



August 13, 2024

Lauren Roth, J.D.
Associate Commissioner for Policy
Office of Policy
FDA White Oak Campus
19903 New Hampshire Avenue Building 32, Room 4239
Silver Spring, MD 20993

RE: Listening Session: Optimizing the Food and Drug Administration's Use of and Processes for Advisory Committees; Public Meeting; Request for Comments. [Docket No. FDA-2024-N-1809]

Dear Ms. Roth:

On behalf of the 49 undersigned organizations representing the Nursing Community Coalition (NCC), we appreciate the opportunity to comment on the Food and Drug Administration's (FDA's) use and processes for advisory committees. The NCC is a cross section of education, practice, research, and regulation within the nursing profession representing Registered Nurses (RNs), Advanced Practice Registered Nurses (APRNs),¹ nurse leaders, boards of nursing, students, faculty, and researchers. Having a broad range of input at the federal level, from all aspects of the health care community, including nursing, is imperative. As such, the NCC has a vested interest in ensuring nurses are among those represented within federal advisory committees, taskforces, and councils. As you work to optimize your committees' processes, we encourage the FDA to consider the following recommendation:

Composition of Advisory Committees: Ensure Nurses are Included on FDA Committees

As the largest segment of the health care profession,² nursing is involved at every point of care. From serving rural, urban, and underserved areas to being on the frontlines of public health challenges and leading the way to ensure today's science translates to tomorrow's cures, having the nursing lens represented on any FDA advisory committee is essential. Currently, RNs and APRNs, with the expertise and qualifications required, are underrepresented on federal advisory committees. While we appreciate those who serve on these federal committees, having diverse viewpoints and skill sets provides vital information for these discussions that directly impact patient's lives. We see this firsthand as nurses are serving on Medicare Payment Advisory

¹ APRNs include certified nurse-midwives (CNMs), certified registered nurse anesthetists (CRNAs), clinical nurse specialists (CNSs) and nurse practitioners (NPs).

² Smith, Sean and Blank, Andrew. U.S. Bureau of Labor Statistics. (June 2023) Healthcare Occupations: Characteristics of the Employed. Slide Two: Employment in the 25 largest healthcare occupations, 2022. Retrieved from: <https://www.bls.gov/spotlight/2023/healthcare-occupations-in-2022/>

Commission (MedPAC),³ National Institute for Occupational Safety and Health (NIOSH),⁴ Patient-Centered Outcomes Research Institute (PCORI)⁵, as Co-Chair of the Physician Focused Payment Model Technical Advisory Committee (PTAC)⁶, and on the National Advisory Council for Healthcare Research and Quality.⁷

As outlined in the Federal Advisory Committee Act (FACA), these types of committees must be “fairly balanced in terms of the points of view represented and the functions to be performed.”⁸ Further, “the legislative history makes clear, the ‘fairly balanced’ requirement was designed to ensure that persons or groups directly affected by the work of a particular advisory committee would have some representation on the committee.”⁹ The General Services Administration (GSA) recently clarified their procedures to ensure a balanced approach and includes, “requiring an agency to provide the Secretariat with an MBP that addresses how the agency will ensure representation of all points of view required for fairly balanced committee membership—including groups and entities potentially affected, those with relevant lived experience, and persons with demonstrated professional or personal qualifications—as well as how the agency intends to conduct broad outreach to ensure that the call for nominees reaches the interested parties and stakeholder groups likely to possess those points of view.”¹⁰

We appreciate FDA’s inclusion of nurses on committees such as Anesthetic and Analgesic Drug Products Advisory Committee¹¹ and in past roles on the Obstetrics, Reproductive and Urologic Drugs Advisory Committee.¹² There are even more opportunities within FDA’s committees and panels for nurses’ professional expertise to be utilized. Therefore, the NCC strongly recommends that the FDA amend its FACA Membership Balance Plans (MBP) to hold each health-related federal committee responsible for ensuring that appointed members proportionately reflect the diverse representation of the health care workforce.

The NCC appreciates your consideration of these recommendations as the FDA works to ensure that these advisory committees include the full breadth of professional experience and expertise, including members of our nursing workforce. Should you have any questions or if the Nursing Community Coalition can be of any additional assistance please contact the coalition’s Executive Director, Rachel Minahan, at rstevenson@thenursingcommunity.org.

