

February 24, 2025

President Donald Trump  
The White House  
1600 Pennsylvania Avenue, NW  
Washington, D.C. 20500

Dear President Trump:

We write to share insights on ensuring the health and wellness of women – including our mothers and daughters - that can reduce avoidable medical expenditures, strengthen our economy with more productive businesses and communities, and save lives. We look forward to working with you as a business leader who knows the importance of government actions to remove barriers to growth and appreciates how government can play a key role in accelerating valuable scientific knowledge; explosive economic returns and job creation; and life-saving medical innovations coming to market and reaching patients.

Many of us have worked for decades to advance the health of women through research, innovation and access and welcome the chance to collaborate with you to close gaps and advance the health of women. Women's health includes those conditions and diseases that solely (maternal health, endometriosis, fibroid tumors, breast cancer, etc.), disproportionately (autoimmune diseases, Alzheimer's, migraines, mental health, etc.) and/or differently (chronic pain, heart disease, lung cancer, etc.) impact the health of women. Despite this touching all of us directly or indirectly, a gap exists due to unnecessary barriers that we must remove to enable innovation to improve and save lives. Moreover, addressing the 25% more time that women spend in poor health relative to men would boost the global economy by at least \$1 trillion annually and generate the equivalent impact of 137 million women in full-time positions by 2040.<sup>1</sup> When medical research is accurate, well-funded and supported by efficacious regulatory approval and coverage policies, the impact on people's lives and the economy can be life-altering.

### **Accuracy in Research**

The gap that exists in the health of women is due to a lack of research over the last several decades. Ensuring research studies include female animals and humans and collecting data on women and men and how various conditions and innovations impact the health of patients is vital not just to more accurate scientific understanding and better health outcomes, but to incentivizing increased investment in businesses innovating in the women's health space. Adverse drug events are twice as common in women as men and without data and understanding as to why this happens for each therapy and how to rectify it with both FDA support and a business strategy for market adoption, many investors shy away from directing dollars toward women's health or investing in examining sex-based differences. By simply increasing female inclusion in studies representative of disease state in the greater population as well as sex-based data collection and analysis in all NIH- and DoD-sponsored studies through the agency's policy on sex as a biological variable and FDA clinical trials and having journal publications include sex-based data in order to be listed in the NIH Library of publications, your administration could close this gap,

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<sup>1</sup> <https://www.mckinsey.com/mhi/our-insights/closing-the-womens-health-gap-a-1-trillion-dollar-opportunity-to-improve-lives-and-economies>

include more accurate labeling and spur more R&D efforts to tailor medical innovations to meet male and female patient needs.<sup>2</sup>

For example, a study on autoimmune disease ideally would have roughly 75-80% women participants since 75-80% of all patients with autoimmune disease are women and it would have significant participation by people of color as African American, Native American and Hispanic women are more susceptible to autoimmune diseases than the general population.<sup>3</sup> Meanwhile a study on cardiovascular disease would have roughly 50% women and 50% men since it is the number one killer of both sexes, but has different symptoms and reactions to therapeutics and devices in women and men.<sup>4</sup> Overall, at least 50% females in the pre-clinical and clinical trials would garner significant gains in furthering more precise research and healthcare for women and men.

### **Research Funding**

Currently, the investment in women's health is quite low as less than 2% private venture funding (when including oncology this rises to 5%) and 8-11% NIH funding is dedicated to this market despite the \$1 trillion opportunity.<sup>5,6</sup> If the various NIH institutes increased their percentage of grant funding toward women's health research to ensure that the total allocation approaches a more equitable rate and the Office of the Director had additional grant funding to fund more worthy grants in women's health, we could enable researchers and clinicians alike to do more with better evidence to back their decision-making in how innovate and treat patients. Another key area of government research funding is the Advanced Research Projects Agency – Health (ARPA-H) that Congress has authorized and appropriated with bipartisan support since 2022. Much like its parent, DARPA, which was created by President Eisenhower, the ARPA-H has consistently supported high-risk high-reward investment in health that traditional venture has been reluctant to back but can transform patient care. It has funded \$113 million in this space, spanning from maternal and fetal health to menopause to pain. This funding is essential to spurring matching private sector investment as it de-risks the opportunities for VCs, entrepreneurial risk-taking ventures that maintain our global competitiveness, and job creation and business growth—all in addition to advancing women's health.

### **FDA Approval Process**

Too often there are unnecessary delays in the FDA approval process in women's health due to the time dedicated to education on sex differences, the biology of women and how innovations work within the female body. Creating an FDA Center of Excellence in Women's Health or related pilot program with appropriate staff trained and experienced in women's health would allow for greater efficiency and

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<sup>2</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7275616/> and <https://pmc.ncbi.nlm.nih.gov/articles/PMC7275616/#:~:text=Women%20experience%20adverse%20drug%20reactions,so%20women%20may%20be%20overmedicated>

<sup>3</sup> <https://medicine.musc.edu/departments/dom/news-and-awards/2022/may-2022/understanding-autoimmune-disease-disparities#:~:text=The%20disproportionate%20rates%20at%20which,Ramos%2C%20Ph>

<sup>4</sup> <https://www.cdc.gov/heartdisease/facts.htm#:~:text=Heart%20disease%20is%20the%20leading,groups%20in%20the%20United%20States.&text=One%20person%20dies%20every%2033,United%20States%20from%20cardiovascular%20disease.&text=About%20695%2C000%20people%20in%20the,1%20in%20every%205%20deaths>

<sup>5</sup> <https://www.mckinsey.com/industries/healthcare/our-insights/unlocking-opportunities-in-womens-healthcare>

<sup>6</sup> [https://orwh.od.nih.gov/sites/orwh/files/docs/ORWH\\_WHC\\_ExecutiveSummary508.pdf](https://orwh.od.nih.gov/sites/orwh/files/docs/ORWH_WHC_ExecutiveSummary508.pdf) and

<https://nap.nationalacademies.org/catalog/28586/a-new-vision-for-womens-health-research-transformative-change-at>

understanding to properly evaluate innovations, convene companies and patients, and guide their approvals, thus accelerating innovations. Many companies and their investors would welcome this additional guidance and incentivization, and get much needed therapies to patients faster.

### **Access to Care and Innovation**

Yet another concern is how innovations can reach patients effectively across rural, urban and all communities. Reaching populations in an accessible, affordable way is key to overcoming current barriers, such as being geographically located far from care with few transportation options. Therefore, we ask you to consider the real world lived experience of patients, their access to innovation and the role of cost and affordability in shaping access.

For example, women often have uniquely challenging barriers to traditional healthcare access: childcare responsibilities, shift work, and the juggling of children and jobs and/or limited access to transportation. In addition, employed women aged 19-64 spend \$15.4 billion (20%) more than employed men in out-of-pocket healthcare costs each year, based on deductibles, coinsurance, and out-of-pocket maximums, worsening existing gender wage disparities.<sup>7</sup> The percentage drops to 18% when maternity-related services are excluded. This differential often called the “pink tax” means as innovations are developed and enter the marketplace, access can remain a significant challenge. Removing out-of-pocket healthcare costs such as taxes on feminine products, diapers and related items would make a significant difference on the ability for women to access care, thrive and contribute to our economy.

