and Presentations**

*No presentations below were sponsored by 3<sup>rd</sup> parties/outside entities*

*Those presentations below sponsored by outside entities are so noted and the sponsor(s) is (are) identified.*

### **Regional**

- 1993 Pharmacy Technicians, Chemotherapy Preparation, as part of the NEAPT IV Proficiency Certification Course, Newton, MA
- 1994 Pharmacy Technicians, review of drug classes and anatomy/physiology, as part of a NEAPT review program for technician certification exam, Newton, MA
- 1995 “Drug-Nutrient Interactions/Compatibility of Medications with Enteral Feedings,” Monthly meeting of the Massachusetts Pediatric Dietitians Association, Boston, MA
- 1999 “Management of Catheter Occlusions,” Yankee Alliance Group Purchasing Organization, Nashua, New Hampshire
- 2000 “Managing the Urokinase Shortage,” New Hampshire Society of Health Systems Pharmacists, Manchester, New Hampshire
- 2001 “Management of Catheter Occlusions,” presented at monthly society meeting, RI Intravenous Nursing Society, Warwick, RI
- 2001 Parenteral Nutrition Basics,” Department of Pharmacy’s monthly continuing education series, St. Vincent’s Medical Center, Worcester, MA
- 2002 “Abstract Preparation,” presented as a workshop to the staff of Baystate Medical Center, Massachusetts Society of Health-System Pharmacists Sturbridge, MA
- 2003 “FDA Aluminum Mandate,” Nutrition Case Conference, Connecticut Children's Hospital, Hartford, CT
- 2003 “Update on Incompatibilities/FDA Aluminum Mandate,” Apria Healthcare, Norwood, MA
- 2004 “Aluminum Exposure and Parenteral Nutrition,” Department of Pharmacy, Women’s and Infants Hospital, Providence, RI (Mayne Pharma)
- 2004 “Aluminum Toxicity,” New England Vascular Access Network, Concord, NH
- 2006 “USP Chapter 797 Update,” First Regional HOPA/MSHP Fall Meeting, Worcester, MA
- 2006 “Reversal of Parenteral Nutrition Associated Cholestasis in Two Infants Using Parenteral Fish Oil,” Pharmacy Grand Rounds, Northeastern University, Boston, MA

- 2008 “Current Challenges in Pediatric Pharmacy Practice,” Massachusetts Pharmacists Association 2008 Spring Conference, Norwood, MA
- 2009 “The Role of Intravenous Fish Oil Lipid Emulsions in the Treatment of TPN-Induced Liver Disease,” 20th Annual Conference of the Connecticut Organization of Neonatal Nurses, Plantsville, CT
- 2009 “An Evening in Pediatrics,” Northeastern University Alumnae, Boston, MA
- 2010 “Parenteral Lipid Emulsions: Nutrition or Drug? A Changing Paradigm,” Massachusetts Dietetics Association, MDA Annual Nutrition Convention 2010, Norwood, MA
- 2010 “Role of Parenteral Fish Oil in Metabolic Support,” Massachusetts Society of Health Systems Pharmacists Annual Meeting, Newton MA
- 2010 “Current Research in Pediatric Nutrition Support,” Introduction to Pediatric Nutrition, Children's Hospital, Boston, Boston, MA
- 2013 “Drug Therapy and Short Bowel Syndrome: What every pharmacist should know,” Massachusetts Pharmacists Association 2013 Spring Conference, Norwood, MA
- 2014 “Drug Delivery in Pediatric Patients: Current Challenges in Pharmacy Practice,” MCPHS University Reed Refresher, Foxboro, MA
- 2016 “Nutrition Support Pharmacy,” AACP Student Chapter, Northeastern University, Boston, MA
- 2017 “Pediatric Challenges in Sterile Products Compounding,” Massachusetts Pharmacists Association, Norwood, MA
- 2018 “The Perils and Practical Pearls of Publishing at the Daily Planet,” Massachusetts Society of Health Systems Pharmacists Annual Meeting, Framingham, MA
- 2018 “Nutrition Support Pharmacy Practice,” MCPHS University, Boston MA
- 2018 “ASHP Delegate Gotham Town Hall: Pharmacy Issues Relevant to You,” Massachusetts Society of Health Systems Pharmacists Annual Meeting, Framingham, MA
- 2018 “Pharmacologic Management of Intestinal Failure,” The Salah Foundation Children’s Hospital, Fort Lauderdale, FL
- 2018 “Drug Shortages: Focus on Parenteral Nutrition,” The Oley Foundation Regional Conference, Bentley University, Waltham, MA
- 2018 “Lessons Learned from Omegaven,” Longwood Nutrition Rounds, Harvard Medical School, Boston, MA
- 2021 “The History & Basics of Sterile Compounding,” MCPHS University, Boston, MA [webinar]



- 2021 “Sterile Compounding: Ensuring Safe Prep of Parenteral Nutrition CSPs - 2021/2022 Update,” MCPHS University, Boston, MA [webinar]
- 2022 “The History of Intravenous Lipid Emulsions and Deciding to Know When to Use Which Product in the Pediatric Patient,” New England Chapter American Society for Parenteral and Enteral Nutrition (NEASPEN) [webinar]

**National**

- 1995 “Controversies in Pediatric Parenteral Nutrition,” Pediatric Pharmacy Advocacy Group Annual Meeting, Las Vegas, Nevada
- 1996 “Medication Errors,” Annual meeting of the Abbott Laboratories Advisory Panel, Chicago, Illinois
- 1996 “Management of Catheter Occlusions,” Pediatric Pharmacy Advocacy Group’s Annual Meeting in Beaver Creek, Colorado
- 1996 “Emerging Technologies,” Annual meeting of the Abbott Laboratories Advisory Panel, Chicago, Illinois
- 1996 “Issues in Pediatric Nutrition,” Pediatric Pharmacy Advocacy Group, 5th Annual Pediatric Technology Conference, Scottsdale, AZ
- 1998 “Evolving technologies,” presented to the Abbott Advisory Board, Abbott Laboratories, Deerfield Park, IL
- 1999 “Administration of Medications to Patients on Parenteral Nutrition,” presented at the Midyear Clinical Meeting, American Society of Health Systems Pharmacists, Orlando, FL
- 1999 “Pharmacist Role in Error Prevention,” presented at the Midyear Clinical Meeting, American Society of Health Systems Pharmacists, Orlando, FL
- 1999 “Implementation of the NAG's TPN Guidelines: Pediatric Considerations,” presented at the 23rd Clinical Congress, American Society for Parenteral & Enteral Nutrition, San Diego, CA
- 2000 “Management of Central Venous Catheter Occlusions,” presented as an open forum discussion at the 9th Annual Meeting, Pediatric Pharmacy Advocacy Group, San Antonio, TX
- 2001 “Sweet Relief: Use of Sucrose as an Analgesic in Neonates,” presented as a clinical pearl at the Midyear Clinical Meeting, American Society of Health-System Pharmacists New Orleans, LA

- 2003 “Incidence and Nature of Epidemic Nosocomial Infections,” INS Fall Meeting, Infusion Nurses Society, Boston, MA
- 2003 “Aluminum Exposure in the Pediatric Parenteral Nutrition Therapy: A New Safety Mandate Important in Clinical Practice,” presented with Dr. Winston Koo, CMGI Global, Dallas, TX, and repeated in Houston, TX and Miami, FL
- 2003 “Aluminum Toxicity: Hysteria or Cause for Concern,” American Society of Health-System Pharmacists, Midyear Clinical Meeting, New Orleans, LA
- 2004 “Pediatrics: Acute Complications Associated with Parenteral Nutrition,” Nutrition Week, Las Vegas, NV
- 2004 “Impact of Nutrition on Pharmacokinetics,” Nutrition Week, Las Vegas, NV
- 2004 Issues in Aluminum and DEHP Toxicity,” Annual Meeting, Pediatric Pharmacy Advocacy Group, St., Petersburg, FL
- 2004 “Albumin and Low-Aluminum Therapies: A Hospital Pharmacists’ Perspective,” Orlando, FL (sponsored by JL Associates)
- 2005 “Aluminum Toxicity,” Nutrition Week, American Society for Parenteral and Enteral Nutrition, Orlando, FL
- 2005 “Overview of Pediatric Nutrition,” Pediatric Pharmacy Advocacy Group 14th Annual Meeting, Chicago, IL
- 2005 “Pediatric Nutrition,” American Society of Health-System Pharmacists, Clinical Midyear Meeting, Las Vegas, NV
- 2006 “Secondary Dyslipidemia,” American Society for Parenteral and Enteral Nutrition, Clinical Nutrition Week, Dallas, TX
- 2007 “Pharmacological Management of Intestinal Failure,” American Society for Parenteral and Enteral Nutrition, Clinical Nutrition Week, Phoenix, AZ
- 2007 “Soy Allergy,” American Society for Parenteral and Enteral Nutrition, Nutrition Week, Phoenix, AZ
- 2007 “CPOE vs. Pediatric Parenteral Nutrition: Challenges and Opportunities.” Pediatric Pharmacy Advocacy Group, Pediatric Medication Safety and Technology Conference, Austin, TX
- 2007 “Treatment of TPN Liver Injury,” Oley Foundation 22nd Annual Consumer/Clinician Conference, Hyannis, MA
- 2007 “Treatment of Parenteral Nutrition Associated Cholestasis,” Pediatric Pharmacy Advocacy Group, 16th Annual Meeting, Portsmouth, VA

