December 27, 2017

The Honorable Scott Gottlieb, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

RE: Docket No. FDA–2017–N–5608 for ''Opioid Policy Steering Committee; Establishment of a Public Docket; Request for Comments''

Dear Commissioner Gottlieb:

The National Association of Clinical Nurse Specialists (NACNS) welcomes the opportunity to comment on how the Food and Drug Administration (FDA) authorities can or should be used to address the national opioid crisis. As the voice of more than 70,000 clinical nurse specialists (CNS), NACNS has a significant stake in how FDA regulates opioids and opioid prescribing.

Clinical nurse specialists, one of the four types of advanced practice registered nurses, are required to hold graduate degrees, either a master's or doctoral degree, and are licensed and certified based on a distinct and nationally recognized body of knowledge. CNS work includes specialized skills allowing them to perform as an independent health care provider and clinical expert with prescriptive authority and autonomous patient management. Prescriptive authority, with lawful prescriptive authority for controlled substances, is within the scope of practice of CNSs. Currently CNSs have the state-level authority to prescribe pharmacotherapeutics in 39 states. Since the passage of the ***Balanced Budget Act of 1997*** (P.L. 105–33), CNSs directly bill their services, under Part B participation in Medicare, including the services of prescribing and managing medication-assisted treatment to beneficiaries.

Similar to all stakeholders addressing the opioid crisis, NACNS recognizes the two, intertwined public health challenges of reducing the chronic pain that affects the lives of millions of people in the United States; and of curbing the harms that result from the use of opioid medications. Complicating those dual public health challenges are weaknesses in the nation's health system, such as, the fragmentation of the health care delivery system and the underfunded level of investment in pain research. The limited access to evidence-based and cost-effective comprehensive pain management, incorporating both pharmacologic and nonpharmacologic treatment modalities, is another basic health care system shortcoming that exacerbates the opioid epidemic. NACNS also asserts that access to opioids for patients suffering from pain – whose providers have prescribed these medications responsibly – is possible while simultaneously stemming the tide of opioid-use disorders (OUD) and other opioid-related harms burdening individuals, families, workplaces, communities, and groups of patients.

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Within this context, NACNS offers responses to the following key questions for which FDA seeks input on designing and implementing policies and programs pertaining to prescribing of, access to, and use of prescription opioids:

What more can FDA do to ensure that the full range of available information, including about possible public health effects, is considered when making opioid-related regulatory decisions?

Opioids are highly complex molecules. Prescribing opioids judiciously requires knowledge and integration of basic science, clinical, pharmacological, and psychosocial aspects of opioids. Characterized by a holistic perspective in the advanced nursing management of health, illness, and disease states, CNSs are keenly aware of potential health care consequences at the individual, household, and societal levels. As a consequence, NACNS contends that knowledge of public health factors is critical to policy making, and urges the FDA to use a systems approach for integrating public health considerations into its current framework for making regulatory decisions regarding opioids. Considerations should include not only benefits and risks to individual patients (e.g., long-term efficacy for pain reduction, impact on function, OUD, death), but also benefits and risks to members of a patient's household, as well as the effects on family well-being, and to community health and welfare.

To demonstrate product safety and efficacy, a systems approach would necessitate broadening the current clinical trial protocols to take in data from less traditional FDA sources. Those sources may include reports from families and other third parties affected by the drug, and empirical data on outcomes in populations that are at risk of OUD and/or of mental health comorbidities which are common in patients with pain. Non-health data for the estimated impact of an opioid medication on the demand for other prescription and illicit opioids also should inform FDA's clinical development programs.

What steps can FDA take with respect to dispensing and packaging (e.g., unit of use) to facilitate consistency of and promote appropriate prescribing practice?

NACNS supports FDA interventions in packaging and dispensing technologies (e.g., blister packs, tracking system technology) that could contribute to enhanced opioid safety for legally prescribed opioids by helping patients maintain prescription adherence, monitoring use, and addressing risks related to a growing use or dependence. Grounded in a science-based, holistic perspective, CNSs urge broad attention in technology development to mitigate the unintended consequence of restricting access to analgesics for patients in pain (e.g., increased financial costs passed to consumers, amplified difficulty for patients to physically access medication, e.g., those with chronic pain, cancer, or other disease states who might have limited strength and dexterity). To assess unintended consequences rigorously, NACNS advocates institutionalizing research evaluation into the technology development process that defines (1) the guiding principles that the scientific community must consider in designing new product features and (2) the types of data needed to evaluate how the innovations impact prevention or deterrence of misuse, abuse, or inappropriate access to prescription opioids.

Although the FDA does not regulate health care practice, NACNS recognizes the importance of prescribing practices in helping curtail opioid-related harms. Packaging and dispensing technologies might promote appropriate prescribing practices. Research shows that opioid prescribing practices and, therefore, trends in dispensing vary widely among states and other localities. While a new product feature may offer an important improvement such as a defined duration of use that might be for only a limited number of doses, NACNS contends that packaging and dispensing technologies must be complemented

with education. Without proper education, providers will fail to tailor interventions, including medication prescribing, to ensure safe and proper patient care for each unique patient under the specific conditions the medications are intended to be used.

Should FDA require some form of mandatory education for health care professionals who prescribe opioid drug products, and if so, how should such a system be implemented?

