LAURIE BETH BURKE
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P.O. Box 436
Royal Oak, MD 21662

CAREER PROFILE

Expert in drug labeling, medical product outcomes research, global regulatory strategy, and advertising. Experience in advising global organizations regarding efficiency in achieving drug development goals through state of the science methodologies in measurement and strategic planning. Ability to effectively lead cross-functional teams toward devising and implementing clinical trial solutions. General expertise recognized and demonstrated in work with the Food and Drug Administration, the European Medicines Agency, the National Institutes of Health, the World Health Organization, and multiple pharmaceutical and academic organizations related to outcome measurement, product labeling, health economics, and regulatory issues related to advertising and promotion. Career US Public Health Service officer with a retired rank of Captain (O6).

PROFESSIONAL EXPERIENCE

LORA Group, LLC, Royal Oak, MD 2014 to present
Founder
Provide expert regulatory and scientific advice on medical product development

- Support activities related to labeling, medical product outcomes research and measurement, global regulatory strategy, and advertising
- Lead and partner with measurement experts in development of high-quality clinical outcome assessments including patient-reported, clinician-reported, and observer-reported outcome measures
- Review medical product development strategies, protocols, endpoint measure development summaries, and regulatory submissions for compliance with regulatory requirements and standards, addressing also the integration of these requirements with international health technology assessment needs
- Review clinical outcome assessment development programs intended for regulatory qualification
- Provide training for individuals or groups in product labeling and outcomes research

Center for Drug Evaluation and Research (CDER), FDA, Silver Spring, MD 2002 to 2013
Associate Director for Study Endpoints and Labeling, Office of New Drugs (OND)
Formed and led the Study Endpoints and Labeling Development (SEALD) staff to identify scientific standards and create regulatory policy related to measurement of endpoints in clinical trials and the review and approval of drug labeling.
Key Accomplishments:

- Directed staff and chaired cross-disciplinary working groups to develop and clarify scientific measurement standards, to pursue international harmonization of these standards, and to provide venues for public discussion of these standards.
- Managed the CDER Clinical Outcome Assessment Qualification Program, with oversight of submission review, consultation and advice with COA developers, and coordination with other FDA and international experts concerned with Drug Development Tool Qualification Programs.
- Supervised and trained medical and other professional personnel to provide expert reviews of endpoint development and validation for use in clinical trials.
- Advised companies on measurement considerations related to designing, conducting, analyzing,

and interpreting clinical trials for regulatory determination of medical product benefit and for incorporation into labeling.
- Supervised team of medical and other professional personnel who provided oversight to the implementation of labeling regulations in the review of prescription drug labeling for approval.

Division of Drug Marketing, Advertising, and Communications (DDMAC), FDA 1994 to 2002
Chief, Evidence Review Branch, Division of Drug Marketing Advertising and Communications (DDMAC)
Led team of reviewers of evidence to support promotional claims
Key Accomplishments:
- Managed regulatory oversight and policy development including implementing regulations for manufacturer dissemination of information on new (unapproved) uses, beginning with the passage of the November 1997 amendments to the Food, Drug and Cosmetic Act (FDAMA).
- Led the development of FDA regulatory policy related to health care economic information included in promotional labeling and advertising to managed care organizations in response to FDAMA 114.
- Led the development of FDA regulatory policy related to pharmacy benefit manager dissemination of promotional labeling and advertising on behalf of the pharmaceutical industry.
- Represented FDA in the International Harmonization of HRQL Initiative, resulting in standardized terminology and the creation of the term "patient-reported outcomes."
- Consulted on research design and data analysis issues in support of healthcare economic, health-related quality of life, and other health outcomes claims including gathering input, developing consensus, and communicating issues related to developing regulatory policy in these areas of medical product promotion and labeling.
- Provided expert consultation to the World Health Organization Collaborating Centre for Drug Statistics Methodology in Oslo, Norway, for the development and revision of guidelines for the use of the WHO ATC/DDD classification system.
- Consulted both within and outside FDA on nationally and internationally descriptive drug use study methodologies.

Division of Epidemiology and Surveillance, CDER, FDA 1989 to 1994
Delivered expert consultation regarding drug use analysis and pharmacoepidemiology
Key Accomplishments:
- Designed and conducted original intra- and extramural epidemiologic research investigating drug use and suspected adverse reactions utilizing pharmacoepidemiologic data.
- Trained and supervised other professionals in methods and design of drug use analyses, adverse drug reaction surveillance, data retrieval and manipulation, and application of these techniques to pharmacoepidemiology and Pharmacoeconomics.
- Managed four FDA extramural pharmacoepidemiology cooperative agreements and the large drug use data contract.
- Guided the decision-making process of Agency epidemiologists for the purpose of setting research priorities and expenditure of funds for the extramural pharmacoepidemiology program.
- Prepared administrative reports ranging from forecasting future program expansion needs to documenting current and past Division performance.

