Michelle Candice Fox, M.D., M.P.H., F.A.C.O.G
Distinguished Scientist
Merck Research Laboratories
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PHARMACEUTICAL DEVELOPMENT EXPERIENCE (Merck Sharp Dohme, Corp.):

Distinguished Principal Scientist/Executive Director (2019 to 2021)
Section Leader, Global Clinical Development, Women's Health (2019-2021)
Senior Clinical Director/Senior Principal Scientist (2016-2018)
Clinical Director /Principal Scientist (May 2014 to 2016)

CURRENT ACTIVITIES:

Note: In 2021, the marketed products comprising the Women's Health Merck franchise were transferred to Organon. I remained at Merck to continue exciting roles in clinical drug development. I now spend most of my time supporting the development of islatravir (MK-8591) for treatment and prevention of HIV.

HIV: Early and Late Stage Clinical Development

- Clinical Director MK-8591A-018: daily combination of islatravir and doravirine for treatment of HIV in stable, virologically suppressed patients (6/2021 to present)
  - Medical monitoring of participant safety and protocol compliance
  - Investigator meeting presentations
  - Support investigators and field monitors 1:1 interaction
  - Authored Week 48 Clinical Study Report
- Provide clinical expertise for MK-8591 (islatravir) implant program development
  - Investigator implant procedure training for protocols MK-8591-07, 08, and 043
  - Protocol review (MK-8591-07,08, and 043)
  - Clinical support to Early Development Team
  - Clinical support for human factors testing and implant device risk management plan development
- Clinical monitoring support for protocol MK-8591-022 (women's PrEP program)

Women's Health Late-Stage Clinical Development / Life Cycle Clinical Support

Clinical Director for ongoing **Nexplanon Extended Duration** multicenter trial (MK-8415-060) which is being completed by Merck on behalf of Organon (2019-present); Status: recruiting (on track); goal N=450, 72 sites (US and Puerto Rico)

- Lead author of protocol and amendments
- Led team presentations to governance to secure approval and funding for program prior to Organon spinoff
- Medical monitoring of participant safety and protocol compliance
- Investigator meeting presentations

Company-wide support

- Clinical SME for protocol contraceptive requirements
  - Co-authored current template guiding risk-based choice of contraception requirements for clinical trials
  - Review/ approve protocol exception requests
- Clinical liaison to PLLR oversight committee
- Clinical support to Merck for Mothers: ad-Hoc protocol and grant review

PAST ACTIVITIES:

Product Development Team Chair for contraception (2016-2021) and fertility (2017-2021)
Section Head, Women's Health (2019-2021)

- Led cross-functional teams responsible for research and development of contraceptive and fertility products
- Presented late life cycle development plans to governance to obtain approval and funding
- Clinical SME supporting business development and licensing reviews for Merck and Organon spinoff (2021)
- Assisted in transfer of knowledge to Organon to support the women's health spinoff (2021)
- Clinical support to Global Labeling, Risk Management/ Safety, and Medical Affairs teams
- Fostered company interaction with key scientific leaders
- Presented key data at national women's health conferences and advisory board meetings
- Supervised direct reports

Late-stage clinical development:

- Directed 2 multi-center clinical trials (one in the US and one global) for the MK-8342B Contraceptive Vaginal Ring involving ~250 sites and ~4000 subjects meeting all milestones prior to the discontinuation of product development for business reasons
- Medical Monitoring (MK-8342B 061, 062; MK-8342-063)
- Investigator meeting presentations
- Protocol development (lead author, MK-8342B 061, 062; MK-8342-063)
- Clinical Study Reports (lead author, MK-8342B protocols 057, 061, 062 andMK-8342A-063)
- Authored study manuscripts for publication (see page 4-5)
- Regulatory interactions
  - Nexplanon safety label update (insertion location change): Presented study data to global health authorities to gain regulatory approval for significant change in Nexplanon insertion procedure (2017-2019)
  - End of Phase 2 FDA meetings for MK-8342B for contraception and dysmenorrhea indications
  - Requests for Scientific Advice communications with EMA (MK-8342B, MK-8415)
  - Lead clinical author supporting Nexplanon (re)filing for Health Canada which achieved product approval in 2020 after a decade delay
  - Special Protocol Assessment (SPA) agreements with FDA for MK-8342B Protocols 061, 059, 060
  - Type C FDA interactions (in person, teleconference, and written response) for NuvaRing Applicator, NuvaRing, and Nexplanon clinical development programs
  - NuvaRing Applicator Filing: CE Mark obtained in EU 2016; FDA Approval 2016
  - Pediatric Investigational Program (PIP) negotiation and protocol development for MK-8342B

Device development and regulatory experience

- Clinical support for device risk management file development for Nexplanon, 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.
- Clinical lead for cross-functional team development of rDRMPs for NuvaRing, Nexplanon, and the Puregon Pen

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 & Schering-Plough)
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
2019-2021	Distinguished Principal Scientist / Section Head Women's Health Diabetes, Endocrinology and Women's Health Late-Stage Development / Clinical Research	Merck Research Laboratories
2021-present	Distinguished Principal Scientist Diabetes, Endocrinology & Metabolism; Infectious Disease 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	Master 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 (see Peer-Reviewed Original Research Publication #5)
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) Drive
2018	Results Award, Merck Research Laboratory (leadership in Women's Health) Foster Collaboration Award, Merck Research Laboratory (vaccines, infectious disease) Drive Results
2019	Award, Merck Research Laboratory (leadership in Women's Health)
2020	Ways of Working Award, Merck, program leadership (for efforts supporting the Organon Spinoff)

PROFESSIONAL SOCIETIES

1998-2018	Member, Association of Reproductive Health Professionals
1997- 2005	Junior Fellow, American College of Obstetrics andGynecology
2005-present	Fellow, American College of Obstetrics andGynecology
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	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
2020-2023	**Industry representative to FDA Bone, Reproductive and Urologic Drugs Advisory Committee**

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; 100: 26-30.

15. Reed S, Minh TD, Lange, JA, Koro C, Fox M, Heinemann K. Real world data on Nexplanon procedure-related events: final results from the Nexplanon Observational Risk Assessment study (NORA). *Contraception* 2019; 100: 31-36

16. Mansour D, Frasier IS, Edelman A, et al (Fox M). Can initial vaginal bleeding patterns in etonogestrel implant users predict subsequent bleeding in the first 2 years of use? *Contraception* 2019; 100: 264-8.

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.

PAST 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 Activities:
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

Certification

2003-2015	Maryland Medical License
2016-present	New Jersey Medical License

Specialty Certification

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