Undertreatment of pain and misuse of opioids are enabled in part by suboptimal management of pain and by variability in prescribing practices. These situations speak to a deficiency in the health care system's educational continuum. NACNS recognizes that professional societies, health care organizations, educational institutions, and state and federal agencies collectively are responsible for providers' knowledge of multidisciplinary pain care using nonopioid and nonpharmacologic strategies for managing acute pain, especially chronic painful conditions. Since these institutions are responding to the educational needs of the opioid and pain public health challenges, NACNS believes it is too early to recommend that FDA institute mandatory provider education.

NACNS strongly supports the FDA Risk Evaluation and Mitigation Strategy (REMS) program. Imposed by the FDA is 2012, REMS serves an important role ensuring that the benefits of extended-release and long-acting (ER/LA) opioid analgesics continue to outweigh their risks of adverse outcomes (addiction, unintentional overdose, and death) resulting from inappropriate prescribing, misuse, and abuse.

REMS requires manufacturers to provide unrestricted education grants to accredited continuing education providers, who in turn, develop and provide voluntary prescriber education programs. Presently there is little evidence that, as a voluntary prescriber education program, REMS has had much effect on practice, nor on whether it assures safe use, is not unduly burdensome to patient access, and minimizes the burden on the health care system. The ER/LA opioid REMS also has been criticized for providing inadequate checks on unsafe opioid prescribing and dispensing practices.

NACNS is optimistic, however, that the most recent REMS modification, approved on May 26, 2017, will address some of the program shortcomings. The NACNS supports the modified REMS, which is an updated ***FDA Blueprint for Health Care Provider (HCP) Education*** (to replace the current FDA Blueprint for Prescriber Education for ER/LA Opioid Analgesics). NACNS maintains that providers need addiction education to understand that addiction is a disease, not a symptom of moral weakness, or a willful rejection of societal norms. The neurobiological changes caused by misuse and addiction profoundly affect the judgment, motivation, and priorities of a person with a substance use disorder. Misuse, addiction, and related disorders are immensely more complicated than "just saying 'no'" to drugs.

The updated FDA Blueprint requires additional educational content in pain management, including the principles of acute and chronic pain management; nonpharmacologic treatments for pain; and pharmacologic treatments for pain (both non-opioid analgesic and opioid analgesic). NACNS appreciates that additional information will be included about opioid dose tapering for providers treating both acute and chronic pain. Not all inpatient providers understand that the failure to properly decrease opioid doses during lengthy acute hospitalizations results in higher opioid doses at discharge and, subsequently, more risk for OUD. NACNS supports the REMS training aimed at ensuring providers, who write prescriptions for any opioids, are doing so for properly indicated patients and under appropriate clinical circumstances. NACNS is pleased that the FDA Blueprint will be made available to other health care professionals involved in the management of patients with pain, not only prescribers.

The NACNS applauds the FDA for referring to the Centers for Disease Control and Prevention's (CDC) ***Guideline for Prescribing Opioids for Chronic Pain***, which offers a detailed set of recommendations for prescribing opioids to adults for chronic pain. While the guideline acknowledges the existence of other sets of opioid prescribing guidelines, the CDC guideline, published in 2016, has the advantage of reflecting more recent data on the effectiveness and risks of prescription opioids. In addition to review of the direct clinical evidence and complementary contextual evidence, the CDC process engaged federal partners and other stakeholders, and entailed subjecting the guideline to peer review and publishing it for public comment prior to dissemination. To its credit, the guideline endorsed treating patients as individuals, not numbers.

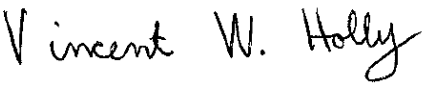
As the CDC guideline is integrated into a wide range of educational resources, including the FDA Blueprint, its publication may be a key event in the education of health care providers in the management of chronic pain, and explicitly with respect to the prescribing practices for opioid analgesics. Moreover, patient-centered management, aided by patient educational materials explaining the risks and benefits of long-term opioid use – including disclosures by manufacturers mandated by the FDA – could be useful in optimal clinical use of the guideline. Regrettably, in the review of evidence conducted to support development of the CDC guideline, investigators found no studies evaluating the effectiveness of patient education as a risk mitigation strategy.

However, evidence suggests that many patients lack knowledge about opioids, indicating a need for patient education. NACNS strongly supports the FDA Blueprint's incorporation of the CDC guideline recommending that before initiating opioid therapy, clinicians and patients weigh the known risks and benefits, available alternatives, and mutual responsibilities for optimal therapy. In connection with its prescribing guideline, the CDC has prepared a number of informational materials for patients on opioids and the risks associated with their use, as well as pharmacologic and nonpharmacologic alternatives for pain management. The FDA Blueprint appears to be similarly comprehensive in its patient education provisions.

Finally, NACNS supports the new FDA REMS for immediate-release opioid analgesic products. NACNS notes that in the interest of public health, and to minimize the burden on the health care delivery system, FDA has determined that all application holders of opioid analgesics intended for use in an outpatient setting should work together, using the existing infrastructure of the ER/LA Opioid Analgesics REMS, to develop a shared system opioid analgesic REMS.

Addressing the opioid epidemic requires a comprehensive effort among all levels of government, health care practitioners, and community leaders to address factors contributing to the opioid epidemic. Initiatives must include efforts to advance prescribing practices, improve the availability of prescriber education resources, enhance prescription drug monitoring programs, expand treatment for substance use disorders, and develop the safety of legally prescribed opioids through tools such as additional consumer education and improved packaging and dispensing options. For any follow up, please feel free to contact Melinda Mercer Ray, NACNS Executive Director, at 703-929-8995 or via email at mray@nacns.org.

Sincerely yours,



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