- 2007 “Clinical Status of Omega-3 Fatty Acids in Special Patient Populations,” American College of Clinical Pharmacy Annual Meeting, Denver, CO
- 2007 “Pediatric Parenteral Nutrition,” American Society of Health-System Pharmacists, Clinical Midyear Meeting. Las Vegas, NV
- 2008 “Omegaven in TPN liver disease,” Expert Workshop on Lipid Emulsions in TPN Liver Disease, Institute of Human Nutrition. Columbia University Medical Center, New York, NY
- 2008 “Omegaven Update,” HomeTPN Consumer Education Conference 2008, Boston MA
- 2008 “Use of Omegaven in Parenteral Nutrition Associated Liver Disease,” NutriThrive Consumer Symposium, Pittsburgh, PA
- 2008 “The Role of Omega-3 Fatty Acids in Lipid Emulsion,” 28th Annual FSPEN Symposium, September 19, 2008, Melbourne, FL
- 2008 "Overview of Parental Nutrition in the Pediatric Patient," pre conference symposium, 17th PPAG Annual Meeting, Baltimore, MD
- 2008 “Issues in Pediatric Standardization,” presented to the Pharmacy Advisory Board, Baxa Corporation, Englewood, Colorado
- 2008 “Clinical Role of Omega 3 Fatty Acids in Special Patient Populations,” New York/Long Island Society for Parenteral and Enteral Nutrition , Annual Meeting 2008, Hixsville, New York
- 2008 “Pediatric Parenteral Nutrition,” American Society of Health-System Pharmacists, Clinical Midyear Meeting. Orlando Florida
- 2009 “Liver Function Tests,” American Society for Parenteral and Enteral Nutrition –Clinical Nutrition Week, 2009, New Orleans, LA
- 2009 “In Case You Missed It: Notable Papers in Pediatric Nutrition 2008” American Society for Parenteral and Enteral Nutrition –Clinical Nutrition Week, 2009, New Orleans, LA
- 2009 “A Whale of a Tale: Use of Fish Oil in PN Liver Disease,” 2009 Pediatric Nutrition Symposium: Putting Pediatric Nutrition into Practice, Pediatric Nutrition Dietetic Practice Group (PNPG) of the American Dietetic Association, Raleigh, North Carolina
- 2009 “The Role of Fish Oil Lipid Emulsions and Omega-3 Fatty Acids in Parenteral Nutrition Associated Liver Disease,” Ohio Society for Parenteral and Enteral Nutrition (OSPEN), Columbus, Ohio
- 2009 “Intravenous Fish Oil Lipid Emulsions: Management of TPN-Induced Liver Disease,” Neonatal Advanced Practice Nursing Forum 2009, Washington, DC

- 2009 “What’s Up with Omegaven?” 24th Annual Oley Consumer/Clinician Conference, St. Petersburg, FL
- 2009 “Case Studies in Nutrition Across the Life Cycle: Neonatal Case Study,” ASHP Midyear Clinical Meeting, Las Vegas, NV
- 2009 “Fish vs. Vegetable: An Update on the IV Lipid Content Debate,” Greater Pittsburgh chapter of the American Society for Parenteral and Enteral Nutrition, Fall Meeting, Pittsburgh, PA
- 2010 “Parenteral Nutrition Associated Liver Disease (PNALD): What are the prevention and treatment options?” American Society for Parenteral and Enteral Nutrition –Clinical Nutrition Week, 2010, Las Vegas, NV
- 2010 “Pharmaconutrient considerations for the critically ill child - a new paradigm,” American Society for Parenteral and Enteral Nutrition, Clinical Nutrition Week, 2010, Las Vegas, NV
- 2010 “Parenteral Lipid Emulsions: Nutrition or Drug? A Changing Paradigm,” Michigan Chapter of the American Society for Enteral and Parenteral Nutrition (MSPEN) Annual Meeting, Livonia, Michigan
- 2011 “Challenges in Medication Administration in PN Dependent Patients,” American Society for Parenteral and Enteral Nutrition –Clinical Nutrition Week, 2011, Vancouver, BC, Canada
- 2011 “Management of Complications of SBS and Intestinal Failure: Drug Therapy,” Holtz Children’s Hospital, University of Miami, Miami, Florida
- 2011 “Efficacy of Parenteral Fish Oil Lipid Emulsions in Parenteral Nutrition Associated Liver Disease: Where are we at?” Annual Meeting, Virginia Society for Parenteral and Enteral Nutrition (VASPEN)
- 2012 “Bringing in unapproved drugs into the market-- Humanitarian exemptions – like HDE-Compassionate use via IRB and Importation,” an A.S.P.E.N. Corporate Scientific Council Informational: How to Get Nutrition Products to Market, November 27, 2012
- 2012 “Don’t Hold the Salt...Impact of Hyponatremia on Growth in Infants Receiving Adequate Calories,” ASHP Midyear Clinical Meeting 2012, Las Vegas, NV
- 2013 “Pediatric Considerations in PN compounding,” 2013 Clinical Nutrition Week, ASPEN, Phoenix, NV
- 2013 “Summary, Recommendations and A.S.P.E.N. Position Statement on the Clinical Role for Alternative IVFE,” 2013 Clinical Nutrition Week, ASPEN, Phoenix, NV
- 2013 “Neonatal Nutrition,” 22nd Annual Meeting of the Pediatric Pharmacy Advocacy Group (PPAG), Indianapolis, Indiana

- 2013 “Pediatric/Neonatal Parenteral Nutrition: The Ins and Outs for the Non-Pediatric Clinician,” American Society for Parenteral and Enteral Nutrition, Webinar August 14, 2013
- 2013 “Lipid Emulsion Update,” B Braun Pharmaceutical Advisory Board Meeting, Bethlehem, PA
- 2014 “Intravenous Fat Emulsions: Nutritional Source or Therapeutic Modality?” American Society for Parenteral and Enteral Nutrition Webinar, June 18, 2014
- 2014 “Swimming with CVCs and G Tubes: yeah or nay?” 2014 Oley Conference, Orlando, Florida
- 2014 “Review of Intravenous Fat Emulsions in Parenteral Nutrition: Past, Present and Future,” B. Braun/CAPS Annual Training Session, Bethlehem, PA
- 2014 “Parenteral Nutrition Associated Liver Disease: It’s the Type of Lipid,” Guts and the City: Intestinal Failure, Rehabilitation and Transplantation Symposium, Icahn School of Medicine at Mount Sinai, New York City, NY
- 2014 “Oils Well That Ends Well, Update on Intravenous Lipid Emulsions,” Annual Meeting, Long Island Society for Parenteral and Enteral Nutrition, Hicksville, NY
- 2014 “Pharmacological Issues with Bacterial Overgrowth: Causes and Treatment Strategies,” Thrive 3rd Annual Professional Short Bowel Conference, Nashville, TN
- 2015 “Lipid Management Strategies in PNALD: Dose Minimization vs. Type of Oil,” Contemporary Forums, Neonatal Pharmacology, Scottsdale, Arizona
- 2015 “Nutritional Considerations in Short Bowel Syndrome,” Contemporary Forums, Neonatal Pharmacology, Scottsdale, Arizona
- 2015 “Compounding Considerations of Neonatal Parenteral Nutrition,” Contemporary Forums, Neonatal Pharmacology, Scottsdale, Arizona
- 2015 “Understanding Lipid Emulsions,” ThriveRx Professional Webinar Series, June 11, 2015
- 2015 “What’s New in Biologics, Premixed Parenteral Nutrition and Lipid Emulsions,” breakout session, Oley Foundation 30th Annual Consumer Conference, Saratoga Springs, New York
- 2015 “Pharmacological Issues with Bacterial Overgrowth: Causes and Treatment Strategies,” Oley Foundation 30th Annual Consumer Conference, Saratoga Springs, New York
- 2015 “Lock it Up: Ethanol Lock,” ASHP Midyear Clinical Meeting, New Orleans, LA
- 2016 “Liver Disease Among Infants Receiving Parenteral Nutrition,” Drug-Induced Liver Injury (DILI) Conference XVI, College Park, MD

