MURIEL BOWSER
MAYOR

June 28, 2024

The Honorable Phil Mendelson
Chairman
Council of the District of Columbia
John A. Wilson Building
1350 Pennsylvania Avenue, NW, Suite 504
Washington, DC 20004

Dear Chairman Mendelson:

In accordance with section 2 of the Confirmation Act of 1978, effective March 3, 1979 (D.C. Law 2-142; D.C. Official Code § 1-523.01), and pursuant to section 204 of the District Columbia Health Occupations Revision Act of 1985, effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code § 3-1202.04), I am pleased to nominate the following individual:

Ms. Brandi Saunders
5th Street, NW
Washington, DC 20011
(Ward 4)

for appointment as a registered nurse licensed and practicing in the District member of the Board of Nursing, filling a vacant seat formerly held by Michelle Clausen, for the remainder of an unexpired term to end July 21, 2026.

Enclosed, you will find biographical information detailing the experience of the above-mentioned nominee, together with a proposed resolution to assist the Council during the confirmation process.

I would appreciate the Council's earliest consideration of this nomination for confirmation. Please do not hesitate to contact me, or Steven Walker, Director, Mayor's Office of Talent and Appointments, should the Council require additional information.

Sincerely,

Muriel Bowser
Mayor

Chairman Phil Mendelson
at the request of the Mayor

A PROPOSED RESOLUTION

IN THE COUNCIL OF THE DISTRICT OF COLUMBIA

To confirm the appointment of Brandi Saunders to the Board of Nursing.

RESOLVED, BY THE COUNCIL OF THE DISTRICT OF COLUMBIA, that this resolution may be cited as the "Board of Nursing Brandi Saunders Confirmation Resolution of 2024".

Sec. 2. The Council of the District of Columbia confirms the appointment of:

Ms. Brandi Saunders
5th Street, NW
Washington, DC 20011
(Ward 4)

as a registered nurse licensed and practicing in the District member of the Board of Nursing, established by section 204 of the District Columbia Health Occupations Revision Act of 1985, effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code § 3-1202.04), filling a vacant seat formerly held by Michelle Clausen, for the remainder of an unexpired term to end July 21, 2026.

Sec. 3. The Council of the District of Columbia shall transmit a copy of this resolution, upon its adoption, to the nominee and to the Office of the Mayor.

Sec. 4. This resolution shall take effect immediately.

BRANDI SAUNDERS, RN, M.S.

[redacted]

EXECUTIVE SUMMARY

An enthusiastic, purpose-driven, resourceful leader with 20 years of experience across Regulatory Affairs, Healthcare Compliance & Ethics, and Drug Safety & Pharmacovigilance built on a solid clinical foundation. Keen ability to discern and prioritize company, client, and stakeholder needs within the context of sometimes varied information or organizational resources. Seamlessly forges and sustains relationships at all levels of a broad network of multidisciplinary colleagues and industry experts. Nimble, solutions-oriented, value-centric, can-do attitude, team player. Agile mindset to adjust as needed to meet changing circumstances, shifting needs and interests. Harmonizes, engages, and motivates cross functional teams and stakeholders to deliver compliant and commercially viable solutions. Therapeutic Area experience in Immunology, Ophthalmology, Neurology (CNS), Dermatology, Rheumatology, Gastroenterology, Oncology, Rare Disease, Regenerative and General Medicine.

AREAS OF EXPERTISE

- Risk Mitigation
- Collaborative Strategist
- Persuasive Communicator
- Competitor and Market Analysis
- Business Process Improvement
- Polished Interpersonal and Diplomacy Skills
- Client and Stakeholder Engagement
- Impeccable Judgment
- Team Leadership
- Regulatory Promotion Strategy
- Cultural Competence
- Regulatory Compliance
- Meticulous Attention to Detail
- Product Claim Substantiation

PROFESSIONAL EXPERIENCE

Opus Regulatory | Cambridge, MA **06/2021-Present**

Principal Consultant, US and Global Regulatory Affairs, Promotional Compliance and Strategy

Client therapeutic areas: Oncology (solid tumor), Rare Disease, Immunology, Covid-19 Vaccines, Regenerative Medicine

