Professionals Call on the CDC to Address Misapplication of its Guideline on Opioids for Chronic Pain through Public Clarification and Impact Evaluation

Authors: Health Professionals for Patients in Pain (HP3)
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I. In 2016, the Centers for Disease Control and Prevention, CDC, issued a Guideline for Prescribing Opioids for Chronic Pain for primary care physicians. Its laudable goals were to improve communication between clinicians and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy. The Guideline reflected the work of appointed experts who achieved consensus on the matter of opioid use in chronic pain.

Among its recommendations are that opioids should rarely be a first option for chronic pain, that clinicians must carefully weigh the risks and benefits of maintaining opioids in patients already on them, and that established or transferring patients should be offered the opportunity to re-evaluate their continued use at high dosages (i.e., > 90 MME, morphine milligram equivalents).

In light of evidence that prescribed dose may pose risks for adverse patient events, clinicians and patients may choose to consider dose reductions, when they can be accomplished without adverse effect, and with possible benefit, according to some trial data.

Nonetheless, it is imperative that healthcare professionals and administrators realize that the Guideline does not endorse mandated involuntary dose reduction or discontinuation, as data to support the efficacy and safety of this practice are lacking.

II. Within a year of Guideline publication, there was evidence of widespread misapplication of some of the Guideline recommendations. Notably, many doctors and

regulators incorrectly believed that the CDC established a threshold of 90 MME as a de facto daily dose limit. Soon, clinicians prescribing higher doses, pharmacists dispensing them, and patients taking them came under suspicion.

Actions that followed included payer-imposed payment barriers, pharmacy chain demands for the medical chart, or explicit taper plans as a precondition for filling prescriptions, high-stakes metrics imposed by quality agencies, and legal or professional risks for physicians, often based on invocation of the CDC's authority. Taken in combination, these actions have led many health care providers to perceive a significant category of vulnerable patients as institutional and professional liabilities to be contained or eliminated, rather than as people needing care.

III. Adverse experiences for these patients are documented predominantly in anecdotal form, but they are concerning. Patients with chronic pain, who are stable and, arguably, benefiting from long-term opioids, face draconian and often rapid involuntary dose reductions. Often, alternative pain care options are not offered, not covered by insurers, or not accessible. Others are pushed to undergo addiction treatment or invasive procedures (such as spinal injections), regardless of whether clinically appropriate.

Consequently, patients have endured not only unnecessary suffering, but some have turned to suicide or illicit substance use. Others have experienced preventable hospitalizations or medical deterioration in part because insurers, regulators and other parties have deployed the 90 MME threshold as a both a professional standard and a threshold for professional suspicion. Under such pressure, care decisions are not always based on the best interests of the patient.

IV. Action is Required: The 2016 Guideline specifically states, "the CDC is committed to evaluating the guideline to identify the impact of the recommendations on clinician and patient outcomes, both intended and unintended, and revising the recommendations in future updates when warranted". The CDC has a moral imperative to uphold its avowed goals and to protect patients.

Therefore, we call upon the CDC to take action:

- We urge the CDC to follow through with its commitment to evaluate the impact by consulting directly with a wide range of patients and caregivers, and by engaging epidemiologic experts to investigate reported suicides, increases in illicit opioid use and, to the extent possible, expressions of suicidal ideation following involuntary opioid taper or discontinuation.

- We urge the CDC to issue a bold clarification about the 2016 Guideline – what it says and what it does not say, particularly on the matters of opioid taper and discontinuation.

Signatories here represent their own views, and do not purport to reflect formal positions of their employing agencies, governmental or otherwise. *For questions please contact Stefan G. Kertesz, MD (skertesz@uabmc.edu) and Sally Satel, MD (slsatel@gmail.com)*

Daniel P. Alford, MD, MPH
Professor of Medicine
Director, Clinical Addiction Research and Education (CARE) Unit
Director, Safe and Competent Opioid Prescribing Education (SCOPE of Pain) Program
Boston University School of Medicine and Boston Medical Center, Boston, MA

Richard C. Dart, MD, PhD
Executive Director, RADARS System, Denver Health and Hospital Authority
Professor of Emergency Medicine, University of Colorado School of Medicine
Former Director, ONDCP (2014-2017)

James DeMicco, PharmD
Adjunct Professor, Long Island University College of Pharmacy
Pharmacist-in-Charge, J&J Pharmacy, Hackensack, NJ

Stefan G. Kertesz, MD, MSc
Professor of Medicine, University of Alabama at Birmingham School of Medicine
Opioid Safety Initiative, Opiate Advice Team, Opioid Risk Mitigation Team
Birmingham VA Medical Center
Birmingham, AL

Sally Satel MD
Lecturer in Psychiatry, Yale University School of Medicine
Resident Scholar, American Enterprise Institute
Washington DC

Organizational Endorsements
Association for Multidisciplinary Education and Research in Substance use and Addiction)

Individual Endorsements
Barry R. McCaffrey, General USA (Ret)
ONDCP White House Drug Control Policy Director (1996-2001)
Chairman Addiction Policy Forum Advisory Council

Jerome Jaffe, MD
Director, U.S. Special Action Office for Drug Abuse Prevention (1971-1973) (“Drug Czar”)
Professor, University of Maryland School of Medicine
Professor-adjunct, Johns Hopkins University

Baltimore, MD

Michael Botticelli
Executive Director, Grayken Center for Addiction, Boston Medical Center
ONDCP White House Drug Control Policy Director (2014-2017)

Ajay Manhapra MD
Lecturer, Department of Psychiatry, Yale School of Medicine
Advanced Pain Clinic, Hampton VA Medical Center, Ha
Asst. Professor, Department of PM&R and Psychiatry, Eastern Virginia Medical School, Norfolk, VA

Richard Saitz MD, MPH, FACP, DFASAM
Chair and Professor, Department of Community Health Sciences
Boston University School of Public Health
Professor of Medicine, Boston University School of Medicine

Scott E. Hadland, MD, MPH, MS
Assistant Professor
Grayken Center for Addiction, Boston Medical Center
Division of General Pediatrics, Boston University School of Medicine
Boston, MA

Colleen LaBelle MSN, RN-BC, CARN
Director STATE OBAT
Director Boston Medical Center OBAT
Grayken Center for Addiction, Boston Medical Center
Boston MA