- 2016 "The Link Between PN Liver Injury and Fat: Is it the Dose or Type of Oil?," PPAG Annual Meeting, Atlanta, GA
- 2016 "Navigating the Seas: Electrolytes, Minerals and Acid-Base Balance," Academy of Nutrition and Dietetics, FNCE Food and Nutrition Conference Expo, Boston, MA
- 2017 "Current Approach and Emerging Therapies in the Management of Intestinal Failure and Parenteral Nutrition Associated Liver Disease," Clinical Nutrition Week, Orlando, FL
- 2017 "Drug-Nutrient Interactions," Clinical Nutrition Week, Orlando, FL
- 2017 "Intestinal Failure," presented to the staff of Children FIRST (Florida Intestinal Rehabilitation Support and Treatment," Salah Children's Hospital, Fort Lauderdale, FL
- 2017 "Developments in Home Parenteral Nutrition: Preventing and Managing Complications in Adult and Pediatric Patients," 2017 National Home Infusion Association (NHIA) Annual Conference and Exposition, Orlando, FL
- 2017 "Oils Well That Ends Well (Lipids That Is!)" 32nd Annual Consumer/Clinician Conference, The Oley Foundation, Old Greenwich, CT
- 2017 "To Swim with a Central Line...or Not? You Decide!" 32nd Annual Consumer/Clinician Conference, The Oley Foundation, Old Greenwich, CT
- 2017 "Pediatric Nutrition," Pediatric Pharmacy Advocacy Group Specialty Meeting/Board Prep Course, Cincinnati, Ohio
- 2017 "Developments in Home Parenteral Nutrition: Preventing and Managing Complications in Pediatric Patients," National Home Infusion Association (NHIA) [webinar]
- 2018 "Drug Nutrient Interactions: Pediatric Issues," ASPEN 2018 Nutrition Science & Practice Conference, Las Vegas, NV
- 2018 "Optimizing TPN in the Face of Shortages," Neonatal Pharmacology, Contemporary Forums, Philadelphia, PA
- 2018 "Lipid Emulsions in the Neonate," Neonatal Pharmacology, Contemporary Forums, Philadelphia, PA
- 2018 "Challenges in Pediatric PN: New Products, New Rule," Pediatric Pharmacy Advocacy Group 27th Annual Meeting, Salt Lake City, UT
- 2018 "General Overview: Nutrition in the Pediatric Population," Global Medical Affairs Wellness, Pfizer, Inc. [webinar]
- 2018 "Pediatric Intestinal Failure-Associated Liver Disease: Challenges in Identifying Clinically Relevant Biomarkers," ASHP Emerging Sciences SAG Meeting [webinar]

- 2018 “Alternative Medicine in the Pediatric Patient: Focus on Herbals,” Global Medical Affairs Wellness, Pfizer, Inc. [webinar]
- 2018 “Pediatric Nutrition,” PPAG University 2018, Philadelphia, PA
- 2018 “Drug Shortages: Focus on Parenteral Nutrition,” Oley Foundation [webinar]
- 2018 “Neonatal PN: Safety and Stability Considerations,” US Numeta Advisory Board, Chicago, IL
- 2018 “A Whale of a Tale: Making Sense of Lipid Emulsions,” Northwest Chapter of ASPEN, Seattle, WA [webinar]
- 2019 “Facts About Fats: SMOF, Omegaven, Intralipid: Which One For PNALD, BPD, ROP,” Pediatric Pharmacy Advocacy Group (PPAG) [webinar]
- 2019 “Practical Implications of the Use of Omegaven and SMOF IV Lipids in the NICU, PICU and Beyond,” Children's Hospital of The King's Daughters, Norfolk, VA
- 2019 “Alternative Lipid Emulsions in Children,” American Society for Parenteral and Enteral Nutrition, ASPEN2019 Nutrition Science and Practice Conference, Phoenix, AZ
- 2019 “Identifying and Managing Intestinal Failure-Related Liver Disease,” 2019 Oley/UI Health Combined Conference, June 23, 2019, Lincolnshire, IL
- 2019 “Minimizing Errors in Pediatric Patients Receiving Home Parenteral Nutrition at Transitions of Care,” ASHP Midyear Clinical Meeting, December 9, 2019, Las Vegas, NV
- 2020 “Nutrient Deficiencies in the Neonate Transitioning from Parenteral to Enteral Nutrition,” ASPEN 2020 Nutrition Science and Practice Conference, March 31, 2020. [virtual]
- 2020 “The Ifs, Ands and Buts of Vitamin Supplementation in the NICU,” Pediatric Pharmacy Association Annual Meeting, May 2, 2020. [virtual]
- 2020 “ASPEN Best Practices in Parenteral Nutrition Training Series: Compounding Parenteral Nutrition Admixtures,” June 4, 2020. [webinar]
- 2020 “Intravenous Fish Oil Monotherapy as a Source of Calories and Fatty Acids Promotes Age-Appropriate Growth in Pediatric Patients with Intestinal Failure-Associated Liver Disease,” Oley 2020 Virtual Conference, August 6, 2020. [virtual]
- 2020 “The Power of Networking and Lessons Learned from Omegaven,” Helms Lecture, PPA Fall Meeting, September 24, 2020. [virtual]

- 2021 “Dudrick Symposium: Advances in Preventing Parenteral Nutrition Associated Side Effects,” ASPEN 2021 Nutrition Science & Practice Conference, March 22, 2021. [virtual]
- 2021 “Neonatal Interventions: Balancing Short and Long-term Outcomes – Zooming in on Neurodevelopment,” ASPEN 2021 Nutrition Science & Practice Conference, March 23, 2021. [virtual]
- 2021 “Micronutrient Needs of the Preterm Infant,” ASPEN, Spring 2021 [virtual]
- 2021 “Central Line Care and TPN Set Up,” Pediatric Intestinal Rehabilitation Center at Columbia University Irving Medical Center (CUMC), New York, NY
- 2021 “Clinical Pearls and the Correlation and Considerations for Parenteral Nutrition Compounding,” NHIA 2021 Annual Conference, April 20, 2021. [virtual]
- 2021 “The History of Intravenous Lipid Emulsions and Deciding to Know When to Use Which Product in the Pediatric IF Patient,” LIFT-ECHO Learn Intestinal Failure TeleECHO, June 1, 2021. [virtual]
- 2021 “Intravenous Lipid Emulsions and IFALD: Different Products and Different Approaches,” Oley2021, June 21, 2021. [virtual]
- 2021 “Fish Oil Emulsion reduces Liver Injury and Liver Transplantation in Children with Intestinal Failure-Associated Liver Disease: A Multicenter Integrated Study,” Oley2021, June 21, 2021. [virtual]
- 2022 “Transitions of Care and Lipid Emulsions: Factors for Consideration”, ASPEN 2022 Nutrition Science & Practice Conference, Seattle, WA. March 28, 2022.
- 2022 “Challenges in Drug Delivery: Influence of Anatomical Differences in Short Bowel Syndrome and Intestinal Failure,” Pediatric Pharmacy Association (PPA) Annual Meeting, Norfolk, VA, May 6, 2022.
- 2022 “Drug Delivery in Pediatric Patients: Current Challenges in Pharmacy Practice,” University of Washington, Seattle, WA, March 1, 2022. [webinar]
- 2022 “Home TPN Pearls and Pitfalls,” Digestive Disease Week DDW2022, San Diego, CA, May 21, 2022.
- 2023 “Differences Between Adults and Kids Meds,” University of Washington, February 21, 2023.
- 2023 “Pediatric Intestinal Failure Literature in Review,” ASPEN 2023 Nutrition and Science Practice Conference, Las Vegas, NV, April 23, 2023.
- 2023 “When Food Becomes Medicine: Eat, Drink and Be Wary,” 2023 NASGPHAN/CPNP/APGNN Annual Meeting, San Diego, CA, October 7, 2023.



- 2023 “Intravenous Lipid Emulsions: Nutrition or Therapeutic Modality?” NY/LISPEN Annual Fall Conference, Plainview, NY, October 24, 2023.
- 2023 “Clinical Management of Short Bowel Syndrome: Pharmacist-Led Strategies in Patient Care,” ASHP Midyear Clinical Meeting, Anaheim, CA, December 5, 2023 (PCTE with an educational grant from Takeda).
- 2024 “Drug Delivery in Pediatric Patients: Current Challenges in Pharmacy Practice,” University of Washington, Seattle, WA, January 23, 2024. [webinar].
- 2024 “Essential Fatty Acid Deficiency: Facts vs. Misunderstandings,” ASPEN 2024 Nutrition and Science Practice Conference, Tampa, FL, March 3, 2024.
- 2024 “Pharmacy Issues in Pediatric Intestinal Failure,” Pediatric Intestinal Failure and Rehabilitation Symposium (PIFRS) 2024, Pittsburgh, PA, September 26, 2024.

**International**

- 1997 “Quality Assurance of Total Parenteral Nutrition Solutions,” presented to pharmacy staff, Royal Hospital for Sick Children, Edinburgh, Scotland.
- 1997 “Automated Compounding of TPN,” Alder Hey Children’s Hospital, Liverpool, England.
- 1997 “Automated compounding of TPN,” Great Ormand Street Children’s Hospital, London, England.
- 2000 “Automated Compounding of Parenteral Nutrition Solutions,” presented to the pharmacy staff, Taiwan University Hospital, Taipei, Taiwan, R.O.C.
- 2000 “Update on the National Advisory Group Recommendations and ASHP Guidelines Regarding Parenteral Nutrition,” 20th Annual meeting of the Korean Society of Health-System Pharmacists, Muju, South Korea.
- 2004 “Co-Administration of Medications with PN Solutions in the Paediatric Patient,” Parenteral and Enteral Nutrition Society of Malaysia, Penang, Malaysia.
- 2004 “The Boston Children’s Hospital Experience in Paediatric Nutrition,” Parenteral and Enteral Nutrition Society of Malaysia, Penang, Malaysia.
- 2004 “Automation in TPN Compounding,” Parenteral and Enteral Nutrition Society of Malaysia, Penang, Malaysia.
- 2004 “Pharmaceutical Issues in Compounding,” Parenteral and Enteral Nutrition Society of Malaysia, Penang, Malaysia.