- Provides commercial regulatory strategy, leadership and operational oversight to enable clients to meet their commercial needs in a compliant manner.
- Closely collaborate with chief compliance officers to develop, revise and train clients on SOPs relevant to both the commercial and medical affairs organizations within the company.
- Closely collaborate with labeling leads and sit on Global labeling committees to ensure label text can support the commercial business objectives and targets.
- Provides strategic regulatory guidance on corporate communications and appropriate pre-approval communications.
- Provides regulatory review of promotional materials, disease education content, new campaigns and launch strategies for assigned products in various therapeutic areas.
- Assists clients with assessment and development of existing advertising and promotion related processes and procedures.
- In-depth knowledge of regulatory requirements associated with US advertising and promotion.
- Evaluates competing perspectives and provides pertinent commercial regulatory guidance.
- Regulatory liaison to OPDP and APLB for US based clients.
- Liaise with local marketing authorization holders in Australia, New Zealand, Singapore and Israel on promotional materials to ensure commercial messages are aligned with local labels/prescribing information and approved publications.
- Facilitates cross-functional and team awareness and understanding of regulatory landscape issues.
- Provides regulatory advice, risk assessment and mitigation strategies to commercial teams, medical affairs, public affairs, market access and other internal groups, on all promotional materials, strategies, concepts, and disease awareness for various therapeutic areas.
- Apply clinical development knowledge in conjunction with health authority regulations and guidance documents to support development of promotional product messages based on the target product profile and target product claims.
- Work directly with advertising agencies and 3rd party publishers for submissions to FDA OPDP, ex-US health authorities and industry organizations.
- Lead and/or assist in interactions with OPDP as well as build and maintain effective relationships with OPDP reviewers on promotional matters.

AbbVie, Inc. | Chicago, IL **05/2014 – 06/2021**

Director, Global Regulatory Affairs, Promotional Compliance and Strategy

- Led the global (ex-US) regulatory promotional strategy for the HUMIRA Franchise, as well as multiple Immunology pipeline compounds ensuring compliance with health authority regulations and company policies.
- Provided critical support and strategic guidance to affiliates across all markets outside of the US on a multitude of topics regarding pipeline and on-market products such as promotional labeling claim substantiation.
- Collaborated extensively with critical internal functions including global/area/affiliate commercial, market access, legal, compliance, medical/public/regulatory affairs on strategic imperatives, opportunities, and other focused activities.
- Contributed to the planning of long-term Global Brand Team strategies, Immunology pipeline and marketed products as well as Global Product Team tactics for the areas of WEC, EEMEA, LATAM, and JAPAC.
- Maintained in-depth knowledge of global codes of practice, regulations, and guidelines that impact the business at an international level.
- Coordinated and collaborated with affiliate regulatory and medical colleagues to conceptualize and implement brand plans, commercial roadmaps, innovative campaigns, and congress plans, guaranteeing feedback obtained is disseminated to global marketing leadership in a timely manner.
- Trained, onboarded, and supervised contractors hired to support increasing workloads and demands ensuring minimal to no disruptions to the business.
- Regulatory Advisory Employee Group (REAG) functional lead responsible for representing colleagues' concerns and insights to senior leaders along with spearheading solutions to improve transparency and morale.
- Participated as an integral member of the Regulatory Advertising and Promotional leadership team, representing the Immunology franchise's priorities, areas of focus and issues.
- Coordinated and leads monthly agenda driven immunology functional team meetings.
- Provided critical analysis and interpretation of the regulatory position of various ex-US health authorities that inform future company messaging and communications with highly visible pharmaceutical content having political, financial, and legal interests.
- Coordinated and led collaboration with Latin American area colleagues in regulatory affairs, medical affairs, compliance, and legal matters pertaining to commercial activities.
- Served as member of the AbbVie Regulatory Affairs Diversity, Equity, Equality & Inclusion Council and the Diversity in Clinical Trials and Recruitment team for AbbVie's aesthetic franchise.

Forest Laboratories Inc. | Jersey City, NJ **05/2012 – 05/2014**

Associate Director, US Regulatory Affairs, Promotional Compliance and Strategy

- Delivered strategic regulatory guidance on promotional and educational content for the Central Nervous System (CNS) franchise, ensuring external communications complied with corporate policies and federal regulations.
- Advised product development teams on advertising and promotional strategies; consulted brand teams/broader regulatory teams on the creation of new product labeling and revisions across all marketed product labeling.
- Formulated and executed product promotion best practices, business practices and Standard Operating Procedures (SOPs), guaranteeing consistency across company brands.
- Facilitated and led training to sales and marketing team, medical and fellow reviewers on industry trends, enforcement reviews, Bad Ad program, proactive vs. reactive communications, and pre-approval communications.

Bausch & Lomb | Madison, NJ **05/2011 – 05/2012**

Senior Manager, US Regulatory Affairs, Promotional Compliance and Strategy

- Analyzed prescription and generic pharmaceutical advertising and promotional materials to ensure alignment with corporate policies and regulatory requirements.
- Positively represented the company to regulatory authorities on all pharmaceutical promotional and advertising matters.
- Delivered strategic regulatory guidance in advance of market research testing of key messages, new campaigns, launch readiness, and NDA (new drug application) submissions.
- Cultivated long-term relationships with reviewers; monitored correspondence and advised the company on the business impact. Prepared product launch packages for submission to FDA for advisory comments.
- Led training on regulatory requirements to guide sales and marketing teams in designing compliant product promotional materials.

- Designed a comprehensive review process and analyzed existing promotional and disease education materials relative to pending Merger & Acquisition (M&A) deals.

