Jennifer Bullard Madsen, MPH

202-465-1949 (mobile)
jenmadsenmph@gmail.com | jen@diagonalhealth.com
Arlington, Virginia USA

SUMMARY

Senior life sciences and healthcare industry strategic advisor, impact investor and consulting executive with a successful track record of strategic ideation, facilitation, coalition building, policy development, philanthropic strategy, and impact measurement. Strategy consultant to ARPA-H, CMS, FDA, NIH; government affairs and policy representative for patient advocacy organizations, industry trade associations, coalitions, and companies; senior business development executive in multiple strategy consulting roles. Creative problem-solver; work featured in the *Washington Post, New York Times, USA Today, US News and World Report, Health Affairs*, government publications, trade press. Broad, bipartisan network of thought leaders; 3K social media followers.

Strengths include strategic planning, creative problem-solving, understanding of stakeholders' motivations, and skill managing complex projects that combine federal and state government relations, data analytics and digital advocacy, traditional and social media.

KEY SKILLS & EXPERTISE

- Leadership & strategic planning
- Business development
- Building & leading teams
- Managing organizational change
- Legislative & regulatory affairs
- Executive-level communicator
- Life sciences & health care industry
- Health policy & economics
- Biomedical innovation ecosystem

PROFESSIONAL EXPERIENCE

BMNT Inc., Rosslyn, VA (www.bmnt.com) **Aug 2023 – present**
Health Practice Leader

- Leader for business development across the Department of Health and Human Services. Responsible for leading engagement with the Advanced Research Projects Agency for Health (ARPA-H) in its second contract year, plus business development initiatives in health across NIH, CMS, VA.
- In its first year, BMNT, a global innovation consultancy for governments and their partners, helped ARPA-H create a "front end" for acquisitions, a "back end" for acquisition management, and leadership training in agile methods. Using its Silicon Valley ecosystem, helped ARPA-H develop a playbook for commercializing technologies, engage a broad ecosystem of non-governmental stakeholders, and design a "bootcamp" for new employees to immerse themselves in human-centered design (HCD) and lean innovation.
- Helped the PATIO office define service offerings for its T3X program (Technology Translation and Transition) including access to entrepreneurs in residence (EIRs) and commercialization advisors, regulatory advisory services, reimbursement strategy and tactical support, and intellectual property advice.
- Advised ARPA-H on the design of new ARPA-H programs, including newly launched Women's Health Initiative, by performing beneficiary discovery and creating a Problem Sourcing Workbook for ARPA-H problem owners.

MITRE Corporation, McLean, VA (www.mitre.org) **Feb 2019 – Aug 2023**
Senior Principal and Department Manager, Health FFRDC *Nov 2021-Aug 2023*
Principal, Health Innovation, & Health Policy, Health FFRDC *Feb 2019-Nov 2021*

- Department Manager at MITRE, a not-for-profit company that works in the public interest. MITRE operates federally funded research and development centers (FFRDCs), including the only FFRDC devoted exclusively to healthcare. Responsibilities include all aspects of business development, project leadership, and people management for a team of 17 professional staff and a $25 million book of business.
- Lead the Health FFRDC's work on a wide range of projects positioned at the crossroads of health innovation and government technology modernization for federal clients including the Centers for Medicare and Medicaid Services (CMS) Office of the Administrator and the Office of the National Coordinator for Health Information Technology.
- Lead multidisciplinary project teams, totaling 70 people matrixed across MITRE, include experts in artificial intelligence and AI assurance, software developers, attorneys, health informatics, clinicians and former regulators. Helped CMS design and launch 13 cross-cutting initiatives in 2021-2023.
- Business development leader for MITRE work with the National Institutes of Health (NIH) and Food and Drug Administration (FDA) focused on accelerating biomedical innovation. Led MITRE technical paper, published October 2021, on the new Advanced Research Projects Agency for Health (ARPA-H) with recommendations for accelerating biomedical innovation across the federal government, powered by an interoperable digital data infrastructure.
- During the COVID-19 pandemic, advised the NIH Rapid Acceleration of Diagnostics for COVID-19 (RADx) "Shark Tank" program and brokered a novel working relationship across the NIH and FDA. The project's impact includes authorizing the first COVID-19 test for use at home without a prescription and shortening the timeline for developing a new diagnostic test from seven years to seven months.
- Led a project to help NIH Office of the Director launch a new SEED Office and Innovator Support team, piloting entrepreneurship, regulatory and reimbursement consulting services for small business innovators.
- Two-time recipient of MITRE's highest honor, the Program Recognition Award, for work with CMS Innovation and NIH.