Sincerely,

³ MedPAC Commission Members. (2024) Retrieved from: <https://www.medpac.gov/member/>

⁴ NIOSH BSC Membership (2024) Retrieved from: <https://www.cdc.gov/niosh/scientific-counselors/members.html>

⁵ PCORI Board of Governors Member, *Finance and Administration Committee* (2023)

Retrieved from: <https://www.pcori.org/people/christopher-friese-phd-rn-aocn-faan>

⁶ Members: Physician-Focused Payment Model Technical Advisory Committee

(2024) Retrieved from: <https://aspe.hhs.gov/collaborations-committees-advisory-groups/ptac/ptac-members>

⁷ The National Advisory Council (NAC) for Healthcare Research and Quality (2024) Retrieved from:

<https://www.ahrq.gov/cpi/about/nac.html#Members>

⁸ 5 USC Ch. 10: Federal Advisory Committees. Section 5(b)(2), (c) (codified at 5 U.S.C. 1004(b)(2), (c)). Retrieved from: <https://uscode.house.gov/view.xhtml?path=/prelim@title5/part1/chapter10&edition=prelim>

⁹ *Nat'l Anti-Hunger Coal. v. Exec. Comm. of President's Priv. Sector Surv. on Cost Control*, 711 F.2d 1071, 1074 n. 2 (D.C. Cir. 1983) Retrieved from: <https://casetext.com/case/nat-anti-hunger-coalition-v-exec-comm>

¹⁰ General Services Administration. Federal Management Regulation: Federal Advisory Committee Management Final Rule (April 18, 2024).

Retrieved from: <https://www.regulations.gov/document/GSA-FMR-2022-0015-0010>

¹¹ Anesthetic and Analgesic Drug Products Advisory Committee Roster (July 1, 2024) Retrieved from:

<https://www.fda.gov/advisory-committees/anesthetic-and-analgesic-drug-products-advisory-committee/anesthetic-and-analgesic-drug-products-advisory-committee-roster>

¹² Obstetrics, Reproductive and Urologic Drugs Advisory Committee (formerly Bone, Reproductive and Urologic

Drugs Advisory Committee) Roster (July 17, 2024) Retrieved from: <https://www.fda.gov/advisory-committees/obstetrics-reproductive-and-urologic-drugs-advisory-committee-formerly-bone-reproductive-and-obstetrics-reproductive-and-urologic-drugs-advisory-committee-formerly-bone-reproductive-and-0>

Academy of Medical-Surgical Nurses
Academy of Neonatal Nursing
Alliance of Nurses for Healthy Environments
American Academy of Emergency Nurse Practitioners
American Academy of Nursing
American Academy of Ambulatory Care Nursing
American Association of Colleges of Nursing
American Association of Critical-Care Nurses
American Association of Heart Failure Nurses
American Association of Nurse Anesthesiology
American Association of Nurse Practitioners
American Association of Occupational Health Nurses
American Nurses Association
American Nephrology Nurses Association
American Nursing Informatics Association
American Organization for Nursing Leadership
American Psychiatric Nurses Association
American Society for Pain Management Nursing
American Society of PeriAnesthesia Nurses
Association of Community Health Nursing Educators
Association of Pediatric Hematology/Oncology Nurses
Association of periOperative Registered Nurses
Association of Public Health Nurses
Association of Veterans Affairs Nurse Anesthetists
Commissioned Officers Association of the U.S. Public Health Service
Dermatology Nurses' Association
Friends of the National Institute of Nursing Research
Gerontological Advanced Practice Nurses Association
Hospice and Palliative Nurses Association
Infusion Nurses Society
International Association of Forensic Nurses
International Society of Psychiatric-Mental Health Nurses
National Association of Clinical Nurse Specialists
National Association of Hispanic Nurses
National Association of Neonatal Nurse Practitioners
National Association of Neonatal Nurses
National Association of Nurse Practitioners in Women's Health
National Association of Pediatric Nurse Practitioners
National Association of School Nurses
National Forum of State Nursing Workforce Centers
National Hartford Center of Gerontological Nursing Excellence
National League for Nursing
National Organization of Nurse Practitioner Faculties
Nurses Organization of Veterans Affairs
Oncology Nursing Society
Organization for Associate Degree Nursing
Preventive Cardiovascular Nurses Association
Society of Pediatric Nurses
Society of Urologic Nurses and Associates