- 2004 “Pediatric Medications: What is the Problem? Current Challenges in Pediatric Pharmacy Practice,” Federation Internationale Pharmaceutique (International Pharmaceutical Federation), 2004 Congress, New Orleans, LA.
- 2005 “Avoiding Aluminum Contamination,” An IPANEMA Satellite Symposium for ESPIG-BPNG, 27th Congress of European Society for Clinical Nutrition and Metabolism, Brussels, Belgium.
- 2007 “Prevention and Treatment of Parenteral Nutrition Associated Liver Disease”, FRANC International Pediatric Nutrition Symposium, Bad Homburg, Germany (Fresenius-Kabi Sponsor).
- 2011 “The Essentiality of AA and DHA,” III Simposio Internacional de Nutricion Neonatal, Cartagena de Indias, Colombia.
- 2011 “Fish Oil-Based Lipid Emulsions Prevent & Reverse Parenteral Nutrition-Associated Liver Disease: The Boston Experience,” III Simposio Internacional de Nutricion Neonatal, Cartagena de Indias, Colombia.
- 2011 “Vitamins and Trace Elements,” “Overview of Parenteral and Enteral Nutrition,” “Compounding Parenteral Nutrition Solutions,” “Complications of Specialized Nutrition Support,” “Selection of IV Fluids,” “Vascular Access Devices,” “Review of Calculations for Parenteral Nutrition,” presented to the Medical/Surgical Staff in conjunction with the Clinical Nutrition Center, Bach Mai Hospital, Ha Noi, Viet Nam.
- 2011 “Liver Disease: Lessons Learned from Omegaven from the Bedside to the Bench: The Role of Inflammation in Pediatric Intestinal Failure Associated Studies,” International Expert Meeting on Inflammation, Orlando, Florida.
- 2012 “Pharmacy Practice in the United States,” presented to the Department of Pharmacy, Bach Mai Hospital, Ha Noi, Viet Nam.
- 2012 “Nutrition Support Formulary Review Process,” presented to the Medical/Surgical Staff in conjunction with the Clinical Nutrition Center, Bach Mai Hospital, Ha Noi, Viet Nam.
- 2012 “Complications of Parenteral Nutrition,” presented to the Medical/Surgical Staff, Nhi Dong Children’s Hospital, Ho Chi Minh City, Viet Nam.
- 2012 “Complications of Parenteral Nutrition,” presented to the Medical/Surgical Staff, Bach Mai Hospital, Ha Noi, Viet Nam.
- 2015 “Parenteral and Enteral Nutrition,” and “Vitamins and Trace Elements,” Nhi Dong 1, Children’s Hospital Number 1, Ho Chi Minh City, Viet Nam.
- 2015 “Special Topics in Surgical Nutrition,” Departments of Nutrition and Surgery, Ha Noi Medical University, Ha Noi, Viet Nam.

- 2015 “Understanding Lipid Emulsions: Focus on SMOFlipid,” Neonatology Group of Wuhan, China, Wuhan, China.
- 2015 “Parenteral Nutrition Associated Liver Disease (PNALD): What are the prevention and treatment options? “The Third International Symposium on Paediatric Digestion and Nutrition,” Shanghai, China.
- 2016 “Compounding Considerations of Neonatal Parenteral Nutrition,” “Lipid Management Strategies in IFALD: Dose Minimization vs. Type of Oil,” and “Nutritional Considerations in Short Bowel Syndrome,” Primera Jornada Epic Latino. Cruzando Fronteras en Nutrición Neonatal, Quito, Ecuador.
- 2016 “Update on Pediatric GI Pharmacology,” American Pediatric Gastroenterology and Nutrition Nurses (APGNN) Annual Meeting as part of the World Congress of Pediatric Gastroenterology, Hepatology and Nutrition, Montreal, Canada.
- 2016 “History of Lipid Emulsions in the United States,” 9th International Pediatric Intestinal Failure and Rehabilitation Symposium, Los Angeles CA.
- 2017 “Let’s Getting Moving (or Not),” 4th Annual TPN Conference, Concord Specialty Pharmacy, Toronto, Canada.
- 2018 “Principles of Healthy Nutrition,” Nutritional Assessment,” “Enteral Nutrition,” “Parenteral Nutrition,” “Nutrition in Metabolic Disorder and Chronic Diseases,” “Nutritional Support in Preoperative and Post-Surgical Patients,” “Nutrition in Oncology,” “Critical Care Nutrition,” “ Pediatric Nutrition,” and “World Trends in Clinical Nutrition & Clinical Nutrition Model in Boston Hospital,” presented as part of a training course on clinical nutrition for health care providers at VinMec International Hospital and affiliates, Ha Noi, Vietnam, January 15-17, 2018.
- 2018 “Pharmacologic Therapies in the Treatment of Intestinal Failure Associated Complications” and “Transition of the Intestinal Failure Patient from Hospital to Home,” Multidisciplinary Management on Intestinal Rehabilitation, Hong Kong Children’s Hospital, Commissioned Training 2018, Queen Elizabeth Hospital, Hong Kong.
- 2018 “Fish oil based parental nutrition for children with intestinal failure,” The Hong Kong Society of Paediatric Surgery, Hong Kong, February 7, 2018.
- 2018 “Fish oil in parenteral nutrition associated liver disease (PNALD),” 19th Congress of the Parenteral and Enteral Nutrition Society of ASIA (PENSA), Seoul, Korea, June 14, 2018.
- 2018 “Pharmacologic management of intestinal failure associate complications,” 19th Congress of the Parenteral and Enteral Nutrition Society of ASIA (PENSA), Seoul, Korea, June 15, 2018.
- 2019 Managing motility,” 6th Annual Concord Specialty Pharmacy TPN Conference, Concord, ON, Canada, October 5, 2019.

- 2021 “The Role of Intravenous Lipid Emulsions in the NICU,” GOLD Neonatal Online Conference Vancouver, B.C. Canada June 8, 2021. [virtual]
- 2021 “Understanding the Differences with Intravenous Lipid Emulsions: Focus on Adverse Effects,” Closing the Gap, 7th Annual TPN Conference, Concord Specialty Pharmacy, Mississauga, Canada. [virtual]
- 2021 “Catheter Lock Solutions: The U.S. Perspective,” AAVA CVAA Collabinar: Locking Solutions: Current Application in Clinical Practice in Canada and the United States, November 16, 2021. [virtual]
- 2022 “Intravenous Fish Oil for PNALD from the Basics to the State-of-Art,” 2nd International Congress, the 21st Annual Congress of Korean Society for Parenteral and Enteral Nutrition (KSPEN 2022), June 11, 2022. [virtual]
- 2022 “Line Locking Solutions (when you can’t get ethanol),” 12th International Pediatric Intestinal Failure and Rehabilitation Symposium (PIFRS), Toronto, Canada, September 30, 2022.
- 2022 “Locking Solutions and Unusual Omegaven Dosing,” Moving Forward: Changing the Model, 8th Annual TPN Conference, Concord Specialty Pharmacy, Mississauga, Canada. November 12, 2022.
- 2023 “Fluid and Electrolytes in Intestinal Failure,” 9<sup>th</sup> Annual TPN Conference, Concord Specialty Pharmacy, Mississauga, Canada. September 30, 2023.
- 2024 “BPNG & ICNS Webinar - Aluminium Contamination in PN: Time for Action,” British Pharmaceutical Nutrition Group and International Clinical Nutrition Section ASPEN, February 7, 2024. [virtual]
- 2024 “Food as Medicine: Eat, Drink and Be Wary,” Claude Roy Lecture, CHU Ste-Justine, Montreal, Canada, May 1, 2024.
- 2024 “Clinical Nutrition for GI Surgical Patients,” 5th VinMec Clinical Pharmacy Conference, Ha Noi, Viet Nam, May 25, 2024. [virtual]
- 2024 “Obese and sarcopenic patients with acute complications in ICU (ARDS),” European Society for Parenteral and Enteral Nutrition (ESPEN), 46<sup>th</sup> ESPEN Congress, Milan, Italy, September 8, 2024.
- 2024 “Nutritional assessment,” European Society for Parenteral and Enteral Nutrition (ESPEN), 46<sup>th</sup> ESPEN Congress, Milan, Italy, September 8, 2024. (moderator)

### **Report of Clinical Activities and Innovations**

#### **Past and Current Licensure and Board Certification:**

1982	Registered Pharmacist, Massachusetts Board of Pharmacy
1983	Registered Pharmacist, District of Columbia, Board of Pharmacy
1993	Board Certified Nutrition Support Pharmacist
2000	Basic Life Support Certified (Healthcare Provider)
2001	Pediatric Advanced Life Support, Provider Certification
2003	Smallpox Vaccination Team Training, Boston Public Health Commission
2003	Pharmacy-Based Immunization Delivery Certificate Program for Pharmacists (Northeastern University)
2005-2025	CITI Course in the Protection of Human Subjects
2012	CITI Course in Biomedical Responsible Conduct of Research
2015	IS-00100.hcb Introduction to the Incident Command System (ICS 100) for Healthcare/Hospitals
2015	IS-00700.a National Incident Management System (NIMS) An Introduction
2016-2025	CITI Good Clinical Practice Course
2020	BCH Clinical Research Operations Certification Exam
2022	FDA Clinical Investigator Course

**Practice Activities:**

1982-1984	Distributive Pharmacy Practice	Children’s National Medical Center, Washington, DC	40 hours per week in a 323-bed, pediatric acute care academic setting
1984-present	Clinical Pharmacy (Nutrition)	Boston Children’s Hospital Boston, MA	40 hours per week in a 447-bed, pediatric acute care academic setting