Food Allergy Research & Education, McLean, VA (www.foodallergy.org) **Sep 2017–Jan 2019**
Chief of Staff / Senior Director, Government Affairs and Public Policy

- Led senior management team's process for five-year strategic plan, financial projections, and recommendations on Board governance for an organization with over 50 staff and annual revenues of $14 million, during a period of significant leadership changes. Staff liaison to new CEO.
- Engaged FDA on patient-focused drug development for patients with food allergies, using authorities in 21st Century Cures Act; resulting publication recommended strategies for FDA review of food allergy therapies. With CEO and CMO, developed strategy for evaluating venture philanthropy investments in new technologies for diagnosing and treating food allergies.
- Established coalition of food allergy patient advocacy organizations; drafted legislation to improve public safety for food allergy patients; received endorsement of all coalition members; FASTER Act legislation (P.L. 117-11) enacted 2021.
- Led organizational response to a global shortage of epinephrine auto-injectors. Sent letter to FDA Commissioner requesting that agency declare a national shortage, give guidance to schools on expired products, and approve new generic alternatives. FDA acted on all recommendations. News coverage on epinephrine shortage garnered est. 335 million online views: CNBC, USA Today, New York Times, Washington Post.

Arnold & Porter LLP, Washington, DC (www.arnoldporter.com) **2015 – Jul 2017**
Health Policy Advisor, Life Sciences / Healthcare Regulatory & Legislative / Public Policy Practices

- Led analysis of MACRA legislation and regulations; advised physician specialty society and pharmaceutical industry clients on implementation of new law. Drafted comments recommending changes to physician Evaluation & Management (office visit) payment codes; CMS adopted.
- Advised *in vitro* diagnostics, biopharmaceutical companies on FDA, NIH regulatory reforms during negotiations on the 21st Century Cures Act.
- Advised laboratory clients on reimbursement for new technology; helped client reverse Blue Cross non-coverage decision on non-invasive prenatal genetic testing; advised major in-vitro diagnostics manufacturer on CPT code compliance for nucleic acid tests.

College of American Pathologists, Washington, DC (www.cap.org) **2013 - 2015**
Senior Director, Economic and Regulatory Affairs, Advocacy Division

- Senior leader in large DC office (25 staff) of global organization ($100 million budget) serving 20,000 clinical laboratories in 100 countries with accreditation programs, and 18,000 physician members. Grew team from eight to 10 professional staff; $3 million annual budget.
- Led coalition of genetic testing labs' opposition to Medicare coverage changes that halted all payment of previously-covered tests in Q1 2013, resulting in a $40 million loss for LabCorp alone. Recommended CMS add MolDX decisions to Medicare coverage database to improve transparency; suggestion was adopted.
- Successfully led opposition to FDA 2014 draft guidance regulating laboratory tests as medical devices, a proposal which directly threatened the $100 million annual revenue of the accreditation business.
- Built in-house capabilities to analyze Medicare claims and model impact of proposed changes in payment policy for the specialty of pathology. Recommended that organization create a clinical data registry, which was ultimately implemented by creating five new jobs in DC office.

American Clinical Laboratory Association, Washington, DC (www.acla.com) **2011-2013**
Vice President, Policy and Regulatory Affairs

- Led organization's response to threat of Medicare payment cuts for laboratory services. Identified public relations strategy emphasizing administrative burden of coinsurance for Medicare patients; proposal was not adopted.
- Guided association's members in implementation of major overhaul of CPT codes for genetic testing and algorithm-based testing; represented association in Pathology Coding Caucus and CPT Editorial Panel review of code change proposals.
- Represented association's members in workgroup to negotiate FDASIA user fee agreement between FDA and medical device industry.

Pricing, Reimbursement & Market Access (PRMA) Consulting, Hampshire, UK *(As of 2023, part of Avalere Health)* **2011**

- Regulatory and launch planning consultant and business development leader for North America, responsible for selling advisory services on drug pricing, reimbursement, and market access to biopharmaceutical companies. Led analysis of new FDA guidance on the regulation of pharmaceuticals with companion diagnostic tests; advised clients on strategy for launching new drugs in international markets and the US.

Podesta Group, Washington, DC **2010**
Principal

- Led company's engagement with healthcare, pharmaceutical, industrial, professional services clients during final negotiation and passage of the Affordable Care Act. Analyzed legislation and guided clients on business impact, political positioning, and federal contracting opportunities.