Sarah E. Wakeman, MD
Medical Director, Mass General Hospital Substance Use Disorder Initiative
Assistant Professor of Medicine, Harvard Medical School

Beth Darnall, PHD
Clinical Professor
Stanford University School of Medicine
Department of Anesthesiology, Perioperative and Pain Medicine
Palo Alto, CA

Mitchell S. Rosenthal, MD
President, Rosenthal Center for Addiction Studies

Theodore J Cicero, PhD
John P Feighner Professor of Psychiatry, Washington University School of Medicine,

St Louis, MO

Cara A. Poland, MD, MEd
Director, Spectrum Health's GREAT MOMs
Medical Director of Addiction, Spectrum Health
Assistant Professor of Medicine and Psychiatry, Michigan State University College of Human Medicine

Matthew J. Bair, MD, MS
Associate Professor of Medicine, Indiana University School of Medicine
Core Investigator, VA Center for Health Information and Communication
Indianapolis, IN

Barbara J Turner MD, MSED
Professor of Clinical Medicine
Keck School of Medicine
University of Southern California
Los Angeles, CA

Christopher W. Shanahan MD MH FACP
Assistant Professor of Medicine
Boston University School of Medicine and Boston Medical Center, Boston, MA
Grayken Center for Addiction, Boston Medical Center
Clinical Addiction Research and Education (CARE) Unit

Sidney H. Schnoll MD, PhD
VP, Pharmaceutical Risk Management
Pinney Associates, Inc.
Bethesda, MD

Robert Twillman, PhD, FACLP
Executive Director
Academy of Integrative Pain Management
Clinical Associate Professor (Volunteer Faculty)
Department of Psychiatry and Behavioral Sciences
University of Kansas School of Medicine

Diana Coffa MD
Associate Clinical Professor
University of California, San Francisco
Director, Family and Community Medicine Residency Program

Daniel G. Tobin, MD, FACP
Associate Professor of Medicine

Medical Director, Primary Care
Yale University School of Medicine

Edwin A. Salsitz, MD, DFASAM
Associate Clinical Professor of Psychiatry
Icahn School of Medicine at Mount Sinai
Mount Sinai Beth Israel
New York, New York

Donna Beers MSN, RN-BC, CARN
Associate Director
Training and Technical Assistance
Office Based Addiction Treatment
Boston Medical Center
617 414.6633

Sheryl Cifrino RN DNP
Curry College School of Nursing
Milton MA 02186

Ruth A. Potee, MD
Medical Director
Franklin Recovery Center
Franklin County House of Corrections
Valley Medical Group
Greenfield, MA

Paula J. Lum, M.D., M.P.H.
Professor of Medicine
HIV, ID and Global Medicine Division
Director, UCSF Primary Care Addiction Medicine Fellowship Program
University of California, San Francisco and San Francisco General Hospital
San Francisco, CA

John Mendelson MD
Chief Medical Officer - Ria Health
Senior Research Scientists - Friends Research Institute
Clinical Professor of Medicine - UCSF
1049 Market St #603
San Francisco, CA 94103

Ellie Grossman, MD MPH
Instructor, Harvard Medical School
Primary care lead for behavioral health integration, Cambridge Health Alliance

Somerville, MA

Carolyn Chu, MD, MSc
Associate Professor
Department of Family & Community Medicine
University of California, San Francisco

Meg D Newman, MD, FACP
UCSF Senate Emeritus- Medicine
HIV, ID and Global Medicine Division
Zuckerberg San Francisco General Hospital and Trauma Center
San Francisco, CA

Hannah Snyder, MD
Assistant Clinical Professor
Department of Family & Community Medicine
University of California, San Francisco

Aimee Moulin MD FACEP
Associate Professor
Dept Emergency Medicine
Dept Psychiatry
University of California at Davis

Lolita Roland
Certified Addiction Registered Nurse
Office Based Addiction Case Manager
Cambridge Health Alliance
Cambridge, MA

Elvin Geng MD MPH
Associate Professor of Medicine
UCSF
San Francisco, CA

Alicia Agnoli, MD, MPH, MHS
Assistant Professor
Department of Family & Community Medicine
UC Davis School of Medicine

Lindsey Kelly, PA-C, MPAS
Windsor Chronic Pain/Chronic Opiates Group
Cambridge Health Alliance
Cambridge, MA

Laura G. Kehoe, MD, MPH
Medical Director
Mass General Hospital Substance Use Disorder Bridge Clinic
Assistant Professor of Medicine, Harvard Medical School

Gabriel Wishik, MD, MPH
Medical Director of the JYP clinic, Boston Healthcare for the Homeless Program
Addiction Fellowship Associate Program Director, Boston Medical Center
Instructor, Boston University School of Medicine

Arianna Sampson, PA-C
APP Lead, USACS
Marshall Medical Center ED
Placerville, CA

Marlene Martin, MD
Assistant Clinical Professor
University of California, San Francisco and Zuckerberg San Francisco General
San Francisco, CA

Scott Steiger, MD, FACP, FASAM
Associate Clinical Professor of Medicine and Psychiatry
University of California, San Francisco
San Francisco, CA

Kenneth Saffier, MD
Clinical Professor
Department of Family and Community Medicine
University of California, San Francisco

Alexander Y. Walley, MD, MSc
Associate Professor of Medicine
Director, Addiction Medicine Fellowship
Boston Medical Center/ Boston University School of Medicine
Boston, MA

Theresa M. Damien MS, PMHNP, CARN-AP
Psychiatric Nurse Practitioner
Mclean Hospital
115 Mill Street
Belmont, MA 02478

Marc R. Larochelle, MD, MPH

Assistant Professor of Medicine
Boston Medical Center/ Boston University School of Medicine
Boston, MA

John L. Barboza, BSN CARN
OBAT Clinical Coordinator
Duffy Health Center
94 Main St.
Hyannis, MA 02601

Vivian M. Fraga, MD LLC
OB-GYN
5454 Wisconsin Avenue St. 1005
Chevy Chase, MD 20815

Dr Michael Dern
Signature Health
Brockton MA

Anne Rossi PCNS
Bridge Clinic
MGH, Boston, Ma

Erin R Lutes, MS, RN, PHN, CNS
University of California, San Francisco
San Francisco Department of Public Health
Samuel Merritt University
San Francisco, CA

