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July 25, 2025

Advisory Committee Oversight and Management Staff
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Silver Spring, MD 20993-0002

Submitted electronically via <https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm>

RE: Nomination for FDA DODAC

On behalf of the American Academy of Dermatology Association (AADA), I am pleased to nominate Mariusz Wojnarski, MD, for appointment to the Food and Drug Administration's (FDA) Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC) for a four-year term.

As the leading society in dermatological care, representing nearly 17,500 dermatologists nationwide, AADA is committed to excellence in the medical and surgical treatment of skin disease, advocating for high standards in clinical practice, education, and research in dermatology and dermatopathology; and driving continuous improvement in patient care and outcomes while reducing the burden of disease.

Effective August 1, 2025, Dr. Wojnarski will assume the position of Chief of Dermatology and Director of the Specialty Clinic at Kimbrough Ambulatory Care Center in Fort Meade, Maryland. He completed his dermatology residency at Walter Reed National Military Medical Center through the National Capital Consortium (NCC), where he distinguished himself through exceptional academic and clinical performance, earning the Joint Service Commendation Medal for leadership and achievement.

In addition to his dermatology training, Dr. Wojnarski brings more than a decade of experience in clinical pharmacology and clinical trials, including seven years as Head of Clinical Trials and Clinical Operations for the Department of Defense (DoD) in Southeast Asia. In that role, he led a \$5 million research portfolio and collaborated with the World Health Organization (WHO), UNOPS, academic institutions, industry partners, and U.S. and host-nation government agencies. As Principal or Associate Investigator on multiple research projects at the Armed Forces Research Institute of Medical Sciences (AFRIMS), he oversaw regulatory compliance with both DoD and FDA requirements and played a key role in advancing therapeutic development in resource-limited settings.

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In addition to his 18 years in clinical practice and research expertise, Dr. Wojnarski brings prior regulatory experience from both the FDA Office of Pharmacovigilance and the FDA Office of Clinical Pharmacology, where he served as a visiting fellow. His understanding of FDA regulations, drug development, and safety surveillance is grounded in both formal training and hands-on experience. He has contributed to the development of international treatment guidelines, served on multiple institutional committees dedicated to patient safety, and led system-wide quality improvement initiatives, including efforts that resulted in Walter Reed National Military Medical Center receiving the highest safety grade (A) from the Leapfrog national program.

Dr. Wojnarski is also a dedicated educator and mentor. He has been appointed to three consecutive terms as a mentor for the Pediatric Dermatology Research Alliance (PeDRA), supporting medical students and early-career physician-investigators in the U.S. and internationally. He introduced clinical trials education into the NCC Dermatology Residency curriculum and helped establish a formal dermatology rotation at the FDA—significantly enriching the training of future dermatologists with real-world regulatory experience.

As a current member of the AADA's Regulatory Policy Committee, Dr. Wojnarski has contributed meaningfully to FDA-related dermatology advocacy, including improving access to generic dermatologic medications. His rare combination of expertise in dermatology, clinical pharmacology, pediatrics, regulatory science, and military medicine positions him to offer a unique and highly valuable perspective to the DODAC's work. His voice would be especially relevant to discussions around innovative therapies, drug-device combinations, and product safety.

A nationally and internationally recognized expert, Dr. Wojnarski has delivered more than 30 podium presentations and published over 40 peer-reviewed articles, including in *the Journal of the American Academy of Dermatology (JAAD)*, where he also serves as a reviewer. His academic productivity, clinical excellence, and leadership make him exceptionally well qualified to advise the FDA on complex issues in dermatologic and ophthalmic drug development.

Given his diverse expertise and experience, and demonstrated leadership, we are confident he would be a valuable contributor to the DODAC's work in advancing safe and effective dermatologic and ophthalmic drug development.

The AADA strongly supports Dr. Wojnarski's nomination and appreciates your consideration of his candidacy.

Sincerely,

A handwritten signature in cursive script that reads "Susan C. Taylor MD, FAAD". The signature is written in dark ink and is positioned above the printed name and title.

Susan C. Taylor, MD, FAAD
President, American Academy of Dermatology Association