Michelle Candice Fox, M.D., M.P.H., F.A.C.O.G
Distinguished Principal Scientist, Clinical Research, Merck Research Laboratories
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PHARMACEUTICAL DEVELOPMENT EXPERIENCE:

Product Development Team Chair for Contraception (11/2016 to present) and Fertility (2/2017 to present)

- Lead cross-functional teams to promote research and development of contraceptive and fertility products
- Collaborate effectively with cross functional team members to assess areas for product growth and development, support worldwide registration activities, advise the pharmacovigilance team, and support commercial team efforts to expand product use

Clinical Director /Principal Scientist (May 2014 to 2016)
Senior Clinical Director /Principal Scientist (2016-2018)
Distinguished Principal Scientist (2019-present)

- Directed two multi-center clinical trials (one in the United States and one global) for the MK-8342B Contraceptive Vaginal Ring involving ~250 sites and ~4000 subjects meeting all milestones (on time or ahead of schedule) prior to the discontinuation of product development for business reasons
- Medical Monitoring
  - Collaborated with cross functional team to develop and execute Medical Monitoring Plan
  - Actively monitored subject safety and protocol compliance using Inform and J-Review
  - Supported investigators and field monitors with training and 1:1 interaction
  - Investigator Meeting presentations for MK-8342B protocols 061 (United States) and 062 (global) to educate investigators, trial monitors and site staff
- Protocol development
  - Lead author for MK-8342B protocols 061,062, 059, and 060 and MK-8342A-063
  - Protocol review within women's health (in house and investigator-initiated studies), cardiovascular and infectious disease therapeutic areas
  - **Subject Matter Expert** for contraception and pregnancy testing during clinical trials
- Regulatory interactions
  - End of Phase 2 face to face FDA meetings for MK-8342B for contraception and dysmenorrhea indications to address agency questions and company concerns and to negotiate key study objective and endpoints
  - Requests for Scientific Advice communications with CHMP to obtain regulatory guidance for requirements to achieve product registration within the EU
  - Special Protocol Assessment (SPA) agreements with FDA for MK-8342B Protocols 061, 059, 060
  - Type C FDA interactions for NuvaRing Applicator and Nexplanon
  - Pediatric Investigational Program (PIP) negotiation and protocol development for MK-8342B and supervision of ongoing Elonva PIP study
  - NuvaRing Applicator Filing: CE Mark obtained in EU 2016; FDA Approval 2016
  - Ongoing health authority filings for Nexplanon

- Authored Clinical Study Reports (MK-8342B protocols 057, 061, 062 and MK-8342A-063)
- Authored manuscripts for publication (MK-8342B protocol 057 and MK-8342A-063)
- Device Development
    - Device risk management file development for MK8342B vaginal ring, the NuvaRing Applicator and the NuvaRing/ NuvaRing Applicator coPack including the following key deliverables: Clinical Evaluation Report (primary author), Instructions for Use, Harm/Hazards List, and Task Analysis/ User Error Analysis, Failure Mode Error Analysis, Device Risk Management Report (primary author), and human factor study reports
    - Retrospective device risk management plan (rDRMP) steering committee: Provided clinical input for new Standard Operating Procedure for development of rDRMPs for legacy combination drug-device products, **Subject Matter Expert** for clinical research contribution to rDRMPs
    - Clinical lead for cross functional team development of the rDRMP for NuvaRing, Nexplanon, and the Puregon Pen
- Product Label Support (NuvaRing, Nexplanon, Livial, Zoely, Marvelon, Cerazette, Puregon/ Follistim and Elonva)
    - Provided clinical input to cross functional team to respond to worldwide regulatory requests and development of documentation to support label changes
    - Clinical input to Risk Management Safety Team
- OB/GYN expertise
    - Fostered company interaction with scientific leaders to seek input regarding business development within women's health
    - Provided specialty specific consultation to other therapeutic areas to guide protocol development and address clinical concerns
    - Consultant and grant reviewer for Merck For Mother's programs (maternal sepsis, maternal mortality/ morbidity)