Division of Drug Experience, CDER, FDA 1976 to 1981
Technical Information Specialist
Administered and managed FDA's drug use data contract and provided expert consultation regarding drug use analysis using national data bases and evaluation of spontaneous reporting of drug safety data

LAURIE BETH BURKE

EDUCATION AND TRAINING

Bachelor of Science, University of Kansas School of Pharmacy, Lawrence, KS, 1976--Pharmacy
Master of Public Health, Uniformed Services University of Health Sciences, Bethesda, MD, 2002--Epidemiology

Other Training
Darden Graduate School of Business Administration, University of Virginia, Charlottesville, VA
Council for Excellence in Government, Washington, DC
Training in Federal Government Grants and Contracts, DHHS, Rockville, MD

SELECT ORGANIZATION MEMBERSHIPS & SERVICE

Academy of Managed Care Pharmacy
American Society of Health-System Pharmacists
Drug Information Association
International Society for Pharmacoeconomics and Outcomes Research
National Pharmaceutical Council
National Quality Forum

FDA COMMITTEE MEMBERSHIPS

Chair, **Patient Reported Outcomes Guidance Development Working Group**, FDA, 1995 to 2009
Chair, **Measuring Clinical Benefit in Oncology—Guidance Working Group**, FDA, 2012-2013
Chair, **Clinical Outcome Assessment Qualification Working Group,** FDA, 2008 to 2013
OND Lead, **Drug Development Tool Qualification--Guidance Working Group,** FDA, 2008-2013
OND Lead, **Pharmacoeconomic Information in Promotion--Guidance Working Group,** FDA, 2013
Chair, **Target Product Profile Working Group,** FDA 2006-2013

NON-FDA COMMITTEE MEMBERSHIPS

External Advisory Committee Member, **PROEM Center of Excellence in CER-PCOR Training,** University of Maryland School of Pharmacy, 2013 to present
Executive Committee Member, **Analgesic, Anesthetic, and Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTTION),** 2011 to present
Board Member, **International Society for Pharmacoeconomics and Outcomes Research**, 2004 to 2006
Chair, **Drug Information Association IMPACT Special Interest Area Community,** 2002-2004
FDA Lead, **International Harmonization of Health-Related Quality of Life/Patient-Reported Outcomes Work Group,** 1999-2001
Advisory Committee Member, **Harvard Center for Risk Analysis**, Harvard University, 1999 to 2004
Expert Consultant, **International Working Group for Drug Statistics Methodology**, World Health Organization, 1997 to 2006

UNIFORMED SERVICE DECORATIONS AND AWARDS

1991 **PHS Achievement Medal**--Management of extramural pharmacoepidemiology cooperative agreements and contracts
1992 **PHS Commendation Medal**--Extramural Program Review Group
1992 **PHS Crisis Response Service Award**--Relief in aftermath of Iniki, Andrew and Omar
1995 **PHS Unit Commendation**--Pharmacoeconomics Working Group
1996 **PHS Commendation Medal**--Regulation of comparative economic claims in pharmaceutical promotion

1996 **PHS Unit Commendation**--Leading the FDA's Conference on Comparing Treatments: Safety, Effectiveness and Cost-Effectiveness
1998 **PHS Unit Commendation**—Communication of information on new uses of human drugs and biological products
1999 **PHS Outstanding Service Medal**—Regulation of promotional activities within the managed care and pharmacy benefit management company environments
2000 **PHS Unit Commendation**--Risk management workshop for reviewers
2001 **PHS Unit Commendation**--Positron Emission Tomography regulation
2002 **PHS Unit Commendation**—Participation in the Commissioned Corps Ensemble
2006 **PHS Crisis Response Service Award**--Response to Gulf Coast Hurricanes
2008 **FDA Team Excellence Award**—Implementation of new labeling regulations
2009 **PHS Outstanding Service Medal**—Leading the FDA Patient Reported Outcomes (PRO) Working Group and publication of the final FDA PRO Guidance

PUBLICATIONS (BEGINNING IN 2001)