### **CMS Reimbursement**

As you know, many innovations approved by the FDA are not covered by CMS, TRICARE uniformed services health care program, and Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA). In addition, the reimbursement rates can be skewed as male urological surgeries have the dollar value on average that is 27.67% higher than their female-specific equivalent procedures (some of which are necessary following childbirth).<sup>8</sup> The government could play a stronger role in closing these gaps by working with innovators as they move through FDA approval and onto CMS, TRICARE, CHAMPVA and private insurers’ reimbursement systems by having companies provide a plan for reaching all patients to be able to access new innovations. Making these plans public and providing annual reports on sex-based data among these patient populations would incentivize intentionality and effectiveness and help insurers to implement this access. These are valuable steps the government can take to increase access to women’s health innovations, improve new business growth opportunities, and de-risk the investments made by VCs.

### **Maternal Health, Mental Health and Gynecological Care**

A critical aspect of innovation access is maternal health that extends into all aspects of the mental and physical health of women. Today, an estimated 2.2 million U.S. women live in “OB-GYN deserts” and 4.7 million more live in areas with limited access – with many of these areas being in rural parts of the country where it can take several hours to reach a medical facility.<sup>9</sup> In addition, inadequate clinician

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<sup>7</sup> <https://www2.deloitte.com/us/en/pages/life-sciences-and-health-care/articles/womens-health-equity-disparities.html>

<sup>8</sup> [https://scholarship.law.bu.edu/cgi/viewcontent.cgi?article=4774&context=faculty\\_scholarship](https://scholarship.law.bu.edu/cgi/viewcontent.cgi?article=4774&context=faculty_scholarship)

<sup>9</sup> <https://www.marchofdimes.org/maternity-care-deserts-report>

training and a shortage of medical professionals is impacting the health of women throughout the country and in all age groups spanning from puberty to pregnancy to menopause.<sup>10</sup> The impact is particularly severe among communities of color. Within maternal health, Black mortality rates are nearly three times higher than among white women and Black infants are almost four times as likely to die from complications related to low birthweight.<sup>11, 12</sup> Research and innovation in pre-eclampsia, preterm labor and postpartum hemorrhage remain direly needed for all women to improve outcomes. We believe that OB-GYN physicians, Women's Health Nurse Practitioners, midwives, and Family Medicine physicians as well as community health workers will play critical, multidisciplinary roles in solving the maternal health crisis and access to care in maternity care deserts. There is a unique role that the government can play in attracting these clinicians to address care gaps.

### **Inter-Agency Coordination**

Overall, government could lead the way in creating economic incentives and dashboards that measure and convene researchers, clinicians, entrepreneurs and patients to exchange information and partner in advancing R&D and medical innovations to address women's health to close these health gaps. Adding meaningful funding to this coordination and data-sharing effort, removing silos and increasing communications and collaborations that include private sector and cross-government cooperation that ensures all agencies work together will enable accelerated pathways to bring innovations to patients will ensure that thorough, holistic and productive advancements are achieved with real impact on the economy.

In conclusion, there are many challenges and opportunities when it comes to advancing women's health and bringing innovation to market that you and your administration are well-positioned to accelerate will generate enormous economic return. The most pressing areas where access to innovation will have the greatest impact are from ensuring accuracy in research with representative pre-clinical and clinical participation, increasing research funding in broad women's health areas, closing the gap between FDA approval and coverage by both private and government payers, prioritizing maternal health and gynecological access for all women in all age groups, and organizing inter-agency coordination to advance knowledge and collaborations in women's health to reach all patients throughout the country.

Thank you for your consideration. We are eager to work with you to address these issues. If you have questions, please contact Liz Powell at [lpowell@G2Gconsulting.com](mailto:lpowell@G2Gconsulting.com).

Sincerely,

Liz Powell, Esq., MPH  
Women's Health Advocates  
Vienna, VA

Kathryn Schubert, MPP  
Society for Women's Health Research  
Washington, DC

*CC: Speaker Johnson, Majority Leader Thune, Minority Leader Jeffries, Minority Leader Schumer and entire U.S. Congress*

<sup>10</sup> <https://www.marchofdimes.org/maternity-care-deserts-report-2022#:~:text=The%20new%20findings%3A&text=In%20maternity%20care%20deserts%20alone,women%20with%20no%20maternity%20care>

<sup>11</sup> [https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2021/maternal-mortality-rates-2021.htm#:~:text=In%202021%2C%20the%20maternal%20mortality,\(Figure%201%20and%20Table\)](https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2021/maternal-mortality-rates-2021.htm#:~:text=In%202021%2C%20the%20maternal%20mortality,(Figure%201%20and%20Table))

<sup>12</sup> <https://minorityhealth.hhs.gov/infant-mortality-and-african-americans#:~:text=Non%2DHispanic%20black%2FAfrican%20American,%2DHispanic%20whites%2C%20in%202020>

Martha Nolan, Esq.  
HealthyWomen  
Washington, DC

Kristen Dahlgren  
Cancer Vaccine Coalition  
Middlebury, VT

Rebecca Cunningham, PhD  
Organization for the Study of Sex Differences  
Fort Worth, TX

Shikha Jain MD FACP  
Women in Medicine  
Chicago, IL

Stefan Niederauer, PhD  
Freyya Inc  
Salt Lake City, UT

Jennifer Garrison, PhD  
Buck Institute for Research on Aging  
San Francisco, CA

Bethany Corbin, Esq.  
FemInnovation  
Charlotte, NC

Kaethe Henning  
Capgemini America, Inc.  
Seattle, WA

Cailin Deal, PhD  
Moderna  
Cambridge, MA

Rachel Sheehan, MSN, RN-BC, C-ONQS  
UHS of Delaware  
King of Prussia, PA

Barbara Schuler, MPH  
VAX 2 STOP CANCER  
Birmingham, AL

Santosh Dhakal, DVM, MS, PhD  
Kansas State University  
Manhattan, KS

Erika Miller, JD  
Women First Research Coalition  
Washington, DC

Sandra Goff  
Retired Educator  
Belmont, WV

Akifa Khattak, Esq, MHA, MS Biotech  
Her Health AI  
Orlando, FL

Lauren Davis  
HerMD  
Athens, GA

Banrida Wahlang, PhD  
University of Louisville  
Louisville, KY

Evyn White, PMP  
Hera Health Tech  
Colorado Springs, CO

Janice Hall, Ph.D.  
Maternal Beats, LLC  
Pontotoc, MS

Karla Loken  
Physician / Fem Select / Lasa Health  
Zionsville, IN

BJ Carter, M.S.  
HealthyDirections/HealthyChildrenHealthyFutures  
New York, NY

Linda Goler Blount, MPH  
Black Women's Health Imperative  
Atlanta, GA

Claire Gill  
National Menopause Foundation, Inc.  
Alexandria, VA

Emily Zarecki  
Clarion Communications  
Sylvania, OH

John McCluskey  
Healthcare Advisor & Investor  
Madison, WI

Millicent Gorham, PhD (Hon), MBA, FAAN  
Alliance for Women's Health and Prevention  
Washington, DC