Alyssa M. Peckham, PharmD, BCPP
Assistant Clinical Professor/Clinical SUDs Pharmacist
Northeastern University/MGH SUDs Bridge Clinic
Boston, MA 02115

Joseph W. Frank, MD, MPH
Assistant Professor, University of Colorado School of Medicine
Rocky Mountain Regional VA Medical Center
Aurora, CO

Janet Grochowski, PharmD, BCPS, AAHIVP
Clinical Pharmacist
Positive Health Program (Ward 86), San Francisco General Hospital
San Francisco, CA

David J. Snyder, PharmD, BCPP
Clinical Operational Pharmacist
McLean Hospital
Belmont, MA 02478

Laila Khalid MD MPH
Assistant Professor, Albert Einstein College of Medicine
Montefiore Medical Center
Bronx, NY 10467

Elisha L. Brownfield, MD, FACP
Associate Professor Internal Medicine
Medical University of South Carolina

William P. Moran MD MS
Professor of Medicine
Medical University of South Carolina

Diana Wingren RN, BSN
OBAT RN Care Manager
Outer Cape Health Services
Wellfleet, MA

James E. Bailey, MD, MPH, FACP
Director, Center for Health System Improvement
Robert S. Pearce Endowed Chair in Internal Medicine & Professor of Medicine and Preventive Medicine
University of Tennessee Health Science Center
Memphis, TN

Nina Vadiei, PharmD, BCPP
Assistant Professor
University of Arizona College of Pharmacy
Tucson, AZ

Joseph Guydish, PhD, MPH
Professor of Medicine and Health Policy
University of California San Francisco
San Francisco, CA

Daniel Robitshek, MD, FACP, FACOI, SFHM
Associate Professor of Medicine
Medical College of Georgia
Assistant Clinical Professor of Medicine

Philadelphia College of Osteopathic Medicine
Director of Graduate Medical Education
Redmond Regional Medical Center
Rome, GA

Peter Phan, MD, FACP
Assistant Professor of Medicine
University of Illinois at Peoria School of Medicine
Peoria, IL

Robert L. Cook, MD, MPH
Professor of Epidemiology and Medicine
Director, Southern HIV Alcohol Research Consortium
University of Florida
Gainesville, FL

Emily Hurstak MD, MPH, MAS
Assistant Director
San Francisco Free Clinic
Instructor, Yale Medical School and University of California San Francisco
San Francisco, CA

Carlos Estrada, MD, MS, FACP
Professor & Division Director, Department of Medicine, General Internal Medicine
Associate Provost for Interprofessional Education
Director, Center for Interprofessional Education & Simulation
University of Alabama at Birmingham
General Internal Medicine Section Chief and Senior Scholar, VA Quality Scholars Fellowship Program, Birmingham VAMC

Ryan R. Kraemer, MD
Associate Professor, Division of General Internal Medicine
University of Alabama at Birmingham

Paul Roman Chelminski, MD, MPH, FACP
Professor, University of North Carolina at Chapel Hill School of Medicine

Barbara Herbert MD, FASAM
Medical Director
Addiction Treatment Center of New England
Brighton, Mass

Robert L. D'Agostino, MD, FAAFP
Clinical Instructor

Tufts University School of Medicine
Canton, Mass

E. Allison Lyons MD, FACP
Assistant Professor of Medicine
Senior Associate Program Director
Associate Medical Director, University Medical Associates
University of Virginia

Jade L. Abudia, BS, PharmD
Psychiatric Pharmacy Resident
Carl Vinson VA Medical Hospital
Dublin, Georgia

Chayan Chakraborti, MD, FACP, SFHM
Vice Chair for Education, Dept of Medicine
Associate Professor of Medicine
Tulane University School of Medicine
New Orleans, Louisiana

Geoffrey Modest, MD
Clinical Professor of Medicine
Boston University School of Medicine
Boston, MA

Lawrence Greenblatt, MD
Professor of Medicine
Duke University School of Medicine

Ellen L. Edens, MD MPE
Assistant Professor of Psychiatry
Yale School of Medicine

Stephen J. Ingram, RPh, BCPP
Clinical Pharmacy Specialist (Psychiatry)
Overmountain Recovery
Gray, TN

Michael Clay MD
Clinical Assistant Professor of Medicine, University of Michigan Medical School
Opioid Safety Initiative and Primary Care Pain PACT Champion
VA Ann Arbor Healthcare System
Ann Arbor, MI

David Tian, MD, MPP
Division of Primary Care, Department of Medicine
Medical Director, Buprenorphine Induction Clinic
Highland Hospital, Alameda Health System
Clinical Assistant Professor of Medicine (Volunteer), UCSF
Oakland, California

Gordon D. Schiff, MD
Director Quality and Safety, Harvard Medical School Center for Primary Care
Associate Professor Harvard Medical School
Asst Director Center for Patient Safety Research and Practice
Brigham and Women's Hospital
Boston. MA

Shelly-Ann Fluker, MD, FACP
Associate Professor of Medicine
Emory University School of Medicine

Laura Read Sprabery, MD, FACP
Associate Professor of Medicine
University of Tennessee Health Science Center

Daniel Pomerantz, MD MPH FACP
Director of Ambulatory Care, Director of Palliative Care
Associate Program Director
Department of Medicine (Einstein College of Medicine)
Montefiore New Rochelle Hospital
New Rochelle, NY 10801

Simeon Kimmel MD, MA
Infectious Disease and Addiction Fellow
Boston Medical Center

Mardge Cohen MD
Boston Health Care for the Homeless Program
Boston, MA

Erica Heiman, MD
Assistant Professor of Medicine
Emory University School of Medicine

Jada Bussey-Jones, MD, FACP
Chief, Grady General Medicine and Geriatrics
Professor of Medicine

Emory University School of Medicine

Christine Soran, MD, MPH
Primary Care Addiction Medicine Fellow
University of California San Francisco

R. Stephen Waters, PsyD
Clinical Supervising Psychologist
Medicated-Addictions Treatment
Edward M. Kennedy Community Health Center

Tracey L. Henry, MD, MPH, MS, FACP
General Medicine and Geriatrics
Assistant Professor of Medicine
Emory University School of Medicine
Atlanta, GA