**Clinical Innovations:**

2002-2022	<u>New treatment for intestinal failure associated liver disease (IFALD).</u> I have been involved in laboratory investigations involving the study of parenteral nutrition and designing methods to reduce its toxic effects on the liver. This involved the replacement of the lipid emulsion with a second less toxic emulsion. Working this team and collaborators within the Division of Gastroenterology, Hepatology and Nutrition, I helped design and carry out a large compassionate use trial funded in part by the FDA to more than 250 patients at Boston Children’s Hospital from 2002 through 2018. Our work is summarized in original articles numbers 10,16,18,20-22, 25,26,30,31,36, 38,41,50,56,58, 65 80, 84, and 85, directly led to the approval of Omegaven by the FDA for the treatment of IFALD.
2015-present	<u>Development of alternative intravenous lipid emulsions for other indications and patients populations, including critical illness and complications associated with preterm birth.</u> Building upon the experienced gain with the use of fish oil lipid emulsions in infants with IFALD, I have been collaborating with colleagues and

research fellows from Boston Children's Hospital and students from Harvard Medical School to create several different lipid formulations that could potentially improve outcomes in preterm infants and critically ill adults. Preliminary research, summarized in papers 52, 68, 69, 73, 74, 75 and 76, discussed how different blends of oils and the types of excipients present in these emulsions could influence outcomes in a variety of murine models. Moreover, as discussed in paper 74, we have investigated how specific fatty acids impact neurodevelopment (i.e., cognitive, motor, visual) in a murine model that could help inform in the development of an alternative intravenous lipid emulsion suitable for use in the preterm infant.

2018-present

Clinical application of a lipase-containing cartridge for delivery of enteral formula to patients with short bowel syndrome (SBS). In conjunction with members in the Department of Surgery, the Division of Gastroenterology, Hepatology and Nutrition and others, we are investigating the use of this device in patients with SBS in hopes of improving bowel adaptation and thus decrease the need for parenteral nutrition (PN). Funded through an FDA orphan drug development grant, I currently serve as a co-investigator on an exploratory study of this device that may offer a safe alternative to reducing PN dependence and achieving enteral autonomy in pediatric intestinal failure. I was also involved in the preclinical studies that demonstrated both improved fat and fat-soluble vitamin absorption in a porcine model of SBS as summarized in original articles 86, 87, 91 and 92.

2020-present

Clinical application of 4% tetrasodium edetate as an alternative to ethanol locking solutions in prevention central venous catheter infections. This compassionate device study arose from a clinical need to find an alternative to ethanol lock solutions to prevent central venous line infections in our PN dependent intestinal failure patients. In conjunction with members of our Home Parenteral Nutrition Program and the Department of Surgery, I identified an alternative therapy, developed a protocol, and currently follow 10-15 patients at any given time receiving this product. An abstract based on preliminary findings was presented at the 2023 ASPEN Nutrition Science & Practice Conference and later awarded the 2023 Oley Foundation's HPN Research Prize.

### **Report of Teaching and Education Innovations**

Bach Mai Hospital  
(BMH)/ Ha Noi, Viet  
Nam  
2010-2018

Working with clinicians from the National Institute of Nutrition, Hanoi Medical University and Bach Mai Hospital, as part of an international effort coordinated through the Abbott Fund Institute of Nutrition, I served as a member of a multidisciplinary team to establish country specific training programs in clinical nutrition. Over 2000 Vietnamese health care professionals received training in nutritional support. At BMH, malnutrition rates among hospitalized patients were 29% lower after the implementation of this initiative.

### **Report of Technological and Other Scientific Innovations**

Treatment and Prevention of Fatty Liver Disease Associated with Total Parenteral Nutrition (TPN) 2004 Nov 5 Application number 20080275119 Australia Patent 2004289353 Awarded: 2011 Canada Patent 2,545,752 Awarded:2013 U.S. Patent 9,566,260 U.S. Patent 9,629,821 U.S. Patent 10,350,186

Methods and compositions Relating comprising fish oil and/or omega-3 fatty acids 2022 U.S. Patent 11,324,697 2022 Russian Federation Patent 2,783,166 2023 Japanese Patent 2020-507088 European Patent EP 18 844969.8 **Licensed**

New lipid emulsion for preterm infants 2021 (patent pending)

**Report of Education of Patients and Service to the Community**

- No presentations below were sponsored by 3<sup>rd</sup> parties/outside entities*
- Those presentations below sponsored by outside entities are so noted and the sponsor(s) is (are) identified.*

**Activities**

2006-present Oley Foundation/Volunteer  
 The Oley Foundation is a national, non-profit organization that provides information, peer support, networking opportunities and more for individuals who depend on home intravenous (parenteral) and/or tube-fed (enteral) nutrition, their families, professionals, and others.

**Educational Material for Patients and the Lay Community:**

***Educational material or curricula developed for non-professional audiences***

2006	Tools for living better on home IV & tube feedings: HPN-Associated Liver Disease in Infant	Co-author (Puder M, Lee S)	Oley Foundation Lifeline Newsletter
2014	Tools for living better on home IV & tube feedings: HPN-Associated Liver Disease in Infant	Author	Oley Foundation Lifeline Newsletter

2018	Omegaven Receives FDA Approval	Co-author (Puder M)	Oley Foundation Lifeline Newsletter
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**Recognition:**

2004-2012	Who's Who in Medicine and Healthcare	Marquis Who's Who
2006-2012	Who's Who in Science and Engineering	Marquis Who's Who
2007	2007 Best of the New Award: "Nutrition Solution"	The Boston Globe
2009, 2020	Who's Who in the World	Marquis Who's Who
2009,2017, 2020	Who's Who in America	Marquis Who's Who
2010-2011	Who's Who of American Women	Marquis Who's Who
2018	Albert Nelson Marquis Lifetime Achievement Award	Marquis Who's Who

**Report of Scholarship**

**Peer-Reviewed Scholarship in print or other media:**

**Research Investigations**

1. Forchielli ML. **Gura KM**. Sandler R. Lo C Aminosyn PF or TrophAmine: Which provides more protection from cholestasis associated with total parenteral nutrition? J Pediatr Gastroenterol Nutr. 1995; 21(4):374-82. PMID: 8583287.
2. Forchielli ML. Lo CW. Richardson D. **Gura K**. Walker WA. Tonelli E. Central venous line related bacteremia during total parenteral nutrition and/or chemotherapy infusions in children. Annali Di Igiene Medicina Preventiva e di Comunita. 1997; 9(1):35-40. PMID: 9284587.
3. Forchielli ML. **Gura K**. Anessi-Pessina E. Richardson D. Cai W. Lo CW Success rates and cost-effectiveness of antibiotic combinations for initial treatment of central-venous-line infections during total parenteral nutrition. J Parenter Enteral Nutr. 2000; 24:119-125. PMID: 10772193.
4. Duggan C. Rizzo C. Cooper A. Klavon S. Fuchs V. **Gura K**. Richardson D. Collier S. Lo C Effectiveness of Clinical Practice Guideline for Parenteral Nutrition: A 5-Year Follow-up Study in a Pediatric Teaching Hospital, J Parenter Enteral Nutr. 2002; 26:377-381. PMID: 12405650.
5. Duggan C. Stark AR. Auestad N. Collier S. Fulhan J. **Gura K**. Utter S. Teixeira-Pinto A. Donovan K. Lund D Glutamine Supplementation in Infants with Gastrointestinal Disease: A Randomized, Placebo-Controlled Pilot Trial, Nutrition: The International Journal of Applied and Basic Nutritional Sciences, Nutrition. 2004; 20:752- 756. PMID: 15325681.
6. Alwayn IP, Javid PJ, **Gura KM**, Nosé V, Ollero M, Puder M. Do polyunsaturated fatty acids ameliorate hepatic steatosis in obese mice by SREPB-1 suppression or by correcting essential fatty acid deficiency. Hepatology. 2004;39(4):1176-7; author reply 1177-8. PMID: 15057926.