Jyoti Gupta, PhD  
GE HealthCare  
Hanover, MD

Yvonne Martinez  
Houston Methodist Hospital  
Houston, TX

Michela Bedard  
Period, Inc  
Portland, OR

Julienne Verdi, Esq.  
Alliance for Headache Disorders Advocacy  
Voorhees, NJ

Abby Mercado  
Rescripted  
Denver, CO

Gabriele Niederauer  
Freyya, Inc.  
San Antonio, TX

Sophia Yen, MD, MPH  
Physician  
Sunnyvale, CA

Monica Cepak  
Wisp  
New York, NY

Janelle Miller, MBA  
Consultant  
Austin, TX

Renata Hoffstetter  
Foundation for NIH  
North Bethesda, MD

Shannon Cohn, Esq.  
Project Endo  
Oxford, MS

Carmela Tafoya, ACSM H.F.I.  
Innerstill  
Honolulu, HI

Linda Greub, MBA  
Avestria Ventures  
San Francisco, CA

Shirley Wang, MS, DDS, CLU  
Financial Advisor  
Nashville, TN

Erin Couchell  
Comfort Keepers  
Spartanburg, SC

Marissa Fayer, MBA  
DeepLook Medical  
New Haven, CT

Jae-ann Rock  
SunStream Consulting, LLC  
Tilton, NH

Dr. Bayo Curry-Winchell MD MS  
Beyond Clinical Walls  
Reno, NV

Crystal Aguh, MD  
Johns Hopkins School of Medicine  
Baltimore, MD

Jocelyn Fitzgerald, MD FACS  
Physician  
Pittsburgh, PA

Carol Johnson, BCPA  
UterineKind  
Boston, MA

Claire Houchen, PhD candidate  
Scientist  
Kansas City, MO

Grace Colón, PhD  
Board Chair, Emm  
Los Gatos, CA

Shruti Valjee  
Women's Health Advocate  
Pittsburgh, PA

Jamie Zahlaway Belsito  
Maternal Mental Health Leadership Alliance  
Topsfield, MA

Anna Bauman, MBA  
Anna Haas Bauman Consulting  
San Jose, CA

Amelia Degenkolb, MS  
Novocuff, Inc.  
Mountain Brook, AL

Chelsea Edge  
Bonafide Health  
Dallas, TX

Ishita Shah, PhD  
Matrubials Inc.  
Davis, CA

Crystal Tyler, PhD, MPH  
Illinois Public Health Institute  
Chicago, IL

Kate Brigham  
Kate Brigham Consulting  
Boston, MA

Piush Vidyarthi  
CrossBay Medical Inc  
San Diego, CA

Madylin Starke, MHA  
Progyny  
Oxford, NC

Laura Wahlberg  
Mother  
Franklin, MA

Rebecca Parr PT, DPT, DHSc  
Resilience Physical Therapy  
Dayton, OH

Shari Beagelman  
BlackDoctor.org  
Chicago, IL

Elizabeth Garner, MD, MPH  
American Medical Women's Association  
Montclair, NJ

Mitzi Krockover, MD  
Woman Centered  
Phoenix, AZ

Kelli Kessell  
Never Sugar Coated  
Grand Junction, CO

Aanchal Arora, FNU, PT, MHS, MBA  
MIT  
Cambridge, MA

Oriana Papin-Zoghbi  
AOA Dx, Inc  
Denver, CO & New York, NY

Sarah Nicholson  
Babyscripts  
Washington, DC

Tracy Warren  
Venture investor  
Langhorne, PA

Samantha Rogers  
California State University East Bay  
Hayward, CA

Hannah Mamuszka, MS  
Alva10  
Lexington, MA

Maria Sophocles, MD, FACOG, IF, NCMP  
The Honey Pot  
Princeton, NJ

Kristin Morris  
Breast Cancer Survivor  
Plymouth, MN

Annette Pompa  
International Heart Spasms Alliance  
Lehigh Valley, PA

Tara Joiner MPT  
The Female Edit  
Park City, UT

Allison London Brown  
EllaVita Solutions  
Raleigh, NC

Dana Sun, MBA  
Venture capitalist  
Chicago, IL

Christa Kast  
Consultant  
Philadelphia, PA

Emily Rymland DNP FNP-C  
Tia  
Los Angeles, CA

Amanda Burkardt Burkardt, MBA  
PHIOGEN  
Houston, TX

Silvia Damen, MBA  
Women's Health Advocate  
San Francisco, CA

Madeline Hinkamp, MBA/MPP  
Consultant  
Chicago, IL

Nicole Shugrue MBA  
Rejoni  
Bedford, MA

Elizabeth Knipp  
Memorial Sloan Kettering Cancer Center  
Brooklyn, NY

Lebone Moses  
Consultant  
Durham, NC

Theresa Patton  
TT Patton Consulting  
Oakland, CA

Laly Havern  
Pharmacist  
Schertz, TX

Melissa Lawlor, MSN, CNM, FNP-C  
Robin's Nest Midwifery  
Pleasant Valley, NY

Carrie Haverty, MS, CGC  
Genetic Counselor  
San Francisco, CA

Madeleine Livingston, MBA  
Healthcare Startups  
New York, NY

Melissa Bowley  
Flourish Care  
Newport, RI

Colby Holtshouse  
Organon LLC  
Mountain View, CA

Laura Okafor Crain  
Perry  
New York, NY

Ivana Magovcevic-Liebisch, PhD, JD  
Vigil Neuroscience  
Watertown, MA

Jami Crist  
Consultant – LERA  
Baltimore, MD

Emily Becker, MS  
OnemataDC  
Arvada, CO



Janet Hardy, PhD, MSc  
Consultant in medication safety in pregnancy  
Richford, VT

