

# K. KIMBERLY McCLEARY

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## Profile

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Kim is a recognized leader in developing patient-centric practices and policy to accelerate research and development and delivery of medical solutions that meet patient needs and contribute to improved health. She has dedicated her career to working collaboratively to build consensus and achieve shared goals by employing exceptional communication, strategic planning, and program management skills, applying a strong work ethic, and leveraging an extensive network of leadership contacts. Her passion for this work is rooted in personal experience, lived and as a family caregiver.

## Professional Experience

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### Founder & CEO

February 2018 to present

**The Kith Collective, LLC** – Washington, D.C.

To work directly with life science companies, not-for-profit organizations, and academic research teams to speed adoption of patient-centered practices, Kim established this consulting practice. To it she brings more than 30 years' experience to clarify objectives and prioritize resource allocations, design and implement custom strategic and tactical plans, bolster resident capacity and capabilities, and advance culture change.

### Senior Advisor

February 2018 to present

**Acting Executive Director**

August 2017 to January 2018

**Managing Director**

May 2015 to July 2017

**Director of Strategic Initiatives**

October 2013 to May 2015

**FasterCures | A Center of the Milken Institute** – Washington, D.C.

As a member of the Institute's senior management team, Kim was the primary architect and builder of programs that accelerate the path for promising therapies to reach patients. With deep content knowledge of patient engagement practices that leverage patient insights to address unmet medical needs and formulate patient-centered policies, she served as a key representative and spokesperson for *FasterCures* on advisory bodies, with the media, and at external events. As senior advisor, she provides ongoing counsel to Institute leadership and staff.

### Selected Accomplishments

- Created a new flagship program, "Patients Count: The Science of Patient Input," bridging projects that advance patient-centered processes for benefit-risk assessment, medical product development, and definition of the value of medical products. This new program showcases our team's content expertise, understanding of the landscape of initiatives to expand the science of patient input, and wide network of leadership contacts within patient organizations, industry, regulatory bodies, academia, and policymaking agencies. Secured first grant to *FasterCures* from the Patient-Centered Outcomes Research Institute.
- Shaped *FasterCures*' participation in and policy proposals for the 21<sup>st</sup> Century Cures Initiative of the U.S. House of Representatives Energy & Commerce Committee, the Senate Health Education, Labor and Pension Committee's "Innovation for Healthier Americans" initiative, and user fee negotiations for prescription drugs and medical devices between industry and the U.S. Food and Drug Administration.
- Participated actively on the Steering Committee for the Medical Device Innovation Consortium's Patient-Centered Benefit-Risk Assessment Project yielding an extensive framework report on how to integrate patient insights into the total product life cycle of medical devices as well as a comprehensive catalog of methods for eliciting and measuring patient preferences.
- Delivered presentations and contributed to panel discussions at more than 70 conferences and workshops convened by the Milken Institute, U.S. Food and Drug Administration, Biotechnology Innovation Organization (BIO), Medical Device Innovation Consortium (MDIC), Institute of Medicine,

Patient-Centered Outcomes Research Institute (PCORI), National Health Council, American Heart Association, DIA, Parent Project Muscular Dystrophy, Global Liver Institute, International Society for Pharmacoeconomics and Outcomes Research (ISPOR), Sanofi, Merck, Biogen, Alkermes, Takeda, Conference Forum, International Medical Device Regulators Forum (IMDRF), and others.

**Principal**

July 2013 to September 2013

**kmc<sup>2</sup> consulting, LLC** – Arlington, VA

Established a solo consulting practice to help actualize the promise of patient-centered research and policy.

- Working with Wake Up Narcolepsy and other community leaders, designed and launched the “Unite Narcolepsy” initiative to educate, engage, and empower narcolepsy patients and their advocates to participate effectively in the Food and Drug Administration’s September 24, 2013 Patient-Focused Drug Development meeting, setting record attendance for the series. Developed and deployed a 30-item patient-focused survey on narcolepsy symptoms and treatments to facilitate patients’ responses to questions posed by FDA; attracted more than 2,000 patient and caregiver responses.
- Developed an extensive report based on a meeting of key opinion leaders convened by *FasterCures* and the Cystic Fibrosis Foundation that addressed the concept of “value” as defined in healthcare and reimbursement systems and specifically how patients and patient-based organizations can inform decision-making to incentivize innovation ensuring patient access to promising therapies.

**President & CEO**

February 1991 to June 2013

**The CFIDS Association of America** – Charlotte, NC

The CFIDS Association of America, now known as the Solve ME/CFS Initiative, is the foremost patient-centered nonprofit organization working to make chronic fatigue syndrome (also known as CFS, chronic fatigue and immune dysfunction syndrome, CFIDS, myalgic encephalomyelitis, and ME/CFS) widely understood, diagnosable, and treatable. As the chief staff executive she was responsible for:

- Charting mission-driven research, policy, advocacy, education, communications, patient engagement, and support programs over two decades of dynamic change.
- Acquiring, expanding, and efficiently investing human, financial, and reputational assets to advance the organization's mission.
- Serving as the chief spokesperson in media, policy, scientific, educational, and fundraising venues.
- Employing excellent verbal and written communication skills to translate complex research and policy issues to several target audiences through a variety of print, electronic, and social media platforms.
- Developing patient-centered programs and projects, providing guidance, support, and continuous process improvement at each step from conception to post-evaluation.
- Implementing best practices for nonprofit governance and fostering a team-oriented workplace that enriched the lives of staff and volunteers working collaboratively in service of the mission.