7. Alwayn IP, **Gura KM**, Nosé V, Zausche B, Javid P, Garza J, Verbesey J, Voss S, Ollero M, Andersson C, Bistrián B, Folkman J, Puder M. Omega-3 fatty acid supplementation prevents hepatic steatosis in a murine model of nonalcoholic fatty liver disease. *Pediatr Res*. 2005;57(3):445-52. PMID: 15659701.
8. Alwayn IP, Andersson C, Zauscher B, **Gura KM**, Nosé V, Puder M. Omega-3 fatty acids improve hepatic steatosis in a murine model: potential implications for the marginal steatotic liver donor. *Transplantation*. 2005; 79(5):606-8. PMID: 15753852.
9. Javid PJ, Greene AK, Garza J, **Gura KM**, Alwayn IP, Voss S, Nose V, Satchi-Fainaro R, Zausche B, Mulkern RV, Jaksic T, Bistrián B, Folkman J, Puder M. The route of lipid administration affects parenteral nutrition-induced hepatic steatosis in a mouse model. *J Pediatr Surg*. 2005; 40(9):1446-53. PMID: 16150347.
10. **Gura KM**, Duggan CP, Collier SB, Jennings RW, Folkman J, Bistrián BR, Puder M. Reversal of parenteral nutrition-associated liver disease in two infants with short bowel syndrome using parenteral fish oil: implications for future management. *Pediatrics*. 2006; 118(1): e197-201. PMID: 16818533.
11. Alwayn IP, Andersson C, Lee S, Arsenault DA, Bistrián BR, **Gura KM**, Nose V, Zauscher B, Moses M, Puder M. Inhibition of matrix metalloproteinases increases PPAR- $\alpha$  and IL-6 and prevents dietary-induced hepatic steatosis and injury in a murine model. *Am J Physiol Gastrointest Liver Physiol*. 2006; 291(6): G1011-9. PMID: 16844679.
12. **Gura KM**, Strijbosch R, Arnold S, McPherson C, Puder M. The Role of an Intravenous Fat Emulsion Comprised of Fish Oil in a PN Dependent Patient with Hypertriglyceridemia. *Nutr Clin Pract*. 2007; 22(6): 664-672. PMID: 18042955.
13. Lee S, **Gura KM** Puder M. Re: Influence of different intravenous lipid emulsions on hepatobiliary dysfunction in a rabbit model. *J Pediatr Gastroenterol Nutr*. 2008 Feb;46(2):224-225. PMID: 18223386.
14. **Gura KM**, Lee S, Valim C, Zhou J, Kim S, Modi BP, Arsenault DA, Strijbosch RA, Lopes S, Duggan C, Puder M. Safety and efficacy of a fish oil-based fat emulsion in the treatment of parenteral nutrition-associated Liver Disease. *Pediatrics*. 2008; 121: e678-e686. PMID: 18310188.
15. Strijbosch RAM, Lee S, Arsenault DA, Andersson C, **Gura KM**, Bistrián BR, Puder M. Fish oil prevents essential fatty acid deficiency and enhances growth: clinical and biochemical implications. *Metabolism*. 2008 May;57(5):698-707. PMID: PMC3364597.
16. de Meijer VE, **Gura KM**, Le HD, Meisel, JA, Puder M. Fish oil-based lipid emulsions prevent and reverse parenteral nutrition-associated liver disease: The Boston experience. *JPEN J Parenter Enteral Nutr*, 2009 Sep-Oct; 33(5):541-7. Epub July 2009. PMID: 19571170.
17. Yang CF, Lee M, Valim C, Hull MA, Zhou J, Jones BA, **Gura K**, Collier S, Lo C, Duggan C, Jaksic T. Persistent alanine aminotransferase elevations in children with parenteral nutrition-associated liver disease. *J Pediatr Surg*. 2009 Jun; 44(6):1084-7. PMID: 19524721.
18. Puder M, Valim C, Meisel JA, Le HD, deMeijer VE, Robinson EM, Zhou J, Duggan C, **Gura KM**. Parenteral fish oil improves outcomes in patients with parenteral nutrition associated liver injury, *Ann Surg*. 2009 Sep;250(3):395-402. Epub Aug 2009. PMID: PMC3366279.

19. Le HD, Meisel JA, de Meijer VE, **Gura KM**, Puder M. The essentiality of arachidonic acid and docosahexaenoic acid. *Prostaglandins Leukot Essent Fatty Acids*. 2009 Aug-Sep;81(2-3):165-70. Epub June 18 2009. PMID: PMC3361712.
20. Lee S, Valim C, Johnston P, Le HD, Meisel J, Arsenault DA, **Gura KM**, Puder M. Impact of fish oil-based lipid emulsion on serum triglyceride, bilirubin and albumin levels in children with parenteral nutrition-associated liver disease. *Ped Res*. 2009 Dec; 66(6):698-703. Epub Aug 14 2009. PMID: PMC3377973.
21. de Meijer VE, Lee HD, Meisel JA, **Gura KM**, Puder M. Parenteral fish oil as monotherapy prevents essential fatty acid deficiency in parenteral nutrition dependent patients. *J Pediatr Gastroenterol Nutr*. 2010 Feb; 50(2):212-8. Epub 2009 Dec 22. PMID: PMC3365554.
22. Le HD, de Meijer VE, Zurakowski D, Meisel JA, **Gura KM**, Puder M. Parenteral fish oil as monotherapy improves lipid profiles in patients with parenteral nutrition-associated liver disease. *JPEN J Parenter Enteral Nutri*. 2010 Jan;46(1):122-7. PMID: 20852175.
23. Bechard L, Feldman H, Gordon C, **Gura KM**, Sonis A, Leung K, Venick R, Guinan E, Duggan CS. A multi-center, randomized, controlled trial of parenteral nutrition titrated to resting energy expenditure in children undergoing hematopoietic stem cell transplantation ("PNTREE"): rationale and design. *Contemporary Clinical Trials* Dec 15 2009 [Epub ahead of print] PMID: 20004739.
24. Ling PR Andersson C, Strijbosch R, Lee S, Silvestri A, **Gura KM**, Puder M, Bistrrian BR. Effects of glucose or fat calories in TPN on systemic inflammation and fat metabolism in rats. *Metabolism*. 2011 Feb;60(2):195-205. Epub. 2010 Jan 25. PMID: 20096898.
25. de Meijer VE, Gura KM, Meisel JA, Le HD, Puder M. Parenteral fish oil monotherapy in the management of patients with parenteral nutrition-associated liver disease. *Arch Surg*. 2010 June;145(6):547-551. PMID: 20566974.
26. **Gura KM**, Puder M. Rapid infusion of fish oil based emulsion in infants does not appear to be associated with fat overload syndrome. *Nutr Clin Pract*. 2010 Aug; 25(4):399-402 PMID: 20702846.
27. Jones BA, Hull MA, Richardson DS, Zurakowski D, **Gura K**, Fitzgibbons SC, Duro D, Lo CW, Duggan C, Jaksic T. Efficacy of ethanol locks in reducing central venous catheter infections in pediatric patients with intestinal failure. *Journal of Pediatric Surgery*. 2010; 45:1287-1293. PMID: 20620333.
28. Meisel JA, Le HD, De Meijer, VE, Nose V, **Gura KM**, Mulkern RV, Sharif MRA, Puder M. Comparison of five intravenous lipid emulsions and their effects on hepatic steatosis in a murine model. *J Pediatr Surg*. 2011 Apr; 46(4):666-73. PMID: 21496535.
29. Le HD, Meisel JA, Meijer VE, Fallon EM, **Gura KM**, Nose V, Bistrrian BR, Puder M. Docosahexaenoic acid and arachidonic acid prevent essential fatty acid deficiency and hepatic steatosis. *JPEN J Parenter Enteral Nutri*. 2012 Jul;36(4):431-41. Epub. 2011 Oct 30. PMID: PMC3380148.
30. Le HD, de Meijer VE, Robinson EM, Zurakowski D, Potemkin AK, Arsenault DA, Fallon EM, Malkan A, Bistrrian B, **Gura KM**, Puder M. Parenteral fish oil-based lipid emulsion improves fatty acid profiles and lipids in parenteral nutrition-dependent children. *Am J Clin Nutr*. 2011 Sep;94(3):749-58. Epub. 2011 Jul 20. PMID: 21775562.

31. Fuchs J, Fallon EM, **Gura KM**, Puder M. Use of omega-3 fatty acid based emulsions in the treatment of parenteral nutrition-induced cholestasis in patients with microvillous inclusion disease. *J. Ped Surg.* 2011 Dec; 46(12):2376-2382. PMID: 22152886.
32. Sharma TS, Bechard LJ, Feldman HA, Venick R, **Gura K**, Gordon CM, Sonis A, Guinan EC, Duggan C. Effect of titrated parenteral nutrition on body composition after allogeneic hematopoietic stem cell transplantation in children: a double-blind, randomized, multicenter trial. *Am J Clin Nutr.* 2012 Feb; 95(2):342-51. [Epub ahead of print] PMID: 22205317.
33. Bechard LJ, Feldman HA, Venick R, **Gura K**, Gordon C, Sonis A, Mehta N, Guinan EC, Duggan C. Attenuation of resting energy expenditure following hematopoietic SCT in children. *Bone Marrow Transplant.* 2012 Oct; 47(10):1301-6. PMID: 22343669.
34. Nehra D, Fallon EM, Carlson SJ, Potemkin AK, Hevelone ND, Mitchell PD, **Gura KM** Puder M. Provision of a Soy-Based Intravenous Lipid Emulsion at 1 g/kg/d Does Not Prevent Cholestasis in Neonates. *JPEN J Parenter Enteral Nutr.* 2012 Jul 5. PMID: 22767698.
35. Le HD, Fallon EM, Kalish BT, de Meijer VE, Meisel JA, **Gura KM**, Nose V, Pan AH, Bistran BR, Puder M. The effect of varying ratios of docosahexaenoic acid and arachidonic acid in the prevention and reversal of biochemical essential fatty acid deficiency in a murine model. *Metabolism.* 2013 Apr;62(4):499-508. PMID: 23151438.
36. Nandivada P, Cowan E, Carlson SJ, Chang M, **Gura KM**, Puder M. Mechanisms for the effects of fish oil lipid emulsions in the management of parenteral nutrition-associated disease. *Prostaglandins Leukot Essent Fatty Acids.* 2013 Apr 18. PMID: 23602846.
37. Díaz JJ, **Gura KM**, Roda J, Perez-Atayde AR, Duggan C, Jaksic T, Lo CW. AST to platelet index is predictive of cirrhosis but not of fibrosis in pediatric patients with intestinal failure *J Pediatr Gastroenterol Nutr.* 2013 May 8. [Epub ahead of print] PMID: 23666459.
38. Nehra D, Fallon EM, Potemkin AK, Voss SD, Mitchell PD, Valim C, Belfort MB, Bellinger DC, Duggan C, **Gura KM**, Puder M. A Comparison of 2 Intravenous Lipid Emulsions: Interim Analysis of a Randomized Controlled Trial. *JPEN J Parenter Enteral Nutr.* 2013 Jun 14. PMID: 23770843.
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40. Miller J, Dalton MK, Duggan C, Lam S, Iglesias J, Jaksic T, **Gura KM**. Going with the Flow or Swimming Against the Tide: Should Children with Central Venous Catheters Swim? *Nutr Clin Pract.* 2013 Dec 17. [Epub ahead of print] PMID: 24347530.
41. Nandivada P, Chang MI, Potemkin AK, Carlson SJ, Cowan E, O'Loughlin AA, Mitchell PD, **Gura KM**, Puder M. The Natural History of Cirrhosis from Parenteral Nutrition-Associated Liver Disease after Resolution of Cholestasis with Parenteral Fish Oil Therapy. *Ann Surg.* 2013 Dec 26. PMID: 24374535.
42. Gosselin KB, Feldman HA, Sonis AL, Bechard LJ, Kellogg MD, **Gura K**, Venick R, Gordon CM, Guinan EC, Duggan C. Serum citrulline as a biomarker of gastrointestinal function during hematopoietic cell transplantation (HCT) in children. *J Pediatr Gastroenterol Nutr.* 2014 Mar 6. [Epub ahead of print] PMID: 24614125.