- Burke L. US regulation of pharmaceutical outcomes research. *Value in* Health 2001: 4;5-7.
- Crawford B, Burke L. Meeting the US FDA's evidence standard with health-related quality of life claims. *Expert Rev Pharmacoeconomics Outcomes Res* 2002: 2;401-402.
- Willke R, Burke LB, Erickson P. Measuring treatment impact: a review of patient-reported outcomes and other efficacy endpoints in approved product labels. *Controlled Clinical Trials* 2004; 25:535-552.
- Delasko J, Cocchetto D, Burke LB. Target product profile: beginning drug development with the end in mind. *Update--Food and Drug Law, Regulation, and Education* 2005; Issue 1:36-39.
- Turk DC, Dworkin RH, Burke LB, et al. Developing patient-reported outcome measures for pain clinical trials: IMMPACT recommendations. *Pain* 2006 Dec 5;125(3):208-15.
- Patrick D, Burke L, Powers J, et al. Patient-Reported Outcomes to Support Medical Product Labeling Claims: FDA perspective. *Value Health* 2007; 10(2):S125-137.
- Rock EP, Kennedy DL, Furness MH, Pierce WF, Pazdur R, Burke LB. Patient reported outcomes supporting anticancer product approvals. *J Clin Oncol* 2007; 25(32):5094-9.
- Lipscomb J, Reeve BB, Clauser SB, et al (including Burke LB). Patient-reported outcomes assessment in cancer trials: Taking stock, moving forward. *J Clin Onc* 2007; 25:5133-5140.
- Rock EP, Scott JA, Kennedy DL, Sridhara R, Pazdur R, Burke LB. Challenges to use of health-related quality of life for FDA approval of anticancer products. *J Natl Cancer Inst Monogr* 2007; 37:1-4.
- Bast RC, Thigpen JT, Arbuck SG, et al (including Burke LB). Clinical trial endpoints in ovarian cancer: Report of an FDA/ASCO/AACR Public Workshop. *Gynecol Oncol* 2007;107(2):173-6.
- Reeve BB, Burke LB, Chiang YP, et al, Enhancing measurement in health outcomes research supported by Agencies within the US Department of Health and Human Services. *Qual Life Res* 2007; 16 Suppl 1:175-186.
- Patrick DL, Burke LB, Powers JH, et al. Patient-reported outcomes to support medial product labeling claims: FDA perspective. *Value in Health* 2007: 7;S125-137.
- Dworkin RH, Turk DC, Wyrwich KW, et al (including Burke LB**).** Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. *Pain* 2008 Feb;9(2):105-21.
- Burke LB, Kennedy DL, Miskala PH, Papadopoulos EJ, and Trentacosti AM. The use of patient-reported outcome measures in the evaluation of medical products for regulatory approval. *Clinical Pharmacol Ther* 2008; 84(2):281-3.
- Turk DC, Dworkin RH, Revicki D, et al (including LB). Identifying important outcome domains for chronic pain clinical trials: an IMMPACT survey of people with pain. *Pain* 2008 Jul 15;137(2):276-85.

- Turk DC, Dworkin RH, McDermott MP, et al (including Burke LB**)**. Analyzing multiple endpoints in clinical trials of pain treatments: IMMPACT recommendations. Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials. *Pain* 2008 Oct 31;139(3):485-93.
- Rothman M, Burke L, Erickson P, Leidy NK, Patrick DL, and Petrie CD. Use of existing patient-reported outcome (PRO) instruments and their modification: The ISPOR Good Research Practices for Evaluating and Documenting Content Validity for the Use of Existing Instruments and Their Modification PRO Task Force Report. *Value in Health* 2009: 12:1075-1083.
- Miskala PH, Burke LB, Kennedy DL, Papadopoulos E, Trentacosti AM. Patient-reported outcome measurement—US Food and Drug Administration regulatory concerns. *Drug: Development* 2009.
- Coons SJ, Gwaltney CJ, Hays RD, et al (including Burke LB). Recommendations on evidence needed to support measurement equivalence between electronic and paper-based patient-reported outcome (PRO) measures: ISPOR ePRO Good Research Practices Task Force report. *Value Health* 2009 Jun; 12(4):419-29.
- Dworkin RH, Turk DC, McDermott MP, et al (including Burke LB). Interpreting the clinical importance of group differences in chronic pain clinical trials: IMMPACT recommendations. *Pain* 2009 Dec; 146(3):238-44.
- Trentacosti AM, He R, Burke LB, Griebel D, Kennedy DL. Evolution of clinical trials for irritable bowel syndrome: issues in end points and study design. *Am J Gastroenterol* 2010 Apr;105(4):731-5.
- Coons SJ, Kothari S, Monz BU, Burke LB. The patient-reported outcome (PRO) consortium: filling measurement gaps for PRO end points to support labeling claims. *Clin Pharmacol Ther* 2011 Nov; 90(5):743-8.
- Patrick DL, Burke LB, Gwaltney CJ, et al. Content validity—Establishing and reporting the evidence in newly developed patient-reported outcomes (PRO) instruments for medical product evaluation: ISPOR PRO Good Research Practices Task Force Report: Part 1—Eliciting concepts for a new PRO instrument. *Value in Health* 2011Dec; 14(8):967-977.
- Patrick DL, Burke LB, Gwaltney CJ, et al. Content validity—Establishing and reporting the evidence in newly developed patient-reported outcomes (PRO) instruments for medical product evaluation: ISPOR PRO Good Research Practices Task Force Report: Part 2—Assessing respondent understanding. *Value in Health* 2011 Dec; 14(8):978-88.
- Deisseroth A, Kaminskas E, Grillo J, et al (including Burke LB). U.S. Food and Drug Administration approval: ruxolitinib for the treatment of patients with intermediate and high-risk myelofibrosis. *Clin Cancer Res* 2012 Jun 15;18(12):3212-7.
- Dworkin RH, Turk DC, Peirce-Sandner S, et al (including Burke LB**).** Considerations for improving assay sensitivity in chronic pain clinical trials: IMMPACT recommendations. Pain. 2012 Jun; 153(6):1148-58.
- Comer SD, Zacny JP, Dworkin RH, et al (including Burke LB). Core outcome measures for opioid abuse liability laboratory assessment studies in humans: IMMPACT recommendations. *Pain* 2012 Dec; 153(12):2315-24.
- Smith SM, Wang AT, Katz NP, et al (including Burke LB). Adverse event assessment, analysis, and reporting in recent published analgesic clinical trials: ACTTION systematic review and recommendations. *Pain* 2013 Jul; 154(7):997-1008.
- Smith SM, Wang AT, Pereira A, et al (including Burke LB**).** Discrepancies between registered and published primary outcome specifications in analgesic trials: ACTTION systematic review and recommendations. *Pain* 2013 Dec; 154(12):2769-74.
- Papadopoulos EJ, Patrick DL, Tassinari MS, et al (including Burke LB). Clinical outcome assessments for clinical trials in children. In *Pediatric Drug Development: Concepts and Applications,* Second Edition, Ed. by Mulberg AE, et al. 2013 John Wiley & Sons, Ltd.
- Basch E, Trentacosti AM, Burke LB et al. Pain palliation measurement in cancer clinical trials: the US Food and Drug Administration perspective. *Cancer* 2014 Mar 1; 120(5)761-7.