Kristen O'Neill, PhD  
Outlier AI  
Cranston, RI

Ariel Watson  
Red Tent PMDD  
San Francisco, CA

Kara Connell  
My Perimeno-Posse  
Arlington, VA

Naseem Sayani, MBA  
How Women Invest, Venture Capitalist  
Los Angeles, CA

Marissa Fayer, MBA  
HERhealthEQ  
New Rochelle, NY

Susan Willig, MBA  
TrueNorth  
Laguna Beach, CA

Susan Vogler, DO, FACOG, MSCP  
Women's Health Expert and Advocate  
Boston, MA

Stephanie Denis, PTA  
PTA  
Brooklyn, NY

Allison Lewin  
Menowar  
San Francisco, CA

Christine Brennan, PhD  
Vertex Ventures HC  
Cambridge, MA

Stefanie Judd-Lee  
Manager, Regulatory Affairs  
Third Lake, IL

Lynette Kozuma  
MedtechWOMEN  
San Francisco, CA

Jane Varian, NP  
FOUNDATION MEDICINE  
Saratoga Springs, NY

Clare Dougherty  
Brem Foundation to Defeat Breast Cancer  
Silver Spring, MD

Stephanie Collins, RN, BSN, BCPA  
Eido Bio  
Dallas, TX

Maura Rosenfeld  
DermAb.io  
Pittsburgh, PA

Sarah Higgins Cheng, DNP, APRN, WHNP-BC  
Nurse practitioner  
Tampa, FL

Ricky Cordova  
Harvard Business School  
Cambridge, MA

Rhea Choudhury, MBA  
Clinical Strategy Leader  
Los Angeles, CA

Ellen Rudolph  
WellTheory  
San Francisco, CA

Vicky RT, RDMS, RVT  
iSonoHealth  
Beaver Falls, PA

Kristin Wagner  
Juniper Biomedical  
Worcester, MA

Pearl Huang PhD  
Dunad Therapeutics  
Boston, MA

Karen Cohn, PhD  
Consultant  
New York, NY

Jennifer Boerer  
Mother  
Glenmoore, PA

Neda Razavi, MBA  
CEO, iSono Health  
Menlo Park, CA

Catherine Sabatos-Peyton, PhD  
CEO, Larkspur Biosciences  
Cambridge, MA

Liza Kunz, MD  
Physician  
Sunnyvale, CA

Dana Consultant  
D. DeSanto Consulting  
New York, NY

Courtney Wagner, INHC  
The Morning Pause  
Atlanta, GA

Anne Bray  
ex-Google  
Concord, MA

Paula Amato  
OHSU  
Portland, OR

Sabrina Johnson  
Daré Bioscience, Inc  
San Diego, CA

Brittany Biggett-Heeren, RHIA, CHTS-IM  
Prismatic Venus Fitness  
Orlando, FL

Robin Austin, PhD, DNP, RN, FAAN  
University of Minnesota School of Nursing  
Minneapolis, MN

