July 13, 2018

Dr. Scott Gottlieb
Commissioner
Food and Drug Administration (FDA)
5630 Fishers Lan, Rm. 1061
Rockville, MD 20852

RE: Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities Draft Guidance

Dear Commissioner Gottlieb:

The American Association of Nurse Practitioners (AANP) is the largest full-service national professional membership organization for nurse practitioners (NPs), which represents the more than 248,000 nurse practitioners across the country. We thank you for the opportunity to comment on the FDA's draft guidance for drug and device manufacturer communications with payors, formulary committees and similar entities.

NPs are advanced practice registered nurses who are prepared at the masters or doctoral level to provide primary, acute, chronic and specialty care to patients of all ages and walks of life. Daily practice includes: assessment; ordering, performing, supervising and interpreting diagnostic and laboratory tests; making diagnoses; initiating and managing treatment including prescribing medication and non-pharmacologic treatments; coordinating care; counseling; and educating patients and their families and communities. NPs practice in nearly every health care setting including clinics, hospitals, Veterans Affairs and Indian Health Care facilities, emergency rooms, urgent care sites, private physician or NP practices (both managed and owned by NPs), nursing homes, schools, colleges, retail clinics, public health departments, nurse managed clinics, homeless clinics, and home health. NPs hold prescriptive authority in all 50 states and the District of Columbia. It is important to note that 86.6% of NPs are certified in primary care, the majority of whom see Medicare and Medicaid patients. NPs complete more than one billion patient visits annually.

We look forward to working with the FDA on industry guidance and the best ways to disseminate this necessary information to health care providers and other stakeholders. We continue to encourage the FDA to include nurse practitioners in all advisory panels and activities. Nurse practitioners play a vital role in our health care system and must be included in all initiatives. As we have noted previously, this inclusion extends to all communications, regulations and guidance in order to ensure that nurse practitioners' patients have access to medically necessary drugs and devices.

Provider Neutral Labeling

We are particularly concerned with the need for provider neutral language in labeling. FDA regulations mandate that over-the-counter (OTC) medications and other products containing certain ingredients use

warning labels instructing purchasers to consult their "doctor" or "physician" in the case of an adverse event, or if they have questions about using the product or medication.[1] Other healthcare providers including nurse practitioners, are the primary care provider for patients using that medication or product and are licensed and qualified to provide this information. We ask that this be reflected in the draft guidance for drug and device communications to payors and other similar entities.

During the warning label rulemaking, the FDA acknowledged that other healthcare providers, including nurse practitioners, would be treating patients in these situations but stated that "[T]he agency has decided not to endeavor to list each specific practitioner who is licensed and qualified in the clinical practice of medicine and in disease management. For OTC drug products, the term ''doctor'' in this subheading is sufficiently broad and inclusive."[2]

We respectfully disagree with this determination and request that the FDA clearly state in the draft guidance that medical product communications should reflect the fact that nurse practitioners and other healthcare providers treat patients using these products. We disagree with the FDA's determination that the label "doctor" is sufficiently broad and inclusive. We are not asking the FDA to list each specific practitioner who is licensed to treat patients; we are asking the FDA to issue guidance using the phrase "health professional" or "clinician" rather than "physician" or "doctor." The FDA has used the phrase "health professional" in labeling a number of products.[3] This is not cumbersome and more accurately reflects the broader scope of clinicians who are licensed and qualified to treat patients.

The use of the term "physician" or "doctor" on the label confuses patients regarding which clinicians are authorized to provide care, and undermines the scope of practice and quality of care provided by nurse practitioners. This can lead to unfair restraints on practice, an unfair competitive advantage in the healthcare marketplace and decreased access to care for patients. The use of provider neutral labeling is also necessary to ensure that when payors are drafting prior authorization and other coverage policies, they do not unnecessarily create a physician order requirement, which can lead to delays in treatment when the patient is seeing an NP or other qualified health professional. It is important that the FDA does not continue to utilize the word "physician" when other qualified health professionals, such as NPs, are licensed and qualified to treat patients using these medications and products. While the subject of this comment is related to industry guidance, we also encourage the FDA to incorporate this language throughout FDA regulation regarding product labeling.

We thank the FDA for issuing this draft guidance and we look forward to working with the FDA on reducing regulatory barriers for nurse practitioners and their patients. Should you have comments or questions, please direct them to MaryAnne Sapio, V.P. Federal Government Affairs, msapio@aanp.org, 703-740-2529.

Sincerely,

David Hebert
Chief Executive Officer

[1] 21 CFR § 201.66. (Additional examples on attached chart).
[2] 64 FR 13254, 13262. March 17, 1999.

[3] 21 CFR § 201.63, 21 CFR § 201.320, 21 CFR § 201.325, 21 CFR § 801.63.