Lucas G. Hill, PharmD, BCPS, BCACP
Clinical Assistant Professor
The University of Texas at Austin College of Pharmacy

Honora Englander, MD, FACP
Director/ PI, Improving Addiction Care Team (IMPACT)
Associate Professor of Medicine, Department
Oregon Health & Science University

Ximena Levander, MD
GIM & Addiction Medicine Fellow
Division of General Internal Medicine, Department of Medicine
Oregon Health & Science University

E-P. Barrette, MD
Associate Professor of Medicine
Medical Director, HIV Clinic
Washington University School of Medicine

Meroë B. Morse, MD
Assistant Professor of Medicine
Department of Internal Medicine
Baylor College of Medicine

Daniel Mullin, PsyD MPH
Director, Center for Integrated Primary Care
Associate Professor, Department of Family Medicine and Community Health

University of Massachusetts Medical School

Sarah Norman, PharmD, BCPS, BCPP
Clinical Assistant Professor
University of Texas at El Paso School of Pharmacy

Jessica Gregg, MD PhD
Associate Professor of Medicine
Section of Addiction Medicine
Oregon Health and Science University

Michael B. First, MD
Professor of Clinical Psychiatry, Columbia University
Research Psychiatrist, New York State Psychiatric Institute

Thomas S. Huddle, MD, PhD
Professor of Medicine, University of Alabama at Birmingham School of Medicine
Birmingham, Alabama

Kevin R. Riggs, MD MPH
Assistant Professor of Medicine
University of Alabama at Birmingham School of Medicine

Amy M. Kukucka, MSN, APRN, CHPN, FNP-C
Certified Nurse Practitioner
Certified MAT provider
Columbus, Ohio

Susan K. Lawson, PhD, LICSW
VAMC- Retired
Private Practice- Mental Health.
Huntington, WV

Scott A. Dollinger, Psy.D
Clinical Neuropsychologist
Clinical Director Comprehensive Counseling P.C.
Lombard, IL

Daniel M. Doleys, Ph.D.
Director
Pain and Rehabilitation Institute
Birmingham, Ala

Jason N. Doctor, Ph.D.

Associate Professor and Chair
Health Policy and Management
Sol Price School of Public Policy
University of Southern California

Anne Fuqua, BSN
Senior Patient Advocate
Alliance for the Treatment of Intractable Pain
Birmingham, Alabama

Cathleen London, MD
Family Medicine
Milbridge, ME

Michelle Wagner Talley MSRC,LPC BCPC
Clinical Psychotherapist
Cape Girardeau,Missouri
Intractable Pain Advocate

James Merikangas MD
Clinical Professor of Psychiatry and Behavioral Sciences
The George Washington University School of Medicine
Washington D.C.

Rick Barnett, PsyD, MSCP, LADC
CARTER, Inc
BPS Health, LLC
Stowe, VT

Luc Frenette MD ABA FRCP ©
Preferred Pain Clinic Associates of Alabama
5057 Pinnacle Square
Birmingham AL
35235

Marlisa Griffith, RN, BSN
Texas Woman's University
Chronic & Intractable Pain Advocate
Core Arachnoiditis Research Team
Hot Springs, AR

Deborah L Withrow , RN
Hibbing Community College, Hibbing
Minnesota Intractable Pain Advocate

Isha Etienne RN,BSN
University of Massachusetts
Hospice, palliative care. Intractable pain
patient advocate. Mental Health
Boston, Massachusetts

Danial Laird, MD, JD
Medical Director
Flamingo Pain Specialists, PLLC
Partner, The Gage Law Firm, PLLC
Las Vegas, Nevada

Karen Yeargain, LPN
Public Health Nurse x 30 ½ years
Communicable Disease Coordinator
Crook County Health Dept
Prineville, Oregon

Kari Moore, RN, BSN
Neonatal ICU
Pain/Interstitial Cystitis Patient Advocate
Denver, CO

Kristie Walters RN
Adhesive Arachnoiditis Patient
Advocate and Research
Albuquerque, NM

Steven Prakken MD
Director Medical Pain Service
Duke Pain Medicine (Assistant Professor, Anesthesiology)
Duke Hospital
Durham, NC

Adam Lake, MD, FAAFP, FACMQ, AAHIVS
Medical Director, LGHP-Comprehensive Care
Human Being
Lancaster, PA

Richard L. Martin, Pharmacist
Member ATIP
Pain Management Consultant (retired)

Pain Patient Advocate

Philip Brown Burnet, Texas
Utilization Manager, Social Worker
Austin Travis MHMR
Retired, Pain Advocate, Patient

Sherry Sherman, BSN, RN
Arachnoiditis Patient
Cancer Patient (diagnosed July 2018)
Patient Advocate

James B. Ray, PharmD, CPE
Clinical Associate Professor
Department of Pharmacy Practice and Science
University of Iowa College of Pharmacy
Iowa City, Iowa

David J Barton MD
Pain Medicine
Hawaiian-Pacific Pain and Palliative Care
Oahu, Hawaii

Martha Miller NP, MSN
Boston Health Care for the Homeless
780 Albany St
Boston, MA

James G. Marx, MD, FASAM
Manager
Nevada Docs Care LLC
Las Vegas, NV

Leigh Ann Tatnall, RN, BA
Hospice, Palliative and Homecare
Milwaukee, WI

Mark J. Albanese, MD
Director, Adult Outpatient Psychiatry and Addictions, Cambridge Health Alliance;
Assistant Professor of Psychiatry, Harvard Medical School
Cambridge, MA

Cynthia Laux RN
Intractable Pain Advocate

Mission Viejo, CA

Melissa Geraghty, Psy.D.
Rago & Associates
Naperville, IL

Jeffrey Bone, PsyD
Psychologist
Newport Beach, CA

Marcelo Hochman MD
Surgeon
Charleston SC

Steve Ariens, BS Pharm R.Ph., PD
Pharmacist
Chronic Pain Advocate/Consultant

Richard H. Barrett, II, Ph.D.
Clinical Psychologist
Fort Smith,

Richard C. Dobson, MD (Retired)
Formerly in Private Practice devoted to Chronic Pain Patients
Rochester, NY