Livia Han  
Compass  
San Francisco, CA

Jodi Neuhauser  
In Women's Health  
Charlottesville, VA

Joyce Lee  
Harvard University  
Boston, MA

Karie Knightly, BS  
Health Advocate  
Annapolis, MD

Katie Pescatello, RN, MSN, FNP-C  
KP Healthwriter  
Arlington, MA

Brandi Combs  
Entrepreneur - Health Coach  
Kyle, TX

Peter Nguyen  
PRO-spectus  
San Diego, CA

Danielle Ralic  
Ancora.ai  
Boston, MA

Magdalene Moran, PhD  
Executive  
Watertown, MA

Shadi Saberi, PhD.  
iSono Health, Inc.  
South San Francisco, CA

Patricia Silveyra PhD  
Scientist  
Bloomington, IN

Nicole Torrillo-Smith  
Advertising  
Port Washington, NY

Maryon Stewart BEM  
Femmar Health Inc  
Hollywood, FL

Sheena Franklin  
K'ept Health  
Washington, DC

Nick Svencer  
Rejoni  
Bedford, MA

Carlene Esposito  
Antodote  
East Greenwich, RI

Katherine Palmer, MPH  
Science Communicator  
Frederick, MD

Kara DeMaio  
Aqua Fem, LLC  
Charleston, SC

Cydnee DeToy, MBA  
Cydnee DeToy Coaching  
New York, NY

Krista Petrosoff  
Teacher  
Highland, NY

Sabra Klein Ph.D  
Johns Hopkins University  
Baltimore, MD

Michelle Wu, MSCEP  
Wu Consulting, LLC  
Cranston, RI

Melissa DeYoung  
Abbie  
Pontiac, IL

Karen Kariv  
K Squared Consulting  
Brookline, MA

Kelly Gonda  
Nurse practitioner  
Superior, CO

Rachel Butler  
Catalytic Impact Foundation  
Hingham, MA

Tracy Bale, PhD  
Neuroscientist  
Denver, CO

Simal Ozen Irmak, PhD, MPH  
Tibi Health  
San Francisco, CA

Amanda Chen, MPhil, PhD  
Vertex Ventures HC  
Cambridge, MA

Margaret Melville MBA  
Lasa Health  
Boulder, CO

Iris Kim  
NBC News  
Los Angeles, CA

Helen Shik  
Shik Communications LLC  
Sudbury, MA

Elridge Proctor, MPA  
GO2 for Lung Cancer  
Washington, DC

Sharon Perelman  
University of Pittsburgh  
Pittsburgh, PA

Sateria Venable  
Fibroid Foundation  
Rockville, MD

Stephanie Bussen, MS MBA  
Clinical Researcher  
San Marcos, CA

Christine Neipert, PhD, JD  
Consultant  
Miami, FL

Samina Bari  
Samina Bari Advisors  
Hayward Hills, CA

Sheryl Silverman  
Consultant  
Pittsburgh, PA

Lydia Acuña  
Founder & CEO at Diagnoza and Åsna Consulting  
Pasadena, CA

Colleen Meehan  
Creative Director, Publicis Groupe  
New York, NY

Jill Liss MD  
Physician  
Denver, CO

Susie Turkson, Ph.D.  
Virginia Commonwealth University  
Richmond, VA

Marcie Caplan  
Retired  
Lakewood Ranch, FL

Paula Soteropoulos, MSChE  
Ensoma, 5AM Ventures  
Boston, MA

Ana Moreno, PhD  
Navega Therapeutics  
San Diego, CA

Erin Patinkin  
MIT  
Somerville, MA

Kendra Broussard, DNP  
KMG-Thirty Madison  
New York, NY

Jenneh Rische, BSN, RN  
The Endometriosis Coalition  
Philadelphia, PA

Cathleen Dohrn, PhD  
The Chrysalis Initiative & HerHealthX  
Libertyville, IL

Rosana Kapeller, M.D., Ph.D.  
ROME Therapeutics  
Boston, MA

Martha Kirk, PA-C  
Physician Assistant  
Burlington, VT

Angie You  
Architect Therapeutics  
San Diego, CA

Shehnaaz Suliman  
Recode  
Burlingame, CA

Kathleen Lemaitre, MD, FACOG  
Premier Research  
Weston, MA

Maria Soloveychik  
SyntheX  
San Francisco, CA

Alise Reicin MD  
Tectonic Therapeutic  
Watertown, MA

Hong Wan  
Tallac Therapeutics  
Burlingame, CA

Joanne Kotz, PhD  
Former CEO, Jnana Therapeutics  
Boston, MA

Loreanne Jacob  
Passionista Collective, LLC  
Wilmington, NC

JeenJoo Sophia Kang, PhD  
Appia Bio  
Culver City, CA

Angelique Hopkins, PhD, MPH  
Pharma  
Mount Laurel, NJ

Bridgette Blazek MD  
Celerion  
Phoenix, AZ

Sheila Gujrathi  
Physician  
San Diego, CA

Susan Seletz  
Caregiver  
Pittsburgh, PA

Katherine Vega Stultz  
Board member and advisor  
Burlingame, CA

Rhonda Horvitz, RDH  
Dental Hygienist  
Pittsburgh, PA

Autumn Ehnou  
Medicines360  
San Francisco, CA

Jennifer Arnold  
Engineer and current MBA student  
Cambridge, MA

Dominique Verhelle, PhD, MBA  
NextRNA Therapeutics  
Boston, MA

Monica Hahn  
Owner of Elements Massage Walnut Creek  
Walnut Creek, CA

Sarah Boyce  
Avidity Bio  
San Diego, CA

Amar Sawhney, PhD  
Rejoni, Inc.  
Lexington, MA

Lynn Banaszak  
The Caileigh Lynn McDowell Foundation  
Pittsburgh, PA

Vickery Prongay, MPA  
Research Consultant  
Seattle, WA

Julia Owens  
Verto Therapeutics  
Boston, MA

Daisy Robinton, PhD  
Consultant  
Los Angeles, CA

Abigail Jenkins  
Aquestive  
Melbourne Beach, FL

Callae Snively, MS  
Thyme Care  
Riverside, CT

Barbara Woods  
Educator  
New York, NY

Rekha Hemrajani  
Biotech Board Member  
Burlingame, CA

Aldona Spiegel, MD  
Surgeon  
Houston, TX

Deb Geraghty, PhD  
Anokion  
Cambridge, MA

Audrey Jones  
Houston Methodist Hospital  
Houston, MA

Burton Carbino IV MS  
Clinical Scientist  
Philadelphia, PA

Hillary Boswell MD  
Complete Midlife Wellness Center  
Houston, TX

Kelly Beck  
Trench Therapeutics  
Romansville, PA

Rebecca Smith, CADC  
Consultant  
Wyoming, PA

Tao Wen  
CMO  
New York, NY

Sara Dean, DNP, APRN, WHNP-BC  
Clinician  
Houston, TX

Helen Jonsen  
Journalist  
Hudson, NY

Jade Curtis  
Blackdoctor.org  
Atlanta, GA

Leena Das-Young, Pharm.D.  
Caliber Biosciences  
New York, NY

Tanya Herzog, DVM, DCLAM  
Houston Methodist Research Institute  
Houston, TX

Amanda Skerski  
Woman  
Los Angeles, CA

Wendye Robbins  
Incendia Therapeutics, Inc.  
Boston, MA

Jodi Andrews  
ProTrials Research, Inc.  
Los Gatos, CA

Bunny Ellerin, MBA  
Founder  
Brooklyn, NY

Elridge Proctor, MPA  
GO2 for Lung Cancer  
Washington, DC

Kira Navarre  
Self  
Santa Monica, CA

Lyn Baranowski  
Avalyn Pharma  
Cambridge, MA

Erika Smith, MBA  
CEO, EpiTET Therapeutics  
New Haven, CT

Amy Millman  
Stagenext llc  
Bethesda, MD

Wendy Davis  
GestVision, Inc  
Guildford, CT

Santosh Pandipati, MD, FACOG  
Lōvu Health  
Los Gatos, CA

Yelena Wetherill, PhD  
CEO, Angara Bio  
Boston, MA

Jill Davis  
Pharmaceutical  
Guilford, CT

Omolade Alawode, MSc, CHES  
Public health educator  
Columbia, MD

Lisa Lechner  
FemmeBright Health  
New York, NY

Marianne Slight  
Society for Women's Health Research  
Cambridge, MA

Susan Solinsky  
Healthcare innovator, investor, and board member  
San Francisco, CA

Katir Severt MBA  
Let's Talk Wimen  
Minneapolis, MN

Sheena Aurora MD  
Physician  
Palo Alto, CA

Teonna Woolford  
Sickle Cell Reproductive Health Education Directive  
Owings Mills, MD

Sandra Dunn  
Business  
San Diego, CA

Andrea Moreira  
Physician  
Pittsburgh, PA

Christina Young  
Rejoni, Inc  
Woburn, MA

Julie Wood  
Consultant  
El Sobrante, CA

Corinne Gardner, MSN, CEO and Investor  
Investor, clinician  
Charlottesville, VA

Rachel Braun Scherl, MBA  
SPARK Solutions for Growth  
West Orange, NJ

Heather Pitorak, MPH  
Public health professional  
Seattle, WA

Zuri Hawkins-Jarrett, PharmD, MPH  
Pharmacy Consultant  
Smyrna, GA

Natalie Herzog  
Real Estate  
Houston, TX

Serene Issa  
Author  
New York, NY

Meilin Zhu  
MIT/Harvard  
Cambridge, MA

Emily Serebryany  
Institute FLE  
Los Angeles, CA

Margaret Jackson, D.Phil.  
BYOMass Inc.  
Boston, MA

Emily Stein  
Gaia  
New York, NY

John Stallone, PhD  
Biomedical Research Scientist, University Professor  
Hempstead, TX

Lena Rice  
The Health Management Academy  
Washington, DC

Samantha Tanner, RN  
Nurse  
Jackson, WI

Debbie Garner, MBA  
FEMSelect Inc.  
San Francisco, CA

Ana Radeljevic  
Adventus Partners  
Cambridge, MA

Jessica Foley, PhD  
Focused Ultrasound Foundation  
Bethesda, MD

Valerie Toler, RN  
Pharmacovigilance Consultant, Registered Nurse  
Oakland, CA

Carolyn Kay  
OB/GYN Physician  
Seattle, WA

Rizwana Fareeduddin, MD, MBA  
Physician  
Orlando, FL

Tammy Mahaney, DNP-FNP  
Bella Primary Care  
Lafayette, CA

Brenna Finegan, MPH Candidate 2025  
University of Connecticut  
Hartford, CT

Michelle Agudelo  
Haus of Flow LLC  
San Francisco, CA

Geri Stengel  
Ventureneer  
New York, NY

Marisa Guajardo  
Student researcher  
Charlottesville, VA

Carolyn Moor  
Widow Advocate  
Winter Park, FL

Natalie Shew  
EmployWell  
Fayetteville, AR

Adedayo Adeniyi Adeniyi  
GO2 for Lung Cancer  
Washington, DC

Yousef Tanas, MD  
Postdoctoral Fellow at Houston Methodist Hospital  
Houston, TX