EMPLOYMENT

Dates	Position	Institutions
2001-2003	Visiting Clinical Instructor	University of Pittsburgh School of Medicine (Dept. OB/GYN)
2003-2009	Assistant Professor Director, Family Planning Program	University of Maryland School of Medicine (Dept. OB/GYN)
2009-2014	Assistant Professor Assistant Director, Family Planning Fellowship	Johns Hopkins School of Medicine (Dept. Gyn/ OB)
2006-2014	Consultant Implanon/ Nexplanon Clinical Training Program (Senior Trainer)	Merck (formerly Organon & Sherring-Plough)
2009-2014	OB/GYN Board Review Faculty Exam Pro™	
2014-2016	Clinical Director Women's Health Late Stage Development / Clinical Research	Merck Research Laboratories
2016-2018	Senior Clinical Director Women's Health Late Stage Development / Clinical Research	Merck Research Laboratories
2019-present	Executive Clinical Director Women's Health Late Stage Development / Clinical Research	Merck Research Laboratories

EDUCATION AND TRAINING

Year	Degree / Certificate	Institution	Discipline
Undergraduate			
1989-1993	Bachelor of Arts	University of Pennsylvania	Psychology
Graduate			
1993-1997	Doctor of Medicine	Johns Hopkins School of Medicine	Medicine
2001-2003	Masters of Public Health	University of Pittsburgh Graduate School of Public Health	Public Health
Postgraduate			
1997-2001	Internship & Residency	Beth Israel Deaconess Medical Center (Harvard Medical School)	OB/GYN
2001-2003	Fellowship	University of Pittsburgh School of Medicine / Magee-Women's Hospital	Family Planning

AWARDS / HONORS

1992 Phi Beta Kappa, University of Pennsylvania
1992 Mortar Board Honor Society, University of Pennsylvania
1993 Graduated *Summa Cum Laude*, University of Pennsylvania
1993-1997 The Joanna Reed Medical Scholarship; Brewton, Alabama
1999, 2001 CREOG Scholarship; Dept. of Obstetrics & Gynecology, Beth Israel Deaconess Medical Center
2001, 2002 Wyeth-Ayerst New Leaders Award: Advancing a New Generation of Reproductive Health Professionals
2003 Berlex Foundation Faculty Development Award
2004 Roy M, Pitkin Award for Excellence in Research (Creinin MD, Fox MC, Teal S, Chen A, Schaff EA, Meyn LA. A Randomized Comparison of Misoprostol 6-8 Hours Versus 24 Hours After Mifepristone for Abortion. *Obstetrics and Gynecology* 2004; 103: 851-859.)
2014 Award of Excellence, Merck Research Laboratory (NuvaRing applicator program)
2016 Award of Excellence, Merck Research Laboratory (MK-8342B program)
2017 Drive Results Award, Merck Research Laboratory (leadership in Women's Health)

PROFESSIONAL SOCIETIES

1998-2018 Member, Association of Reproductive Health Professionals 1997-
2005 Junior Fellow, American College of Obstetrics and Gynecology
2005-present Fellow, American College of Obstetrics and Gynecology
2006-present Fellow, Society of Family Planning

ADVISORY COMMITTEES / RESEARCH REVIEW PANELS

2005-2014 Center for Maternal and Child Health, Maryland Department of Health And Mental Hygiene Advisory Committee, Pregnancy Risk Assessment Monitoring System
2008 Research Review Panel, Society of Family Planning
2008 Scientific Review Committee, Association of Reproductive Health Professionals
2008-2014 Manuscript Reviewer, *Contraception*
2012-2014 American College of Obstetrics and Gynecology, Committee on Gynecologic Practice
2013-2014 American College of Obstetrics and Gynecology, Patient Safety and Quality Initiative
2015-2017 Grant review committee, Society of Family Planning

PUBLICATIONS (over 300 citations to date)

Peer-Reviewed Original Research Publications

1. Paul M, Lackie E, Mitchell C, Rogers A, Fox M. Is Pathology Examination Useful After Early Surgical Abortion? *Obstetrics and Gynecology* 2002; 99:567-571.

2. Paul ME, Mitchell CM, Rogers AJ, Fox MC, Lackie EG. Early Surgical Abortion: Efficacy and Safety. *American Journal of Obstetrics and Gynecology* 2002; 187:407-411.

3. Fox MC, Creinin MD, Harwood, B. Mifepristone and vaginal misoprostol on the same day for abortion from 50 to 63 days' gestation. *Contraception* 2002; 66:225-229.

4. Fox MC, Creinin MD, Murthy AS, Harwood B, Reid LM. Feasibility Study of the Use of E-Mail to Improve Oral Contraceptive Compliance. *Contraception* 2003; 68:365-371.