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44. Moniz TT, Chu S, Tom C, Lutz P, Arnold A, **Gura KM**, Patterson A. Sterile product compounding using an I.V. compounding workflow management system at a pediatric hospital. *Am J Health-Syst Pharm*. 2014; 71:1311-7. PMID: 25027539.
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### **Other non-peer reviewed scholarship**

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### **Local/Unpublished Clinical Guidelines and Reports:**

1. Arsenault D, Brenn M, Kim S, **Gura K**, Compher C, Simpser E; Board of Directors American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.), Puder M. A.S.P.E.N. Clinical guidelines: Hyperglycemia and hypoglycemia in the neonate receiving parenteral nutrition. *JPEN J Parenter Enteral Nutr*. 2012 Jan; 36(1):81-95. Epub. 2011 Dec 16. PMID: 22179520 (Standard of Care)

2. Fallon EM, Nehra D, Potemkin AK, **Gura KM**, Simpser E, Compher; Board of Directors American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.), Puder M. A.S.P.E.N Clinical guidelines: Nutrition support of neonatal patients at risk for necrotizing enterocolitis. *JPEN J Parenter Enteral Nutri*. 2012 Sep;36(5):506-23. Epub. 2012 Jun 29. PMID:22753618 (Standard of Care)

3. Nehra D, Carlson S, Fallon EM, **Gura KM**; Board of Directors American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.), Puder M. A.S.P.E.N. Clinical guidelines: Nutrition support of neonatal patients with metabolic bone disease. *JPEN J Parenter Enteral Nutri*. 2013 May 17. [Epub ahead of print] PMID:23685349 (Standard of Care)

4. Standardized Competencies for Parenteral Nutrition Administration: The ASPEN Model. Guenter P, Worthington P, Ayers P, Boullata JI, **Gura KM**, Marshall N, Holcombe B, Richardson DS; Parenteral Nutrition Safety Committee, American Society for Parenteral and Enteral Nutrition. *Nutr Clin Pract*. 2018 Mar 23. doi: 10.1002/ncp.10055. [Epub ahead of print]

### **Abstracts, Poster Presentations, and Exhibits Presented at Professional Meetings:**

1. Broyles K , Hoch R, McClelland J, **Gura K**, Carey A. Hypertriglyceridemia secondary to rapid infusion of an intravenous lipid emulsion due to shortage of dual chamber bags in a parenteral

- nutrition dependent patient. 11th International Pediatric Intestinal Failure and Rehabilitation Symposium, Toronto, Canada, June 26, 2020. [Poster Presentation]
2. Cho BS, Fell GL, Anez-Bustillos L, Dao DT, Pan A, **Gura KM**, Puder M. Loss of function of the hepatic fatty acid translocase receptor CD36 is insufficient to protect from liver steatosis in a murine model of parenteral nutrition-induced liver injury. Association of American Physicians, American Society for Clinical Investigation, and American Physician-Scientists Association Joint Meeting. Chicago, IL. April 2018. [Poster Presentation]
  3. Anez-Bustillo L, Yu L, Ko V, Dao DT, Hurley AK, **Gura KM**, Puder M. Vitamin E Levels in Children Treated with an Intravenous Fish Oil Lipid Emulsion. American Society for Parenteral and Enteral Nutrition. Poster of Distinction. March 2020. [Podium Presentation]
  4. Tsikis ST, Hirsch T, Fligor SC, Pan A, Joiner MM, Mitchell P, **Gura KM**, Puder M, Direct Thrombin Inhibitors as Alternatives to Heparin to Preserve Lung Growth and Function in Congenital Diaphragmatic Hernia. Podium Presentation 28th Annual New England Surgical Resident and Fellow Research Presentation Day. May 2022. [Virtual], [First Place Basic Science]
  5. Lumeng JY, Anez-Bustillos L, Mitchell PD, Ko VH, MD, Secor JD, Potemkin Hurley A, Dao DT, Fligor SC, Cho BS, Tsikis ST, **Gura KM**, Puder M. Incidence and Development of Cholestasis in Surgical Neonates Receiving a Soy, MCT, Olive, Fish Oil-Based ILE. 11th Annual Harvard Surgery Research Day - March 12, 2022. [Platform Presentation],[2nd Place Clinical Research]
  6. Behbahan RK, Kiritsy P, **Gura K**. Compatibility profiles of two newer lipid emulsion formulations with various intravenous medications following USP <729> method I and method II standards. ASPEN 2022 Nutrition Science & Practice Conference, Seattle, WA. March 27, 2022. [Poster Presentation]
  7. Lumeng JY, Anez-Bustillos L, Mitchell PD, Ko VH, MD; Secor JD, Potemkin Hurley A, Dao DT, Fligor SC, Cho BS, Tsikis ST, **Gura KM**, Puder M. Incidence and Development of Cholestasis in Surgical Neonates Receiving a Soy, MCT, Olive, Fish Oil-Based ILE. ASPEN 2022 Nutrition Science & Practice Conference, Seattle, WA. March 28, 2022. [Platform Presentation],[Henry M. Vars Award Candidate]
  8. Fligor S, Tsikis S, Hirsch T, Pan A, Mitchell P, Moskowitsova K, Rincon-Cruz L, Whitlock A, Nedder A, **Gura K**, Puder M. A Structurally Engineered Fatty Acid (SEFA-6179) Prevents Cholestasis, Steatosis, and Fibrosis in a Preterm Piglet Model of Intestinal Failure-Associated Liver Disease. Late-Breaking Basic Science Plenary (one of 6). Digestive Disease Week, San Diego, CA. 2022. [Podium Presentation]
  9. Fligor S, Tsikis S, Hirsch T, Pan A, Mitchell P, Moskowitsova K, Rincon-Cruz L, Whitlock A, Nedder A, **Gura K**, Puder M. SEFA-6179 Prevents Cholestasis, Steatosis, and Fibrosis in a Preterm Piglet Model of Intestinal Failure-Associated Liver Disease. International Pediatric Intestinal Failure and Rehabilitation Symposium, Toronto, Canada. September 2022. [Podium Presentation] [Top Abstract Award]
  10. Gray M, Murphy M, Chang D, Turner A, Carey A, Modi BP, **Gura K**. Novel Dosing of Fish Oil ILE to Promote Euglycemia during PN Cycling in and Infant with Intestinal Failure: A Case Report. . International Pediatric Intestinal Failure and Rehabilitation Symposium, Toronto, Canada. September 2022. [Poster Presentation]