Michelle L. Caccamisi RN
Hospital Staff Nurse
Roseville, CA

Leah Sies RN
Critical Care Nurse
CVICU
Texas City,Texas

Mary Kathryn Orsulak, MD, MPH, MSc
Resident Physician
Department of Family & Community Medicine
University of California Davis

Wanita Umer RPN
Perioperative Nurse
Niagara Health System

Lynn Webster MD
Vice President Scientific Affairs
PRA Health Sciences
Salt Lake City, Utah

Jeffrey Fudin, PharmD, DAIPM, FCCP, FASHP, FFSMB
CEO, Remitigate LLC
Adjunct Associate Professor , Albany College of Pharmacy & Health Sciences; Albany NY
Adjunct Associate Professor , Western New England University College of Pharmacy; Springfield MA

J. Julian Grove MD
Pain Consultants of Arizona
President, Arizona Pain Society

Suffolk, VA

Inga Dawson, RN
Hagerstown, MD

Jeanne Kaake RN BSN
Sterling Heights, Mi

Jenny Wesner, RN, BSN
Hospice Nurse
Chronic Pain Pt, Failed Back Surgery Syndrome, Failed Spinal Fusion, Discectomy, Osteoarthritis, War on Pain Patients Member
Oshkosh, WI

Marcella Autry, LVN
Pediatric Home Health Nurse

Kari Kruska, RN
Intractable Pain Advocate
Oklahoma Don't Punish Pain Rally Organizer
Ankylosing Spondylitis Patient
Oklahoma City, OK

Jill Ackerman, MD
Ophthalmologist
Irvine, CA

Angela Willis, RN
Indiana

Michele L. Matthews, PharmD, BCACP, CPE, FASHP
Associate Professor of Pharmacy Practice
MCPHS University
Advanced Practice Pharmacist - Pain Management
Brigham and Women's Hospital
Boston, MA

Rebecca A. Brandt, RN
Cofounder: Central Pain Nerve Center
CPS/CRPS, Intractable Pain Patient & Advocate
Orondo, Washington

Douglas Stamp, PA-C
Pain Medicine
Peninsula Pain Clinic
Silverdale, WA

Vicki Ratner, M.D.
Orthopedic Surgeon, retired
Founder and President of the Interstitial Cystitis Association 1984-2008
Los Gatos, CA 95030

Jane Liebschutz, MD MPH
Chief, Division of General Internal Medicine
University of Pittsburgh School of Medicine
UPMC
Pittsburgh, PA 15213

Terri A. Lewis, PhD, NCC
Rehabilitation, Mental Health
Southern Illinois University Carbondale
Rehabilitation Institute
Silver Point, TN

Julia Lindenberg, MD
Primary Care Physician
Beth Israel Deaconess Medical Center
Boston, MA

Lisetta Shah, MD, MA
Family Medicine Physician
Edward M. Kennedy Community Health Center
Worcester, MA

Sarah King McKeon, RN, BSN
Addiction Nurse Care Manager
OBAT, BMC
Boston, MA

Jordan Tishler, M. D.
President/CMO InhaleMD
Instructor of Medicine Harvard Medical School
Founder/President Association of Cannabis Specialists
Boston MA

Stacie Schmidt, MD
Medical Director, Primary Care Center, Emory @ Grady
Assistant Professor, Emory University
Department of General Medicine and Geriatrics
Atlanta, GA

Ken Freedman, M.D., MS, MBA, FACP, DFASAM, AGAF
Clinical Professor of Medicine, Tufts University School of Medicine
Chief Medical Officer, Lemuel Shattuck Hospital
Boston, MA

William M. Tierney, MD, MACP, FRCP
Professor and Chair, Department of Population Health
Professor of Medicine and Oncology
Dell Medical School
Professor, Steve Hicks School of Social Work
University of Texas at Austin

Kurt Kroenke, MD, MACP
Chancellor's Professor of Medicine
Indiana University School of Medicine
Indianapolis, Indiana

Hannah Simon-Girard, RN, MPH, MA
Medicated Addiction Treatment Nurse, EMK CHC
DNP-FNP candidate University of Massachusetts Medical School GSN
Worcester, MA

Meg Devoe, MD
Assistant Professor of Medicine
Oregon Health & Science University

Department of Internal Medicine
Portland, OR

Manik Chhabra, MD, MS
Medical Director
Chronic Pain PACT
CMC VA Medical Center
Philadelphia, PA

Daniel A. Graubert, MD
Immediate Past President Northern New England Society of Addiction Medicine
Board Certified in Pain Medicine

Michael Fingerhood MD, FACP, FASAM
Associate Professor of Medicine and Public Health
Johns Hopkins University

Patt Denning, PhD
Director of Clinical Services and Training
Fellow, Prescribing Psychologists Register
Center for Harm Reduction Therapy
San Francisco, CA

Chad D. Kollas, MD FACP FAAHPM
Medical Director, Palliative & Supportive Care
Orlando Health UFHealth Cancer Center
Orlando, FL

Robert V. Brody, MD
Attending physician, Medicine and Pain Services and Clinics
San Francisco General Hospital
Clinical Professor of Medicine and Family & Community Medicine
University of California, San Francisco

Darryl George, DO
Affordable Integrative Medicine
Roseburg, OR

Jennifer Barnhouse, Retired Nurse
Long term care, hospice and palliative
Director of Legislative Advocacy
The Alliance for the Treatment of Intractable Pain
Geneva, OH

Nancy Jeanne Marr, MSW, MPH
Patient Advocate
Los Angeles, CA

J. Craig Allen, MD
Medical Director
Rushford Center
Chief of Psychiatry
Midstate Medical Center
Chair, Opioid Management Council
Hartford Healthcare
Hartford

Jenny M Heuck, MSN, PMHNP
Sheridan, WY

George Woody, MD
Perelman School of Medicine at the Univ. of PA
Philadelphia, PA

Jerry Cochran, MSW, PhD
Associate Professor, Epidemiology
University of Utah School of Medicine

R. Keith McAfee, MD
UC Davis School of Medicine
PCN Clinic
Yuba City, CA

Carol A Froese, MD
Psychiatry
Honolulu, HI

Katherine M Hurlbut, MD
Clinical Assistant Professor
Denver Health Department of Emergency Medicine
Denver, CO