Gregg Klang  
Cern Corporation, Inc.  
Coto de Caza, CA

Amanda Pick  
Mayne Pharma  
Raleigh, NC

Kathryn Zamiela  
Pre-Medicine student at Northwestern University  
Chicago, IL

Jessica Kirkland Caldwell, PhD  
Cleveland Clinic  
Las Vegas, NV

Maura Gildea, MPH  
Public Health Professional  
Washington, DC

Andre Conner  
Consultant  
Cary, NC

Bhuchitra Singh, MD, MPH, MS, MBA  
Research Physician  
Baltimore, MD

Margaret Karow  
Karow Consulting  
Gainesville, FL

Nicole Stockenberger, PMP  
Consultant  
Houston, TX

Allison O'Brien  
LERA Health  
Baltimore, MD



Morgan Collier  
Women in Medicine  
Chicago, IL

Kim Ledgerwood  
HealthyWomen  
Towson, MD

Stella Goulopoulou, PhD  
Loma Linda University  
Loma Linda, CA

Jennifer Realo  
LERA Health  
Denver, CO

Morgan Stanton, PhD  
Opal Therapeutics  
San Francisco, CA

Jessica Bradshaw, PhD  
UNTHSC  
Fort Worth, TX

Sandra Butler, MPH  
Mass General Brigham  
Boston, MA

Emily Post  
Research Assistant  
Las Vegas, NV

Maria Cardenas, MD  
Endeavor Health  
Chicago, IL

Carolyn Witte  
Founding CEO, Tia  
San Francisco, CA

Zack Lyon  
H3Pelvic Therapy Systems  
Lewisville, NC

Roxana Belciu-Kerns  
Amarastesia  
West Palm Beach, FL

Shannon Topinka, MBA  
The Collaborative Strategists  
Los Angeles, CA

Sheridan Orison, CNA  
Prime Healthcare  
Las Vegas, NV

Lauren Gage  
Triplemoon  
Dallas, TX

Michelle Oyen, PhD  
Professor  
Detroit, MI

Eris Hanson  
GenWell  
Washington, DC

Sara Brown  
Prevent Blindness  
Chicago, IL

Anish Sebastian  
Babyscripts  
New York, NY

Annie Scolamieri, MHA  
Healthcare Consultant, Asymmetry Group, LLC  
Boston, MA

Lindsey MBA  
Consultant  
Denver, CO

Elizabeth Vaysman, Esq.  
ConceiveAbilities  
Philadelphia, PA

Natalia Pozuelo, MS  
Kent State University  
Cleveland, OH

Kristen Schultz, MBA, MPP  
Woodland Strategic Advisors  
Chicago, IL

Taylor Janvrin  
Consultant  
New York, NY

Kenny George, PhD  
AcreTrader  
Fayetteville, AR

Molly Bachmann PT, DPT, Birth Doula  
University of Michigan  
Ann Arbor, MI

Catherine Stehman-Breen MD  
Physician  
Boston, MA

Omonseigho Talton, PhD  
University of Detroit Mercy  
Detroit, MI

Contessa Ricci, PhD  
Washington State University  
Seattle, WA

Melisa Oliva  
Jackson Health System  
Miami, FL

Denise Paleothodoros  
Citrine Minds  
Orland Park, IL

Lauren Coates, MA  
Healthcare business leader  
Lakewood, CO

Laura Elliott  
Maryland Institute College of Art  
Owings Mills, MD

Sara Della Ripa, M.S., M.S.  
ArcHealth Foundation  
Los Angeles, CA

Courtney Carter, MSN, APRN, FNP-C  
Nurse Practitioner  
Dallas, TX

Chris Helms  
Mamaya Health  
Nashville, TN

Somna Pati MS  
Rosy Wellness  
New York, NY

Whitney Stout  
athenahealth  
Princeton, TX

Rachel Gelman, DPT  
RMG Physical Therapy Inc  
San Francisco, CA

Julia Rozman, ACRP-CP  
Senior Consultant/SME  
Miami, FL

Maria Pienaar  
Advocate  
San Francisco, CA

Thomas de Vlaam  
Pillar VC  
Boston, MA

Kate Hermans  
Board Chair, Clue  
Wayne, PA

Deborah Denis, MPA.  
Policy Analyst. NYU.  
Brooklyn, NY

Marissa Reeder  
Unified Women's Healthcare  
Massapequa, NY

Deirdre O'Connor  
Gibson Sotheby's International Realty  
Newton, MA

Heather Pierce  
Homeward Health  
Flagstaff, AZ

Kate Liebelt  
Springboard Enterprises  
Chicago, IL

Jennifer Henius, LCSW  
Caregiver Whole Health  
Palm Harbor, FL

Emily Kraus, MD  
Stanford physician and researcher  
Portola Valley, CA

Jenny LaCross, PT, DPT, PhD, ATC  
Physical Therapist, MOVE Physical Therapy  
Ypsilanti, MI

Ketki Karanam, PhD  
investor  
Boston, MA

Pamela Price, RN, BS  
The Balm In Gilead, Inc.  
Richmond, VA

Christine O'Brien, PhD  
Armor Medical Inc  
Saint Louis, MO

Cherando Dubose, MPH  
Advocate  
Charlotte, NC

Alissa Erogbogbo, MD FACOG  
Physician  
Los Altos, CA

Katie Thurer, MD  
Gynecologist  
Chicago, IL

Kedra Priest  
Counselor  
Austin, TX

Summer Owen  
Peach Tree Healthcare  
Sacramento, CA

Ingrid Harm-Ernandes PT, WCS  
Physical Therapist, National Presenter, Author  
Efland, NC

Shannon Chapman, Esq.  
Fulton Jeang, PLLC  
Austin, TX

Munira Ahmed  
Consultant, NY-SBC  
Queens, NY

Bria Butler  
Consultant  
Cupertino, CA

Kylie Jones, MS  
UNT Health Science Center  
Fort Worth, TX

Alexandra Fennell, Esq.  
Grace  
Cambridge, MA

Juliana Kling  
Physician  
Cave Creek, AZ

Amanda Osse, PhD  
Postdoctoral Scholar  
Las Vegas, NV

Natalie Tronson  
University of Michigan  
Ann Arbor, MI

Kristen Schuh, MS  
University of Michigan  
Ann Arbor, MI

Ruth Zuniga  
Consultant  
Tacoma, WA

Sarah Browning, MA  
Matter Communications, Health Division  
Dallas, TX

Elif Arsoy  
Advocate  
Princeton, NJ

Sally Wolf, M.Ed, MBA  
LightWorks  
New York, NY

Robin Lommori, CPM  
Making Mommies  
Phoenix, AZ

Mackenzie Woock  
University of Michigan  
Ann Arbor, MI

Emily Lindblad  
AllPaths Family Building  
Hudson, MA

Heather Guidone, BCPA  
Center for Endometriosis Care  
Atlanta, GA

Katie Kirsch MM  
AsteriskDAO  
Detroit, MI

Dana DeSanto, Founder  
Consultant  
New York, NY

Dixie Swartwood  
My Density Matters  
Hawthorn Woods, IL

Nirshila Chand, DrPH, MPH  
Public Health Specialist.  
Redwood City, CA

Lyn Behnke, DNP, FNPBC, PMHNPBC, CHFNP  
Harmony Wellness Center  
Tawas City, MI