Amgen | Thousand Oaks, CA **02/2005 –05/2011**

Senior Manager, Healthcare Compliance and Business Ethics

- Served as the compliance business partner to assigned business units and contributed to the development of a best-in-class compliance organization to support commercial therapeutic area business planning.
- Identified compliance risks and co-developed plans to mitigate potential areas of compliance vulnerability.
- Managed the compliance hotline and provided counseling on compliance questions, concerns, or issues to commercial and sales team colleagues.
- Reviewed, revised, and enhanced healthcare compliance policies, procedures, templates, forms, and other controlled documents.
- Supported client interactions with healthcare operations to improve operational efficiency.
- Liaised with cross-functional departments including HR, compliance investigations, compliance monitoring, and compliance audit to implement identified corrective actions.
- Co-developed and led customized compliance training, materials and job aids to business units and external vendors; incorporated training feedback to enhance policies and training. Trained field staff on corporate code of conduct.
- Trained 500+ sales and marketing professionals on SOPs, contributing to the successful launch of new assets.
- Led compliance discussions with commercial leadership to encourage engagement, while infusing compliance into business activities focused on interactions with healthcare professionals.
- Provided an expert-level compliance perspective in the review of marketing materials and activities during Material & Approval Compliance meetings.
- Trained field staff on the corporate Code of Conduct and compliance policies.
- Assisted with monitoring activities and provided training to new monitors.

Senior Manager, US Regulatory Affairs, Commercial Strategy and Compliance
Manager, Drug Safety and Pharmacovigilance

CLINICAL EXPERIENCE

University of Southern California Medical Center | **Clinical Research Nurse** **10/2004-12/2007**
University of California, San Francisco Medical Center | **Clinical Research Nurse** **9/2002-7/2004**
University of California, Los Angeles Medical Center | **Post-Surgical Travel Nurse** **2/2002-9/2002**
National Institutes of Health (NIH) | **Clinical Research Nurse** **4/2000-1/2002**

EDUCATION AND CREDENTIALS

Master of Science | *Clinical Research Management* | University of California, San Francisco | SF, CA **8/2002-6/2004**
Bachelor of Science | *Nursing* | Hampton University | Hampton, VA **8/1995-6/1999**

Certifications and Affiliations

- Registered Nurse (RN) licensure | Certified Compliance and Ethics Professional (CCEP), Society of Corporate Compliance & Ethics (SCCE), 2010 | Drug Information Association (DIA) | Regulatory Affairs Professional Society (RAPS) | American Nurses Association (ANA) | Health Care Compliance Association (HCCA) |

Executive Office of the Mayor – Mayor's Office of Talent and Appointments
John A. Wilson Building | 1350 Pennsylvania Avenue, Suite 600 | Washington, DC 20004

Brandi Saunders

Ms. Brandi Saunders is a seasoned Registered Nurse (RN) and brings a wealth of experience and passion to the healthcare landscape. She embodies purpose driven leadership making her an invaluable asset to any healthcare team. Ms. Saunders journey began at the National Institutes of Health, where she mastered medical-surgical care and clinical research nursing before taking on opportunities as a travel nurse. Her solid clinical foundation ensures patient-centered decision-making.

After years of direct patient care, Ms. Saunders transitioned to the BioPharma industry. Her roles in Global Safety/Pharmacovigilance, Healthcare Compliance, and Global Regulatory Affairs demonstrate her commitment to patient safety and industry excellence. Ms. Saunders agile mindset allows her to adapt seamlessly to changing circumstances. She easily forges strong relationships with multidisciplinary colleagues and industry experts, ensuring collaborative success. Ms. Saunders's therapeutic expertise spans Immunology, Aesthetics, Ophthalmology, Neurology, Dermatology, Oncology, Rare diseases, Rheumatology and more. Her solutions-oriented approach delivers compliant and commercially viable outcomes. When not shaping healthcare, Ms. Saunders enjoys exploring the world through travel and food.

A Ward 4 resident, Ms. Brandi Saunders earned her Bachelor of Science in Nursing from Hampton University and Master of Science of Clinical Research Management from the University of California.

GOVERNMENT OF THE DISTRICT OF COLUMBIA
Executive Office of Mayor Muriel Bowser

Office of the General Counsel to the Mayor

To: Tomas Talamante, Steve Walker
From: Betsy Cavendish
Date: June 4, 2024
Subject: Legal sufficiency review of Resolutions nominating Enrique (Rick) Garcia, Patricia Howard-Chittams, Laverne Plater, Tiffany Simons, Anne Ford, and Brandi Saunders as members of the Board of Nursing

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This is to Certify that this office has reviewed the above-referenced resolutions and found them to be legally unobjectionable. If you have any questions in this regard, please do not hesitate to call Erika Satterlee, Deputy General Counsel, Executive Office of the Mayor, at 202-724-1303, or me at 202-724-7681.

Elizabeth A. Cavendish

Elizabeth A. (Betsy) Cavendish