Avalere Health LLC, Washington, DC (www.avalere.com) **2003 – 2009**

- Progressively responsible general manager and leader in high-growth startup consulting firm focused on health policy and business strategy. Member of firm's Leadership Team for four years.
- Senior strategic advisor to the world's largest biopharmaceutical companies over a four-year period of implementation of

the Medicare Prescription Drug Benefit. Analyzed legislation, modeled financial impact and future scenarios, developed company positions on regulatory parameters, influenced CMS policy decisions, subject matter expert for consulting teams from McKinsey, Deloitte. Work was a key driver of company's growth from 17 employees in 2003 to 125 in 2009.

- Developed online and in-person events to showcase firm's thought leadership. Led creative and events team of 7 staff.
- Led strategic consulting projects worth $2 million per year; second-line manager of client teams; deputy practice leader.

Congressional Budget Office (CBO), Washington, DC (www.cbo.gov) **1999 – 2002**
Associate Analyst, Health and Human Resources Division

- Advised congressional staff on impact of legislation on mandated insurance benefits, prescription drugs, disease management, mental health services on federal government and private sector, economic models, CBO cost estimates.

EDUCATION

Yale University, New Haven, CT
Master of Public Health in Health Policy, 1999
Honors Thesis

Rice University, Houston, TX
Bachelor of Arts in Biochemistry, 1997
President's Honor Roll

AFFILIATIONS

Member of the Board of Directors, Mental Health America, Alexandria, VA, 2021-present
Senior Warden, St. Andrew's Episcopal Church, Arlington, VA, 2018; Vestry Member, 2016-2018

SOCIAL MEDIA

www.linkedin.com/in/jenbullardmadsen www.x.com/jenmadsenmph

SELECTED PRESENTATIONS

1. *Health Policy Issues for the Laboratory Industry*. HIDA Laboratory and Diagnostics Conference. Orlando, FL, Feb 2018.
2. *The U.S. Healthcare System's Drive to Value-Based Payment: What Will It Mean for Precision Medicine?* Advances in Companion Diagnostics Congress and Precision Medicine Conference. London, UK, 2017.
3. *The Quality Payment Program: Implications of MACRA for Pathologists and Laboratories.* California Clinical Laboratory Association Annual Meeting. San Diego, CA, 2016.
4. *The Federal Government Innovates, Too*. GTC Bio Precision Medicine Conference. Boston, MA, 2016.
5. *FDA Regulation of Laboratory-Developed Tests: What to Expect, How to Prepare*. G2 Intelligence Webinar, 2016
6. *Medicare's New Physician Payment System: What's Now, and What's Next*. Arnold & Porter Webinar, 2015.

SELECTED PUBLICATIONS

1. Accelerating Innovation For Better Health: A MITRE Framework Supporting The Proposed Advanced Research Projects Agency For Health (ARPA-H). MITRE Corporation, Sep 15, 2021
2. *FDA Regulation of Laboratory-Developed Tests: What to Expect, How to Prepare*. Arnold & Porter Advisory, 2016.
3. *Post-Election Analysis 2016: Healthcare, Life Sciences & FDA*. Arnold & Porter Advisory, 2016.
4. *Medicare physician payment: Prepare to 'MACRA-mize' your practice.* www.healio.com, 2015.
5. *Final Meaningful Use Rules Add Short-Term Flexibility*. Arnold & Porter Advisory, 2015.
6. *FDA Regulation Catches Up To Next-Gen Gene Sequencing.* Health Law360 New York, 2015.
7. *House Energy and Commerce Committee Approves 21st Century Cures Legislation.* Arnold & Porter Advisory, 2015.
8. *Saying Farewell to the Sustainable Growth Rate: Are Physicians Better Off Now?* Arnold & Porter Advisory, 2015.
9. Ferdinand KC, Orenstein D, Hong Y, Journigan JG, Trogdon J, Bowman J, et al. "Health Economics of Cardiovascular Disease: Defining the Research Agenda." *CVD Prevention and Control*, 2011.
10. Ali R, Bowman J, Carino T. *Untangling the Potential Impact of Comparative Effectiveness Research on Pharmaceutical Innovation*. National Pharmaceutical Council, 2009.
11. Bowman J, Rousseau A, Silk D, Harrison C. "Access to Cancer Drugs Under Medicare Part D: Formulary Placement and Beneficiary Cost Sharing in 2006." *Health Affairs*, 2006.
12. Blum J, Bowman J, White C. The Impact of Enrollment in the Medicare Prescription Drug Benefit on Premiums. Kaiser Family Foundation 2005.
13. Congressional Budget Office. *A Detailed Description of CBO's Cost Estimate for the Medicare Prescription Drug Benefit*, Jul 2004.