Anastasia Perez Ternent  
Billion Minds Institute  
San Francisco, CA

Jeanette Contreras, MPP  
Latina Health Collab  
Reston, VA

Caitlin Keliher  
Consultant  
Washington, DC

Sarah Sheffield, MPA  
Consultant  
Brooklyn, NY

Smita Asrani  
UE LIfeSciences  
Philadelphia, PA

Molly Martell, MSc  
Consultant  
San Francisco, CA

Pearl DCruz  
Consultant  
Mercersburg, PA

Jennifer Newell  
Betty's Co.  
San Antonio, TX

Brittany Barreto, PhD  
Femhealth Insights  
Phoenix, AZ

Leah Conrad  
University of Michigan  
Ann Arbor, MI

Ramani Varanasi, MS, MBA  
Biopharmaceutical Executive  
Boston, MA

Tint Tint Yap  
Retired Executive  
West Orange, New Jersey

Sally Oberski  
Sally Oberski Consulting  
Toledo, OH

Marianne Kaiser  
Contrary Collective  
Kansas City, MO

Jasmin Castañeda  
Student  
Los Angeles, CA

Tamara Goldschmidt MPH  
Elephant Impact  
Asheville, NC

Ashyil Kumar  
Chanel & Ether Collective  
Hayward/ Sacramento, CA

Renée Meyer, MBA, MIM  
REM Consult  
Tiffin, OH

Tracy Rode, CNE  
Patient Empowerment Network  
Nashville, TN

Charu Gupta, MD  
Physician  
Chicago, IL

Ella Murthi  
University of New England  
Bedford, NH

Jodi Smith, Esq.  
WomenHeart: National Coalition for Women with  
Heart Disease  
Washington, DC

Natasha Giordano, BSN  
Afaxys  
Sarasota, FL

Pooja Majmudar, PhD  
Consultant  
New York, NY

Ariel Kramer  
Klover Communications  
Irvine, CA

Shweta Gohil MSN,RN, MPH  
LEVY Health  
San Francisco, CA

Christina Vosbikian  
Student  
Cambridge, MA

Rachael Kim  
Femtech Salon  
Los Angeles, CA

Rachel Rakvica Sprague, MS  
Consultant  
Boston, MA

Luke Janchenko MBA  
Consultant  
New Lenox, IL

Valerie Palmieri, BS MT (ASCP), CLS  
CEO/Founder  
Monroe, CT

Sara Teppema, FSA, MAAA  
Alta Advisers  
Brookfield, IL

Missy Lavender  
Renalis Health  
Cleveland, OH

Suzie Bergman, DDS, FTMJF  
President Elect American Association of Women  
Dentists  
Vancouver, WA

Kate LeBlanc  
AllPaths Family Building  
Malden, MA

Michael MacKinnon  
CEO  
Boston, MA

Malissa Harris, M.A.  
Parent  
Columbus, OH

Leslie Ferris Yerger, MBA  
My Density Matters  
Hawthorn Woods, IL

Sarah Naumes, MA  
Columbia University  
New York, NY

Tara Kochis  
Consultant  
Herndon, VA

Chelsea Hedrick, MS, RAC  
Women's Health advocates  
Ventura, CA

Catherine Klapperich  
Boston University  
Boston, MA

Alisa Mahan-Zeitz, MBA, MA  
American Cancer Society  
Warren, OH

Bethany Haskell  
Coverys  
Columbia, MD

Carolyn Sufrin, MD, PhD  
Johns Hopkins School of Medicine  
Baltimore, MD

Lisa McDonald, MPH  
Consultant  
Larchmont, NY

Lisa-Jean Clifford  
Gestalt Diagnostics  
Spokane, WA

Christina Gomez, MPH  
IL Breast and Cervical Cancer Program  
Elgin, IL

Michael Nall  
Board Member - Clarity, PRECEDE  
Dana Point, CA

Sarah Rosen, PhD  
Scientist at WashU school of medicine  
St. Louis, MO

Ashley Lyden  
NA  
Ventura, CA

Genevieve Douglas  
Consultant  
Truckee, CA

Jen Barth  
Consultant  
Portland, OR

Brittany Mayberry  
Women's health advocates  
Bakersfield, CA

Jessica Bell van der Wal  
Frame  
San Francisco, CA

Catherine Unruh, MS  
Medical Synergy and Innovation Inc  
Reading, PA

Angela Zagorsky  
Director  
Vancouver, WA

Priyanka Jain  
Evvy  
New York, NY

Nicolette Possemato  
Aspira Womens Health  
Shelton, CT

Mia DuBose-Pettway  
Histotech  
Stratford, CT

Sunny Huang, MD, PhD  
Physician scientist  
Iowa City, IA

Bertha Alarcon, DDS  
Western University of Health Sciences, College of  
Dental Medicine  
Pomona, CA

Rachel Troy  
Consultant  
Washington, DC

Edie Greenberg  
Talent Collective  
Chicago, IL

Maddi Holman  
VC Investor  
New York City, NY

Viviana Coles, DMFT, LMFT-S, CST  
Psychotherapist at Houston Relationship Therapy  
Houston, TX

Yvonne Cherell, MPA  
Ohio Urban Community Action Network  
Columbus, Ohio

Jessica To-Alemanji, PT, DPT, PhD  
Physical Therapist  
Fairfax, VA

Laura Ibragimova MPH  
Anteros Bio  
Brooklyn, NY

Phyllis Greenberger, MSW  
Consultant HealthyWomen  
Washington, DC

Jackie Froeber  
HealthyWomen  
Henderson, NV

Nityasree Srialluri, MD, MHS, MS  
Johns Hopkins  
Baltimore, MD

Sherry Marts, Ph.D.  
Former VP for Scientific Research, SWHR (retired)  
Washington, DC

Shannon Weatherly, MS3, MA, CNA  
Medical Student, Nova Southeastern University;  
Former Consultant at Booz Allen Hamilton  
Fort Lauderdale, FL

Claire Buck  
Claire Sommers Buck LLC  
Austin, TX

Rheanna Platt, MD  
Johns Hopkins University  
Baltimore, MD

Monica McGrath, ScD  
Professor  
Baltimore, MD

Chi Chiung Grace Chen, MD MHS  
Johns Hopkins School of Medicine  
Baltimore, MD

Andrea Wirtz, PhD, MHS  
Johns Hopkins Bloomberg School of Public Health  
Baltimore, MD

Nancy Hicks  
NJH Healthcare Communications, LLC  
Washington, DC

Astha Ramaiya  
Johns Hopkins University  
Baltimore, MD

Anne Steele, MSN, RN, CPHQ  
Johns Hopkins Health System  
Baltimore, MD

Anna Lettieri, MA  
Johns Hopkins University  
Burtonsville, MD

Allison McFall, PhD  
Johns Hopkins University  
Baltimore, MD

Keri Althoff, PhD, MPH  
Johns Hopkins Bloomberg School of Public Health  
Baltimore, MD