11. Fligor S, Tsikis S, Hirsch T, Ashish Jain A, Sun L, Pan A, Rockowitz S, Sliz P, **Gura K**, Puder M. Next Generation RNA-SEQ Implicates New Pathways in Pathogenesis of Intestinal Failure-Associated Liver Disease in a Preterm Piglet Model. North American Society of Pediatric Gastroenterology, Hepatology and Nutrition, NASPGHAN 2022- Orlando, FL, October 14, 2022. [Poster Presentation]
12. Tsikis S, MD, Fligor SC, Secor JD, Yu LJ, Pan A, Mitchell PD, Loring G, First E, Nedder AP, Grammer RM, Pattison B, **Gura KM**, Puder M. An In-line Digestive Cartridge Reduces Dependence on Parenteral Nutrition and Increases Intestinal Growth in a Porcine Model of Short Bowel Syndrome. North American Society of Pediatric Gastroenterology, Hepatology and Nutrition, NASPGHAN 2022- Orlando, FL, October 14, 2022, [Podium Presentation] [NASPGHAN Nutrition Prize]
13. Fleet SE, Ariagno K, Turner A. Takahashi K, Marcley S, **Gura K**, Leichtner A, Wolbrink T. Development of an Online Parenteral Nutrition Simulator. North American Society of Pediatric Gastroenterology, Hepatology and Nutrition, NASPGHAN 2022- Orlando, FL, October 14, 2022. [Poster Presentation]
14. Fligor S, Tsikis S, Hirsch T, Pan A, Mitchell P, Quigley M, Carbeau S, Arthur Nedder A, **Gura K**, Puder M. Absorption of an Engineered Medium Chain Fatty Acid in Two Short Bowel Syndrome Minipig Models. ASPEN Nutrition Science & Practice Conference: April 20-23, 2023 (Las Vegas, NV. JPEN J Parenter Enteral Nutr. 2023. [Podium Presentation] [Winner, Harry M. Vars Award]
15. Tsikis S, Fligor S, Hirsch T, Mitchell P, Amy Pan A, Moskowitzova K, Whitlock A, Loring G, First E, Nedder A, **Gura K**, Puder M. A Digestive Cartridge Reduces Parenteral Nutrition Dependence and Promotes Intestinal Adaptation in a Porcine Model of Short Bowel Syndrome. ASPEN Nutrition Science & Practice Conference: April 20-23, 2023 (Las Vegas, NV. JPEN J Parenter Enteral Nutr. 2023. [Poster Presentation]
16. Bharani T, Mogensen K Rosen JH, **Gura K**, McManus KD, Robinson, M. Concomitant use of Monoamine Oxidase Inhibitor and Tyrosine in Parenteral Nutrition. ASPEN Nutrition Science & Practice Conference: April 20-23, 2023 (Las Vegas, NV. JPEN J Parenter Enteral Nutr. 2023. [Poster Presentation]
17. Hirsch T, Fligor S, Tsikis S, Carbeau S, Mitchell P, **Gura K**, Puder M. 4% Tetrasodium-EDTA and Catheter Complication Rates in a High-Risk Population of Pediatric Intestinal Failure Patients. ASPEN Nutrition Science & Practice Conference: April 20-23, 2023 (Las Vegas, NV. JPEN J Parenter Enteral Nutr. 2023. [Poster Presentation]
18. Fligor SC, Hirsch TI, Tsikis ST, Joiner MM, Mitchell PD, McClelland J, Carey A, **Gura KM**, Puder M. Use of 70% Ethanol Lock Solution, Compared to Heparin, Increases Mechanical Line Complications in a Pediatric Intestinal Failure Population. ASPEN Nutrition Science & Practice Conference: April 20-23, 2023 (Las Vegas, NV. JPEN J Parenter Enteral Nutr. 2023. [Podium Presentation] [Winner, DNI Abstract of Distinction]
19. Wang SZ, Hirsch TI, Fligor SC, Tsikis ST, Pan A, Quigley M, DeVietro A, Mitchell PD, **Gura KM**, Puder M. An engineered medium-chain fatty acid analogue protects against lipopolysaccharide-induced liver injury in a murine model of intestinal failure-associated liver

disease. Podium Presentation. 13th Annual Harvard Surgery Research Day. Boston, MA. March 2024.

### **Narrative Report**

I am a trained pediatric pharmacist with a focus on clinical nutrition. My primary research is in the area of intestinal failure associated liver disease (IFALD). My interest in omega-3 fatty acids peaked when I discovered that fish oil-based intravenous lipid emulsions could be safely used to treat essential fatty acid deficiency (EFAD) (peer-reviewed paper 12). This adolescent had undergone hematopoietic stem cell transplantation and developed life-threatening complications of his EFAD and was made DNR. After obtaining emergency FDA approval, I obtained intravenous fish oil from its European manufacturer, obtained urgent FDA and IRB approval, oversaw its administration, and successfully treated his nearly fatal deficiency. He survived and was later discharged home.

More fundamentally, I led a team that discovered that intravenous fish oil reversed IFALD in infants receiving parenteral nutrition (PN), one of the most recalcitrant problems of PN use. It has been reported that patients with sustained cholestasis >3 months had <20% survival at 5 years of age. (J Pediatr 2004;145:157–63) Our laboratory work demonstrated that the injury of IFALD results, in part, from the conventional intravenous lipid emulsion used with PN. We discovered a treatment for IFALD in which that lipid emulsion is replaced with a less toxic one. This therapy was part of an FDA-funded compassionate use trial that offered intravenous fish oil to patients with IFALD. Previously, the primary treatment for IFALD was liver/small bowel or multivisceral transplantation. Following its implementation, the prior 38% mortality rate for this disease decreased dramatically. At its peak in 2006, there were 15 liver/small bowel transplants performed in the US in children < 1 year of age with IFALD. Overall, from 2007 to 2012, there was a 25% reduction in the intestinal transplantations in the US because of the improved care of these patients (Am J Transplant. 2014 Sep;14(9):1976-84). According to experts at Toronto's Hospital for Sick Children, the use of this lipid emulsion represents a major paradigm shift in the management of children with IFALD (J Pediatr Gastroenterol Nutr. 2009 Feb; 48(2):209-15). Rather than rushing toward transplant, the emphasis is currently on intestinal rehabilitation as the children now have the time necessary to allow for bowel adaptation. Steven Abrams MD, a professor in the Department of Pediatrics at Dell Medical School, has written that this treatment has been responsible for the substantial reduction in the number of liver and multivisceral transplantations in children due to IFALD (Adv Nutr 2013 4: 518-520). In July 2018, the drug (Omegaven) received FDA approval. Based on our findings, intravenous fish oil is now used to treat IFALD globally.

Since Omegaven's approval, I have been involved in several additional projects that have led to the development of alternative lipid emulsions and other innovative therapies that will impact the quality of life of patients with intestinal failure. We have received patents (US Patent 11,324,697, Russian Federation Patent 2,783,166) on these new emulsions and have begun to work with industry to bring these products to market. We are also working to create intravenous lipid emulsions for general use in critically ill patients (peer-reviewed paper 46) and a product specifically designed to meet the unmet needs of the neonate (peer-reviewed paper 74).

My aforementioned research experience has led me to assume an additional role as the manager of the Investigational Drug Service at Boston Children's Hospital (BCH). I work with a variety of clinicians throughout the institution to help design their interventional protocols and as work with study sponsors to improve the safety of their studies. In several instances, studies previously approved by other institutions were significantly revamped after our team critically reviewed their design and found major dosing errors and methods of administration that could have potentially resulted in patient harm. I also work closely with the staff of our Experimental Therapeutics Unit and other members of the research community at BCH to optimize educational offerings as they relate to investigational protocols involving medications or devices.

Similarly, as an extension of my current position, I educate surgical research fellows and medical students on various aspects of PN and lipid emulsion technologies. I also work with them on manuscript preparation and assist in research study design. Furthermore, I oversee the PGY2 pharmacy residents' research projects and those enrolled in the honors program at MCPHS University.

In my role as a clinical pharmacist within the Division of Gastroenterology, Hepatology, and Nutrition and as a member of Center for Advanced Intestinal Rehabilitation (CAIR), I am constantly challenged with identifying solutions for problems identified while caring for these patients with complex nutritional needs and educating students, residents, and fellows in the process. This has often led to collaborating with these trainees to develop guidelines and to summarize our experiences, such as a case report, review paper or book chapter. Several times per year, I lecture locally, regionally and internationally on parenteral nutrition, drug nutrient interactions and the pharmacologic management of intestinal failure and inflammatory bowel disease. I have been working with a multidisciplinary team within the GI Division to develop an online parenteral nutrition simulator that is being piloted and will eventually be offered through OPENPediatrics. I am currently working with several surgical research fellows in the CAIR program to develop a tool to improve patient compliance and assist in transitions of care as these patients enter adulthood. For more than 20 years, I have worked closely with many residents, fellows, and visiting physicians on a variety of research projects and publications. In the process, I teach them about pediatric nutrition, the challenges in providing medications to infants and children with intestinal failure, and the nuances of drug formulation design. This has led to many of the practice-based research projects previously described.

From 2010-2018, I had the unique privilege to work with Bach Mai Hospital (BMH), Hanoi Medical University (HMU) and the National Institute of Nutrition (NIN) in Viet Nam through the Abbott Fund Institute of Nutrition Science (AFINS) and Boston University School of Medicine to address hospital malnutrition and strengthen hospital nutrition knowledge, attitudes, and practices. We helped Vietnamese clinicians establish country specific growth curves, create training programs in clinical dietetics, and develop multidisciplinary clinical nutrition services. We provided technical support for the development of nutrition and dietetics degrees at HMU with more than 30 nurse-nutritionist and 50 bachelor's in nutrition and dietetics graduates, six research projects with the NIN tracking hospital nutrition, and the training of more than 2,000 Vietnamese health care professionals to improve capacity in nutrition. Additionally, as summarized in original paper 49, we found that hospitalized patients surveyed in 2013 at BMH after the establishment of our training program were 29% less likely to be malnourished compared to those surveyed in 2010.

In summary, my career path has allowed me to take clinical issues and bring them to the laboratory to develop new approaches to old problems, and then bring these solutions to the bedside. I have been fortunate to work in an environment that allows me to work simultaneously on numerous clinical, academic, and research problems that have resulted in new therapies, and subsequently share this knowledge through teaching and publication.