Elizabeth M. Pace, MSM, RN, CEAP, FAAN
Chief Executive Officer
Peer Assistance Services, Inc.
Denver, CO

Margaret Lowenstein, MD, MPhil

National Clinician Scholars Program
Department of Medicine
Perelman School of Medicine at the University of Pennsylvania
Philadelphia, PA

Debbie Holt, RN
Writer and Advocate

Mark A. Jacobson, MD
Professor of Medicine Emeritus (Active)
Division of HIV, Infectious Diseases, and Global Medicine
University of California San Francisco

Marguerite Gump, MD
Valley Medical Group
Greenfield, MA

Lesley Ann Hughes RN, Ret NP
Former Corrections NP

Joseph O'Donnell, MD
Professor of Medicine and Psychiatry Emeritus
Senior Scholar Emeritus, C Everett Koop Institute
Geisel School of Medicine at Dartmouth
Hanover, NH

Jeanne Ernst, APRN
Granite State Pain Associates
Somersworth, NH

Katherine Murphy APRN
medication /pain specialist
GRANITE STATE PAIN
24 bridge street
Concord NH

Andrea Rubinstein, MD
Chief, Department of Pain Medicine
Local Research Chair & Assistant Chief of Medical Legal Affairs
Kaiser Permanente, Santa Rosa, CA
Assistant Clinical Professor, UCSF
3559 Roundbarn Blvd
Santa Rosa, CA 95403

Geralyn Datz, PhD
Southern Pain Society, Past President
Clinical Director, Southern Behavioral Medicine Associates PLLC
1 Commerce Drive, Ste 106
Hattiesburg, MS 39402

Scott Schaeffer, RPh, DABAT
Managing Director
Oklahoma Center for Poison and Drug Information
Oklahoma City, OK

Diane P. Calello, MD
Executive and Medical Director
New Jersey Poison Information and Education System
Rutgers New Jersey Medical School
Newark, NJ

Janetta L. Iwanicki, MD
Scientific Director of Research and Surveillance
Rocky Mountain Poison and Drug Center
Denver Health and Hospital Authority
Denver, CO

Ashley N. Webb, MSc, PharmD, DABAT
Director, Clinical Toxicologist
Kentucky Poison Control Center
Louisville, KY

Raymond Y. Ho, PharmD, DABAT
Director, Clinical Toxicologist
California Poison Control Center - San Francisco Division
San Francisco, CA

Jeffrey P Palmer MD
Valley Medical Group
329 Conway St
Greenfield

Jay L. Schauben, PharmD, DABAT, FAACT
Director, Florida Poison Information Center - Jacksonville
Professor, Department of Emergency Medicine, College of Medicine, and
Department of Pharmacotherapy and Translational Research, College of Pharmacy
University of Florida Health Science Center
Jacksonville, FL

Henry A. Spiller , MS, DABAT, FAACT
Director, Clinical Toxicologist
Central Ohio Poison Center
Assistant Professor, The Ohio State University, School of medicine, Department of Pediatrics
Columbus OH

Shan Yin, MD, MPH
Director, Cincinnati Drug and Poison Information Center
Associate Professor, Department of Pediatrics, University of Cincinnati School of Medicine
Cincinnati, OH

Diana Schaeffer, MPH, MSN, APRN-CNP
ProCure Proton Therapy Center
Oklahoma City, OK

Earl Siegel, Pharm. D.
Managing Director
Cincinnati Drug & Poison Information Center
Cincinnati Children's Hospital Medical Center

Jami Johnson, PharmD, DABAT
Assistant Director, Oklahoma Center for Poison & Drug Information
Adjunct Assistant Professor, University of Oklahoma College of Pharmacy
Oklahoma City, OK

Niccole Winistoerfer, PharmD, BCPS BCPP
Clinical Pharmacist - Mental Health
Shawnee Mission Medical Center
Shawnee Mission, KS

Julie Aliff Miles, RN
Richmond, VA

Adam Overberg, PharmD, BCPS
Co-Director, Clinical Toxicologist
Indiana Poison Center
Indianapolis, IN

Steven A. Seifert, MD, FAACT, FACMT
Professor, University of New Mexico School of Medicine
Medical Director, New Mexico Poison and Drug Information Center
Albuquerque, NM

Reena Hemrajani, MD
Associate Professor of Medicine
Emory University
Atlanta, GA

Karin van der Gaarden, PA-C, MPAS
Albuquerque, NM

James Cleary, MD
Professor of Medicine
Director and Walther Senior Chair of Supportive Oncology
Department of Medicine and IU Simon Cancer Center,
Indiana University School of Medicine, Indianapolis, IN

Kimber P. Richter PhD MPH NCTTP
Joy McCann Professor of Women in Medicine & Science
Department of Preventive Medicine and Public Health
University of Kansas School of Medicine
Kansas City, KS

Jennifer McNeely, MD, MS
Associate Professor
Department of Population Health and Department of Medicine, Division of General Internal Medicine and Clinical Innovation
NYU School of Medicine
New York, NY

Kelly-Anne Bryan, RN
Narvon, PA

Tiffany Greer, LCSW, MPA
Vacaville, CA 95688
Clinician in private practice focused on psychological needs of individuals with chronic/intractable pain and chronic illnesses. Personally impacted by pain secondary to EDS, fibromyalgia, dysautonomia, and small fiber neuropathy

Daniel C. Vinson, MD, MSPH
Professor Emeritus
Family and Community Medicine
University of Missouri
Columbia, MO 65212

David D. Acevedo, Surgical Technician

Waukesha, Wisconsin

Michelle Wagner Talley MSRC, LPC, BCPC
Licensed Board Certified Clinical Psychotherapist
Cape Girardeau, Missouri

Gantt P. Galloway, Pharm.D.
Executive Director, New Leaf Treatment Center, El Cerrito, CA
Senior Research Scientist, Friends Research Institute

Gary Larson, MD
Medical Director, Procure Proton Therapy Center
Oklahoma City, OK

Carole Attisano (retired LPN state of Pa)
Geriatric nursing
West Pittsburg, PA

Lisa K Kronus, RN (CHPN 2004-2008)
3430 Flagler Ave
Key West fl. 33040

James Andrew Lauerman, PA-C
Physician Assistant at University Pain Consultants
Riverside, CA.