5. Creinin MD, Fox MC, Teal S, Chen A, Schaff EA, Meyn LA. A Randomized Comparison of Misoprostol 6-8 Hours Versus 24 Hours After Mifepristone for Abortion. *Obstetrics and Gynecology* 2004; 103: 851-859.

6. Creinin MD, Harwood B, Guido RS, Fox MC, Zhang J. Endometrial thickness after misoprostol use for early pregnancy failure. *International Journal of Gynaecology and Obstetrics* 2004; 86: 22-6.

7. Reeves MF, Fox MC, Lohr P. Endometrial thickness following medical abortion is not predictive of subsequent surgical intervention. *Ultrasound Obstet Gynecology* 2009; 34:104-9.

8. Bakhru A, Mallinger J, Fox MC. Post-exposure prophylaxis for victims of sexual assault: treatments and attitudes of emergency department physicians. *Contraception* 2010; 82: 168-173.

9. Fox MC, Oat-Judge J, Severson K, Jamshidi RM, Singh RH, McDonald-Mosely R, Burke AE. Immediate Placement of Intrauterine Devices After First and Second Trimester Pregnancy Termination. *Contraception* 2011; 83:34-40

10. Perritt JB, Burke A, Jamshidi R, Wang J, Fox M. Contraception counseling, pregnancy intention and contraception use in women with medical problems: an analysis of data from the Maryland Pregnancy Risk Assessment Monitoring System (PRAMS). *Contraception* 2013; 88: 263-8.

11. Woo I, Seifert S, Hendricks D, Jamshidi RM, Burke AE, Fox MC. Six-month and 1-year continuation rates following postpartum insertion of implants and intrauterine devices. *Contraception* 2015; 92: 532-5.

12. Feldman R, Frenkl TL, Yacik C, Wang Y, Fox MC. An Open-Label, Two-Period, Randomized Crossover Study of the NuvaRing Applicator in Healthy Women. *Contraception* 2016; 94: 362-5.

13. Fox MC, Klipping C, Nguyen AM, Frenkl TL, Cruz SM, Wang Y, Korver T. A phase 2b multicenter, randomized, double-blind, placebo-controlled clinical trial to evaluate the efficacy and safety of vaginal rings containing nomegestrol acetate or etonogestrel and 17β-estradiol in the treatment of women with primary dysmenorrhea. *Contraception* 2019; 99(2):125-130.

14. Iwanaga J, Fox MC, Rekers H, Schwartz L, Tubbs RS. Neurovascular anatomy of the adult female medial arm in relationship to potential sites for insertion of the etonogestrel contraceptive implant. Contraception 2019 (in press).

Invited Peer-Reviewed Publications:

1. Fox MC, Creinin MD. Modern management of first trimester miscarriage. *Contemporary Clinical Gynecology and Obstetrics* 2002; 2: 47-58.

2. Fox MC, Hayes JL. Cervical Preparation for Second Trimester Surgical Abortion Prior to 20 Weeks Gestation [Society of Family Planning Clinical Guidelines 20072]. *Contraception* 2007; 76: 486-495.

3. Hayes JL, Fox MC. Cervical dilation in the Second Trimester. *Clinical Obstetrics and Gynecology*: 2009; 52: 171-178.
4. American College of Obstetrics and Gynecology, Committee on Gynecologic Practice. (Lead Author) Committee Opinion 567: Professional Liability and Gynecology-Only Practice. *Obstetrics and Gynecology* 2013; 122: 186.

5. American College of Obstetrics and Gynecology, Committee on Gynecologic Practice. (Lead Author) Committee Opinion 571: Surgical Preparation for Vaginal Procedures. *Obstetrics and Gynecology* 2013; 122: 718-20.

6. American College of Obstetrics and Gynecology, Committee on Gynecologic Practice. (Lead Author) Committee Opinion 577: Endorsement of the CDC's Selected Practice Recommendations for Contraceptive Use. *Obstetrics and Gynecology* 2013; 122: 1132-3.

7. Fox MC, Krajewski C. Cervical Preparation for Second Trimester Surgical Abortion Prior to 20 Weeks Gestation [Society of Family Planning Clinical Guidelines 2013-4]. *Contraception* 2014; 89; 75-84.

Abstracts, Posters, and Oral Presentations:

Over 20 research presentations (poster/ oral abstracts) and published abstracts presented at national meetings including Society of Family Planning, Association of Reproductive Health Professionals, American College of Obstetrics & Gynecology, and Federation of International Obstetricians & Gynecologists. Comprehensive listing provided upon request.