**Selected Accomplishments**

- Evolved organization from local support group to traditional nonprofit research grantmaker to performance-based venture philanthropy organization, retooling the sponsored medical research program to return \$8 in follow-on funding from larger institutions for every \$1 invested.
- Earned first position for ME/CFS in FDA’s Patient-Focused Drug Development initiative with a workshop held April 25, 2013.
- Co-authored the 2010 report, “Chronic Pain in Women: Neglect, Dismissal and Discrimination” that helped shape a 2011 Institute of Medicine report and 2012 Senate Appropriations Committee hearing on chronic pain.
- Secured and tightly managed federal government contracts totaling \$9 million to support a multi-media public awareness campaign and professional education activities, greatly exceeding anticipated outcomes.
- With Social Security Administration officials, developed SS Ruling 99-2p that recognizes CFS as a potentially disabling condition and dramatically transformed the ability of disabled CFS patients to obtain federal benefits.
- Moderated eight Congressional briefings and a National Press Club event; coordinated 14 annual lobby day events involving hundreds of patient advocates; oversaw dozens of other national and regional special events.

**Vice President**

November 1985 to February 1991

**Blair/McGill & Company – Charlotte, NC**

Coordinated all programs offered by this national consulting firm serving dental professionals. Provided in-office management consulting; organized, marketed and delivered national seminar series; and developed follow-up services for seminar attendees. Produced monthly management and financial newsletter. Administered financial planning and practice brokerage services. Performed internal accounting and human resource functions.

**Education**

**Bachelor of Arts:** Organizational Communications & English  
**University of North Carolina at Chapel Hill**

1984

**Selected Affiliations**

Development Officer | The Falls Church Endowment Fund (2018-present)  
 Co-Principal Investigator | "Heath Data Basics" project funded under a Eugene Washington Engagement Award by the Patient-Centered Outcomes Research Institute (2017-2018)  
 Member | American Heart Association/American Stroke Association Research Committee (2017-2018)  
 Member | National Institutes of Health Review Panel for "All of Us" Program Community Engagement Proposals (2017)  
 Steering Committee | Patient-Focused Medicines Development (2016-present)  
 Member | DIA Advisory Council of North America (2015-present)  
 Member | ISPOR Patient Engagement Roundtable (2015-present)  
 Co-Chair | Parent Project Muscular Dystrophy Research Roundtable (2015-present)  
 Vestry | the Falls Church Episcopal (2015-2017)  
 Member | ALS Association Expert Review Committee for Draft Regulatory Guidance (2015-2016)  
 Member | BIO Expert Review Committee for Patient Preference (2015-2016)  
 Member | PCORI Patient Engagement Advisory Panel (2014-2016)  
 Steering Committee | Medical Device Innovation Consortium Patient-Centered Benefit-Risk Project (2014-present)  
 Member | DIA Patient Engagement in Benefit-Risk Assessment Program Committee (2014-2015)  
 Participant | FDA Patient-Focused Drug Development Initiative Process Consultation (2012-2013)  
 Member | AABB Interorganizational XMRV Blood & Cellular Products Task Forces (2010-2012)  
 Co-Founder | Chronic Pain Research Alliance (2009) and Campaign to End Women's Pain (2010-2012)  
 Member | Department of Health and Human Services CFS Advisory Committee (1997-2002, 2013)  
 Member | Centers for Disease Control & Prevention External Scientific Review Panel (1996, 2000, 2007)  
 Recipient | "Mothers and Shakers" award by Redbook magazine. Fellow honorees that year included (then) Senator Hillary Rodham Clinton, former Surgeon General Dr. Regina Benjamin and Marlo Thomas. (September 2001)

**Selected Publications**

"Top 10 Medical R&D Issues to Watch in 2018," Health Affairs blog, January 2018 (with Kristin Schneeman)  
 "From Aspiration to Application: 5 Years of Patient-Centricity," *FasterCures*, July 2017  
 "Listening to the Patient Voice in Narcolepsy: Diagnostic Delay, Disease Burden, and Treatment Efficacy," *Journal of Clinical Sleep Medicine*, March 15, 2017 (with Maski, Steinhart, et al.)  
 "Pulse Check on Patient-Centricity: 7 Vital Signs," Timmerman Report, February 10, 2017  
 "A Framework for Incorporating Patient Preferences Regarding Benefits and Risks into Regulatory Assessment of Medical Technologies," *Value in Health*, September-October 2016 (with Ho, Saha et al.)  
 "On the Path to a Science of Patient Input," *Science Translational Medicine*, April 26, 2016 (with Margaret Anderson)  
 "Expanding the Science of Patient Input: Pain Points and Promise," *FasterCures*, April 2016  
 "Expanding the Science of Patient Input: Building Smarter Patient Registries," *FasterCures*, February 2016  
 "From Anecdotal to Actionable: The Case for Patient Perspective Data," *FasterCures*, November 2015  
 "From Passengers to Co-Pilots: Patient Roles Expand," *Science Translational Medicine*, June 2015 (with Margaret Anderson)  
 "Value and Coverage: How Reimbursement Decisions Impact Innovation Needed to Improve Health," *FasterCures*, January 2014