Donna Durgin, RN, MSN
Roselle, IL

Peter Liepmann MD MBA FAAFP
Advocate for treatment of both pain and SUD,
as well as psychiatric conditions predisposing to misuse and pain
Glendale, CA

Aimee C. Chagnon, MD
Neurology/Pain Management
Founder/CEO Sonoma Pain Management
Sonoma, CA

Tammy C. Gates
Registered Nurse
Polk City, Florida
Sharon Dunbar, Texas , chronic severe pain for over 9 yrs. Kept in bed 24/7!

Carrie Monroy MD, HMDC
Medical Director, Northland Hospice & Palliative Care
Associate Medical Director, Steward Health Choice Arizona
Contracted provider, Arizona Independent Medical Associate
Flagstaff, Arizona

Michael K. Angevine, MSW, LMSW
Licensed Social Worker
Glen Cove, NY

Anne Platzner, MD
Family Physician
Greenfield, MA

Brett Sharp, LPN
Saint Paul, Mn

William Mangino II, M.D. Philadelphia, Pa.
National Pain Consultants Inc.,
Anesthesiologist/Pain Management/ Pain Care Advocate

Monica Cleveland, RN, BSN.
Fernandina/Jacksonville, FL

Tricia DLuna, LPN
Peoria, Arizona

James Chenoweth, MD MAS
Assistant Professor
Director of Toxicology Research
Division of Medical Toxicology
UC Davis Department of Emergency Medicine
Sacramento, California

Gary W. Jay, MD, FAAPM, FACFEI
Clinical Professor
Department of Neurology
University of North Carolina
Chapel Hill, North Carolina

Kevin B. Guthmiller, MD
Clinical Associate Professor
Department of Anesthesiology

Keck School of Medicine of USC
Los Angeles, California

Nel E. Gerig, MD
Medical Director
The Pelvic Solutions Center
Denver, Colorado

Sarah E. Rome, MS, DPT
Director of Physical therapy
Ivyrehab Physical Therapy
Montague, NJ

Charles Solender R.N-retired
Post anesthesia care Unit
Pain Management
Methodist Hospital
St. Louis Park MN

Peter Grinspoon, M.D.
Massachusetts General Hospital
Instructor, Harvard Medical School

James J. O'Connell, MD
Founding physician, Boston Health Care for the Homeless Program
Assistant Professor, Harvard Medical School
Boston, MA

Michael E. Schatman, Ph.D.
DIrector of Research and Network Development
Boston Pain Care
Waltham, MA
Adjunct Clinical Assistant Professor
Department of Public Health and Community Medicine
Tufts University School of Medicine
Boston, MA

Jeffrey Curtis, MD MS MPH
Marguerite Jones Harbert – Gene Ball Endowed Professor of Medicine
University of Alabama at Birmingham School of Medicine
Division of Clinical Immunology & Rheumatology

Timothy Lahey, MD, MMSc

Director, Department of Clinical Ethics
Professor of Medicine
University of Vermont Medical Center
Burlington, VT

Deborah A. Levine, MD, MPH
Associate Professor of Medicine
Division of General Medicine
Department of Internal Medicine
University of Michigan Medical School
North Campus Research Complex
2800 Plymouth Road
Building 16, Room 430W
Ann Arbor, MI 48109-2800

Cricket Fausek, MS, RN
GHC-SCW Hatchery Hill Clinic
Madison, WI

Lipi Roy, MD, MPH, MS, DABAM
Kingsboro Addiction Treatment Center
Clinical Assistant Professor, NYU Langone Health
Department of Population Health
New York, NY

Andrea Cherrington, MD MPH
Director, Cooper Green Mercy Health System Diabetes Clinic
Professor of Medicine, Department of Medicine
University of Alabama, Birmingham
Birmingham, AL

John Guenst, MD
St Thomas Medical Group
Nashville,TN

Phoebe Cushman, MD, MS
Assistant Professor, General Internal Medicine
University of Massachusetts Medical School
Worcester, MA

Saul J. Weiner, MD
Professor of Medicine, Pediatrics and Medical Education
University of Illinois at Chicago
Staff Physician, Jesse Brown VA Medical Center

Ryan Marino, MD
Division of Medical Toxicology (Fellow)
Department of Emergency Medicine
University of Pittsburgh School of Medicine

Michael Springer, MHS, Nurse Practitioner
CalFire Medical Services Unit
California CDFFP
Consultant, Rural Health Division
California Department of Health Services
Retired

Keith Susko, MD
Pain Relief and Physical Rehab, Inc.
Fort Myers, FL

Jonathan Giftos, MD, AAHIVS
Instructor of Clinical Medicine
Albert Einstein College of Medicine

Jennifer Sharpe Potter, PHD, MPH
Professor of Psychiatry
Vice Dean for Research
Long School of Medicine
UT Health San Antonio
San Antonio, TX 78229

John F. Kelly, PhD, ABPP
Elizabeth R. Spallin Associate Professor of Psychiatry,
Harvard Medical School
Boston, MA 02114

Jeffrey H. Samet, MD, MA, MPH
Chief, General Internal Medicine
John Noble MD Professor in General Internal Medicine & Professor of Public Health
Boston University Schools of Medicine & Public Health
Boston Medical Center

Robert W. West, Jr., Ph.D.
Emeritus Associate Professor of Biochemistry and Molecular Biology
SUNY Upstate Medical University
Syracuse, NY 13063

M. Kit Delgado, MD, MS
Assistant Professor of Emergency Medicine and Epidemiology
Perelman School of Medicine, University of Pennsylvania

Sarah Horton, PT
Medical College of Georgia
Disabled Physical Therapist
Lupus Advocate
Chronic Pain Advocate
Augusta, GA

Michael Picchioni, MD
Assistant Professor of Medicine
UMass Medical School - Baystate
Springfield, MA 01199

Nancy Osborne-Smith, RN
Intractable Pain Advocate
Athens, Georgia

Sarah Merritt, MD
Medical Director
Lifestream Health Center
Bowie, MD

Mark Phillips, MD
Director, Guilford Pain Management
Greensboro, NC

Mary Bodea, MD
2Co-Director, Guilford Pain Management
Greensboro, NC

Matthew Davis, MD
Associate Professor, McGovern Medical School
Houston, TX

Rachel Hardenstine, MD
Brockton Neighborhood Health Center
Brockton, MA

Theresa Tuite, RN
OBOT Nurse Care Manager

Boston, MA

John Winczura, PA
Anchorage Housecall Medicine, LLC
Eagle River, AK 99577
anchorgahousecalls@mtaonline.net
anchoragehousecallmedicine@gmail.com