CLINICAL AND TEACHING ACTIVITIES

Didactic Lectures:

Over 50 lectures on various topics in gynecology to medical students, public health students, nurses, practicing clinicians, and residents. Comprehensive topic list provided upon request.

Clinical (Service) Responsibilities:

University of Maryland Medical Systems / University of Maryland School of Medicine:

2003-2009 Gynecologic Service Attending
2004-2009 Medical Director, Pregnancy Alternatives and Family Planning Program
2006-2008 Medical Director, Resident Colposcopy Clinic

Johns Hopkins University School of Medicine/ Johns Hopkins Bayview Medical Center:

2009-2014 General OB/GYN attending
2009-2014 Labor and Delivery staffing
2009-2014 Family Planning Clinic
2009-2014 Faculty general OB/GYN practice

Rutgers University Hospital

2017-2018 Volunteer attending, Department of OB/GYN

Certification

2003-2015	Maryland Medical License
2016-present	New Jersey Medical License
2001-2015; 2017-present	DEA Registration
2016-present	New Jersey CDS Registration

Specialty Certification

2005-present	Diplomat, American Board of OB/GYN Maintenance of Certification annually

PAST ACADEMIC RESEARCH ACTIVITIES

1. 2001
   Mifepristone and Misoprostol On the Same Day For Early Abortion From 50-63 Days Gestation
   Sponsor: Anonymous Foundation; Principal Investigator: Mitchell Creinin, MD
   Role: Co-Principal Investigator*(20% FTE)
   *Note: Assumed role of PI upon arrival at the University of Pittsburgh

2. 2001-2003
   A Prospective, Randomized, Double Blind, Multicenter Study to Compare the Efficacy, Safety and Tolerance of 10 mg of CDB-2914 to 50 mg CDB-2914 as Emergency Contraception
   Sponsor: NICHD; Principal Investigator: Mitchell Creinin, MD
   Role: Co-Investigator at Study Site (3% FTE)
   *CDB-2914 is now known as ulipristal acetate and is marketed for emergency contraception.

3. 2001-2002
   A Phase I Comparative Post-Coital Testing and Safety Study of Three Concentrations of C31G
   Sponsor: CONRAD (Study A00-064); Principal Investigator: Mitchell Creinin, MD
   Role: Co-Investigator at study site (2% FTE)

4. 2001-2003
   Randomized Trial On Management of Early Pregnancy Failure
   Sponsor: NICHD; Principal Investigator: Mitchell Creinin, MD
   Role: Co-Investigator at Study Site (5% FTE)
   *Misoprostol is now a standard treatment (as an alternative to surgery) for first trimester pregnancy loss.

5. 2001-2003
   A Randomized Controlled Study of the Efficacy, Safety and Acceptability of BufferGel
   Sponsor: NICHD; Principal Investigator: Mitchell Creinin, MD
   Role: Co-Investigator at study site (2%)

6. 2002-2003
   Mifepristone and Misoprostol For Abortion Through 63 days' Gestation: A Multicenter, Randomized Comparison of Misoprostol 6 to 8 Hours versus 24 Hours Following Mifepristone
   Sponsor: Anonymous Foundation; Principal Investigator: Mitchell Creinin, MD
   Role: Principal Investigator at Study Site (20% FTE)

7. 2002-2003
   Pilot Study of a Daily E-mail Reminder To Improve Oral Contraceptive Pill Compliance
   Sponsor: Anonymous Foundation; Principal Investigator: Michelle Fox, MD
   Role: Principal Investigator (20% FTE)

8. 1/1/10-12/31/12
   Contraceptive Efficacy Evaluation of the PATH Female condom
   Sponsor: NICHD; Principal Investigator: Anne Burke, MD, MPH
   Role: Co-Investigator at Study Site (5% FTE)

9. 5/1/12-3/31/13
   A Dose Finding Study To Evaluate The Effect of A Contraceptive Vaginal Ring, Releasing Nestorone and Estradiol, on Cycle Control, Ovulation Inhibition, and Pharmacokinetics In Normal Cycling Women
   Sponsor: NICHD (Identification number: NICHD-CCN-011); Principal Investigator: Anne Burke, MD, MPH
   Role: Co-Investigator at Study Site (15% FTE)