- Gewandter JS, McDermott MP, McKeown A, Burke LB, et al. Reporting of primary analyses and multiplicity adjustment in recent analgesic clinical trials: ACTTION systematic review and recommendations. *Pain* 2014; 155:1871-1877.
- Burke LB. History of patient-reported outcome measurement at FDA: My perspective. *PRO Newsletter* 2014: 52;6-8.
- Perfetto EM, Burke L, Oehrlein EM, Epstein RS. Patient-focused drug development; a new direction for collaboration. *Medical Care* 2015 Jan; 53(1):9-17.
- Perfetto EM, Burke L, Oehrlein EM, and Gaballah M. FDAMA section 114: Why the renewed interest? *J Mngd Care & Spec Pharm* 2015; 21(5);368-374.
- Dworkin RH, Burke LB, Gewandter JS, and Smith SM. Reliability is necessary but far from sufficient: How might the validity of pain ratings be improved? *Clin J Pain* 2015; 31:599-602.
- Walton MK, Powers JH, …, Burke LB. Clinical outcome assessments: Conceptual foundation—report of the ISPOR Clinical Outcomes Assessment-Emerging Good Practices for Outcomes Research Task Force. *Value in Health* 2015; 18;741-752.
- Taylor AM, Phillips K, Patel KV, et al (including Burke LB). Assessment of physical function and participation in chronic pain clinical trials: IMMPACT/OMERACT recommendations. *PAIN* 2016: 157;1836-1850.
- Powers JH, Patrick DL, …, Burke LB. Clinician-reported outcome assessments of treatment benefit: Report of the ISPOR Clinical Outcome Assessment Emerging Good Practices Task Force. *Value in Health 2017; 20:2-14.*
- Benjamin K, Vernon MK, Patrick DL, …, Burke L. Patient-reported outcome and observer-reported outcome assessment in rare disease clinical trials: An ISPOR COA Emerging Good Practices Task Force Report. *Value in Health* 2017: 20;838-855.

HIGHLIGHTED INVITED LECTURES

Regulation of Pharmacoeconomics by FDA, **University of Athens**, 1995
Prescription Drug Promotion Regulation, **University of Maryland School of Pharmacy**, 1997 to 2002
Pharmacoeconomics and Quality of Life, **Pharmaceutical Education and Research Institute**, 1998
Health Related Quality of Life and FDA, **Northwestern University**, 1999
Measuring Outcomes, Pharmacoepidemiology Seminar, **University of North Carolina School of Pharmacy**, 2000, 2004
PRO et promotion: considérations réglementaires par la FDA, Lariboisière, **Université de Paris,** 2002
Drug Labeling, **Pharmaceutical Education and Research Institute**, 2005
Endpoints and Labeling, **Harvard Clinical Investigator's Program**, 2006
Patient Reported Outcomes in Cancer Trials, **National Cancer Institute**, 2006
Target Product Profile, **American Course on Drug Development and Regulatory Sciences**, 2010, 2013

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