Linda Kyvik, RN x 35 years
Pediatrics/Medical prior to OR & OR Educator
Ileofemoral to Ankle DVT '89 Chronic Pain Patient also
Melbourne, FL 32937

Cindy Perlin, LCSW
Psychotherapist, chronic pain survivor and pain patient advocate
Delmar, NY

Louise Silvern, Ph.D.
Licensed Clinical Psychologist (Colorado #374)
President, Pain Education Project
(Nonprofit corporation)
Boulder, Colorado

Stephen A. Wyatt, D.O.
Medical Director, Addiction Medicine
Atrium Health System
Charlotte, NC

Emily Covington, RN, MSN
Critical Care
Irvine, CA

Dee-Dee Stout, MA; Member of MINT
Addiction Clinician, Coach, & Consultant
Director, Dee-Dee Stout Consulting
Professor, Holy Names University
Emeryville, CA

Christine K Cahill RN MSN (Retired)
Infection Prevention Consultant
Chronic Pain Patient
Greenland, NH 03840

Amber L Dewey RN, MSN, NP-C

North Shore Pain Management
Beverly MA 01915
adewey@nspaincare.com

K. Scott Guess,PharmD, MS Pharm, RPh, APh, DAIPM
En Soleil Pharmacy, Inc.
VeraPharm, Inc., a Palliative Care Clinic
Santa Maria, CA 93454
KSG.PharmD@icloud.com

Scott D. Mueller, MD, FAAFP, DABFM
Private Practice, Family Medicine
1900 Bridge Street
New Cumberland, PA 17070
drsmueller@ymail.com

Wesley Haddix, DDS (Retired)
Surgeon/Clinician
Mcdowell, Virginia 24458
drhaddix@gmail.com

Leslie S. Harrington, MD
Boarded in PM&R, Brain Injury, EMG
Denver VA and private inpatient/outpatient practices

Sunil K. Aggarwal, MD
Boarded in PM&R and Hospice and Palliative Medicine
AIMS Institute
Clinical Instructor, University of Washington School of Medicine
Seattle, WA

Tanja Johnson, APN
Radiant Health LLC, Pain & Addiction Medicine
Boulder Colorado

Misdee Kornder-Guess, RN
VeraPharm Palliative Care Clinic
Santa Maria, CA 93454

Marion Mass, M.D.
Perkasie, Pa

Rene Perez, D.O.
Addiction & Pain medicine
Miami, Fl

Garlon L. Campbell, Jr., M.D.
Chair, Anesthesiology, Pain and Addictions Medicine Division
Carolinas Center for Surgery
Carolinas Center for Interventional Pain Medicine
Morehead City, NC 28557

Catherine Coolidge, MSN, APRN-BC
Board Certified in Pain Management
PMC Medical Group
Somersworth and Merrimack, NH

Sandra Schramel RN BSN
Ambul Surg, Pain Mgmt
Former Hospice RN case mgr
Scottsdale, Az

Drew A Rosielle MD, FAAHPM
Medical Director - Palliative Care
University of Minnesota Health / Fairview Health Services
Minneapolis, MN

Laura Cantino, MD
Associate Physician, Palliative Medicine
The Permanente Medical Group
Kaiser Permanente Northern California

Debbie Nickels Heck, MD
White River Health Care, PC
Muncie, IN
Family Physician, retired.
Previous community pain management physician. Now doing free online consults as a ministry.

David Nagel, MD
DavidNagelMD.com
Pain Management Specialist,
Concord, New Hampshire
Author: Needless Suffering: How Society Fails Those with Chronic Pain

Joshua Klapow, PhD

Clinical Psychologist

Denise Niemi RN
Disabled

Susanne Fogger, DNP, PMHNP-BC, CARN-AP, FAANP
Professor, Addictions Specialist
UAB School of Nursing
University of Alabama at Birmingham
Birmingham Alabama

Howard Kornfeld, M.D.
Clinical Faculty
Pain Fellowship Program
School of Medicine
University of California, San Francisco

Wendy S. Cohen MD
palliative care fellow at Virginia Commonwealth University: 7/2002 -- 6/2003
psychiatrist
Commonwealth Counseling Associates
5213 Hickory Park Drive, Ste. A
Glen Allen, VA 23059

Angela Willis RN
Disabled, chronic pain patient due to rare neurological disease 1999 but still attempt to work prn when allowed (w/c dependent).
Rossville, IN 46065

Steven Freedman, MD
Palliative Care Physician
John Muir Hospital
Concord, CA 94520

Marian Wilson, PhD, MPH, RN-BC
Certified Pain Management Nurse/Pain Researcher
Assistant Professor, College of Nursing
Washington State University
Spokane, WA

A.J. Rush, MD

Wendy R Burnett, OTR,CHT(retired)

Director
NY Hand Rehabilitation, OT, PC
New York, New York

Rachel Katz, FNP
Valley Medical Group
Greenfield MA

John Fairbanks, M.D.
Riverpark Medical Center
Vidalia, La. 71373

Bruce Stark, MD
Addiction Medicine/Internal Medicine
Burbank, CA

Paul Perez DMD
VA Hospital Dentist
Albuquerque, NM.

Amanda Neucks, RN, BSN
Hospice Nurse, Case Manager
Indianapolis, IN

Jennifer Richards, MS LPC-S
Licensed Professional Counselor
UTSW MS in Rehabilitation Counseling Psychology
Specializes in chronic pain & chronic illness
Arlington, Texas

Michael Stuart MD
Clinical Assistant Professor, Department of Family Medicine
University of Washington School of Medicine
Seattle, Washington

Theresa E. Vettese, MD
Associate Professor, Division of General Medicine
Department of Medicine
Emory University School of Medicine

Sean Mackey, M.D., Ph.D.
Redlich Professor
Chief, Division of Pain Medicine
Director, Stanford Systems Neuroscience and Pain Lab