Lydia Pecker  
Johns Hopkins University School of Medicine  
Baltimore, MD

Deva MD  
Physician  
Nashville, TN

Corrine ne Parver, Esq.  
Women Lawyers On Guard Action Network  
McLean, VA

Christine Vaccaro, DO  
Physician (retired military)  
Bethesda, MD

Michael Recht, MD, PhD, MBA  
National Bleeding Disorders Foundation  
New York, NY

Kaitlin Mann  
Boston Scientific  
Somerville, MA

Hannah Markle, ScM  
Research Scientist  
Baltimore, MD

Ariela Marshall MD  
University of Minnesota, American Medical  
Women's Association  
Minneapolis, MN

Caroline Moreau, PhD  
Professor  
Baltimore, MD

Catrina Marcell, Patient Advocate  
Catrina Marcell Consulting  
McKinney, TX

Clare Conry-Murray, Ph.D.  
Johns Hopkins University  
Merion Station, PA

Taylor Hahn, MD, FACOG, MSCP  
Physician  
Westfield, IN

Laura Ensign, PhD  
Johns Hopkins University  
Baltimore, MD

Jaime Long  
Penn State College of Medicine  
Hershey, PA

Casey Taylor  
Johns Hopkins University  
Baltimore, MD

Kathleen Keefe, Owner  
Activities To Go Inc.  
Westlake, OH

Nancy Glass, PhD, MPH, MSN, RN  
Nurse  
Baltimore, MD

Kerry Funkhouser, EdD  
Foundation for Women & Girls with Blood  
Disorders  
Montclair, NJ

Fenna Sille, PhD, MS  
Assistant Professor  
Baltimore, MD

Kenneth Mann PhD  
Professor Emeritus Biochemistry and Medicine  
University of Vermont  
Atlantic Beach, FL

Jennifer Finucane  
Advocate  
Portland, OR

Alison Sizer  
Growth Impact LLC  
Midlothian, VA

Margo Harrison MD MPH  
CEO, Wave Bye Inc; Adjoint Assistant Professor,  
University of Colorado  
Denver, CO



Jennifer Dusenbury  
Self advocate  
Clayton, NC

Kaitlin Christine  
Gabbi, Inc.  
Brooklyn, New York

Elizabeth Finucane  
Consultant  
San Francisco, CA

Sarah Horvath, MD, MSHP, FACOG  
Physician  
Hershey, Pennsylvania

Kerry Krauss, MD FACOG  
Physician, Medical Director at Natural Cycles  
Ambler, PA

Nathan Schaefer  
National Bleeding Disorders Foundation  
New York City, NY

Felicia Lane MS, MD  
Professor Obstetrics and Gynecology, University of  
California Irvine  
Newport Beach, California

Carly Crowder, MD  
UC Irvine Urogynecologist and Reconstructive  
Pelvic Surgery  
Orange, CA

Kate Meriwether, MD  
Society of Gynecologic Surgeons  
Albuquerque, NM

Cara King, DO, MS  
Surgeon  
Cleveland, OH

Ashley Palmieri  
Consultant  
Brooklyn, NY

Amy Park, MD  
Cleveland Clinic  
Cleveland, OH

Miles Murphy  
Axia Women's Health  
Philadelphia, PA

Jeanne McPhee, PhD  
UCSF  
San Francisco, CA

Dominique Borchard, PA-C  
UCI Department of OB/GYN  
Orange, CA

Krista Reagan, MD  
Physician  
Tacoma, WA

Pavitra Kotini-Shah, MD  
Physician consultant  
Chicago, IL

Mofiyin Obadina, MD  
UNC  
Chapel Hill, NC

David Rahn, MD  
Physician, Professor of Ob/Gyn  
Dallas, TX

Cathleen Dohrn, PhD  
Princeton10  
Green Oaks, IL

Suzy Leous, MPA  
American Society of Hematology  
Washington, DC

ADi Diner, PhD  
iFocus Health  
San Jose, CA

Scott Blood, RAC  
Consultant  
Stow, MA

Julie Silverstein  
Springboard 2000 Enterprises Inc  
McClean, VA

Katherine Cameron, MD MSCE MBE  
Physician  
Baltimore, MD

Claire Larson  
Magnite  
Brooklyn, NY

Filippo Cieri Psy.D. Ph.D.  
Researcher at Cleveland Clinic  
Las Vegas, NV

Bridget Richard, LISW-S  
Lamplight Counseling Services, LLC  
Strongsville, OH

Sonnet Daymont, LMFT  
Psychotherapist  
Los Angeles, CA

Rebekah Foster, MBA  
Head of Data  
New York, NY

Noelani Guaderrama, MD  
Physician  
Dana Point, CA

Laura McKain, MD, FACOG  
McKain Consulting LLC  
San Antonio, TX

Melisa Holmes, MD  
Girlogy  
Athens, GA

Zainab Wadood  
Strategist  
Jersey City, NJ

Christine Sam, PharmD  
Pfizer  
New York, NY

Shannon Wood, PhD, MSc  
Johns Hopkins Bloomberg School of Public Health  
Baltimore, MD

Robin Christenson, MPT  
Reborn Pelvic Health and Wellness  
Sandy, UT

Laura Molloy, LMSW  
Social Worker  
Arlington, VA

Andrea Conner  
Consultant  
Cary, NC

Diona Jaslow  
Consultant  
Edmonds, WA

Leslie Taylor  
Half the Sky LLC  
San Francisco, CA

Megan Loy, CMD  
Consultant  
Denver, CO

Tracey Welson-Rossman  
Journal My Health  
Fort Washington, PA

Christine Rohan  
Vasowatch Inc  
Philadelphia, PA

Guillaume Skalli  
Paloma Health  
New York, NY

Gail Feltham  
Shore Strategies Life Sciences  
Brielle, NJ

Catherine Mott  
BlueTree VC  
Pittsburgh, PA

Laura Volgenau  
Marketer  
New York, NY

Tarul Kode, PharmD  
LOUD Capital  
Sammamish, WA

Anna Bauman  
Consultant  
San Jose, CA

Sarah Khan  
Business Leader  
Alamo, CA

Susana Craig  
COO  
San Jose, CA

Nicole Danos, PhD  
Associate Professor  
University of San Diego  
San Diego, CA

Rebecca McNeilly, BSME, MBA  
Consultant  
McLean, VA

Mary Lonergan  
Mary Lonergan Art  
Oakland, CA

Kathryn Bowsher, MBA  
Act One Healthcare  
San Francisco, CA

Lynn Brusco  
Executive  
Consultant  
Irwi, PA

Leslie Cohen  
Consultant  
New York, NY

Sharon Moayeri, MD, MPH, MS  
OC Fertiltiy + OC Biogenix  
Hoag Hospital, UC Irvine Faculty  
Newport Beach, CA

*Friends Abroad:*  
Gillian Houghton  
Brooke  
London, UK

Lamia Guellif  
HÉra Care Solutions  
Anjou, QC

Agnès Arbat  
Oxolife  
Barcelona, Spain

Dr. Delaya Thampi  
TLHAI  
Bangalore, Karnataka, India

Beatrice Chemla  
Cukierman  
Raanana, Israel