AMERICAN ACADEMY OF FAMILY PHYSICIANS

STRONG MEDICINE FOR AMERICA

December 7, 2011

Margaret Hamburg, MD,
Commissioner
Food and Drug Administration
Via email

Re: Draft Blueprint for Prescriber Education for Long-Acting/Extended-Release Opioid Class-Wide Risk Evaluation and Mitigation Strategy
[Docket No. FDA-2011-D-0771]

Dear Commissioner Hamburg:

On behalf of the 100,300 members of the American Academy of Family Physicians (AAFP), I am writing to provide comments on the "Draft Blueprint for Prescriber Education for Long-Acting/Extended-Release Opioid Class-Wide Risk Evaluation and Mitigation Strategy (REMS)" or "Blueprint."

A key mission of the AAFP is to protect the health of the public and we are deeply aware of the serious problem of prescription drug abuse and the resulting deaths. At the same time, we need to address the ongoing public health requirement to provide adequate pain management. In addition, the AAFP is uniquely positioned in the continuum of continuing medical education (CME), as the AAFP was the country's first national CME accreditor, established in 1947. However, the AAFP is also an Accreditation Council for Continuing Medical Education (ACCME) provider. As a result, we are interested in the Blueprint's compliance with both the AAFP CME Credit System Criteria, as well as with the Accreditation Council for Continuing Medical Education Standards for Commercial Support (ACCME SCS). Due to these various perspectives, AAFP is committed to working with you on this issue.

Background for the Draft Blueprint

Last spring, the FDA notified pharmaceutical companies that produced long-acting (LA) extended-release (ER) opioid drugs that they were required to submit a REMS for their products in this category. The intent was to address the risks for patients of serious adverse outcomes, including addiction, unintentional overdose and death. A critical component of this particular strategy was to include an education program for prescribers and patients. The LA/ER opioid drug training was to be conducted by independent continuing medical education and continuing education (CME/CE), without cost to the healthcare professionals, under unrestricted grants from industry to those CME/CE providers. In addition, companies would be required to "establish goals for the number of prescribers trained, collect the information about the number of prescribers who took the courses and report the information to FDA as part of periodic required assessments."

On November 4, 2011, the FDA released the draft Blueprint for public comment. This document outlines the core educational points that the FDA believes should be conveyed to prescribers in a basic two to three hour

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educational activity designed to instruct on minimization of risks associated with the use of this category of drug. Further, the intent is that this education would be delivered in CME/CE activities.

After the Blueprint is completed and approved as part of the REMS, it will be posted on the FDA Web site for use by CME/CE providers in developing CME/CE activities.

Goals in the Blueprint for the Prescriber Continuing Education Program
In the introduction, the FDA emphasizes the important role that health care providers play in "balancing the benefits of prescribing opioids to treat pain against the risks of serious adverse outcomes." This section also underscores the increasing non-medical use of opioids and the resulting public health problem. Thus, the learning objectives of the prescriber continuing education program are listed as the following:

- Understand how to assess patients for treatment with ER/LA opioids;
- Be familiar with how to initiate therapy, modify dose, and discontinue use of ER/LA opioids;
- Be knowledgeable about how to manage ongoing therapy with ER/LA opioids;
- Know how to counsel patients and caregivers about the safe use of ER/LA opioids, including proper storage and disposal;
- Be familiar with general and product specific drug information concerning ER/LA opioids.

AAFP Comments on the FDA Blueprint
Clearly, content in the Blueprint, e.g., "Assessing Patients for Treatment with ER/LA opioid therapy; Initiating Therapy, Modifying Dosing and Discontinuing Use; Managing Therapy; Counseling Patients and Caregivers about the Safe Use of Opioids; and General and Specific Drug Information," is expansive.

The goal of the Blueprint appears to be providing an overview of many topics, rather than give extensive education on specific topics within the education modules. In addition, the content includes topics related to prescriber education, as well as training on providing information to patients. It is unclear how the information would be shared with patients (based on this draft of the Blueprint) and would like clarification.

According to our analysis, the FDA Blueprint content appears to be compliant with CME certification guidelines and with the **Accreditation Council for Continuing Medical Education** Standards for Commercial Support (ACCME SCS). However, the specific individual drug content, to be provided by industry, will need to be evaluated, once it is available, to ensure that it conforms to existing CME/CE guidelines for independence and fair balance. In sum, the current Blueprint lists "topics" that need to be covered. The CME "content" addressing each topic is then to be developed by the CME providers and faculty. As drafted, the Blueprint allows for the certified CME to be the responsibility of the profession and, as such, aligns with AAFP CME Credit guidelines.

AAFP believes that, in some cases, CME/CE provider interpretation of the Blueprint could result in varied content in the education. It is not clear how CME providers will create programs to meet so many disparate goals within the two-three hour education module. Nevertheless, we support allowing CME providers to interpret how to meet these goals and realize it is the FDA's responsibility to make the requirements consistent.

Third, the one-size-fits-all approach may not be well received by learners. Some physicians may think that they are familiar with one section of the Blueprint, e.g., "Managing Therapy," but not as aware of another portion of the requirements. Again, we are unclear as to how CE organizations can individualize education so that it is relevant to learners. However, we support allowing CME providers to create their own programs. It is easier to design education that meets minimal requirements and, as a CME provider, the AAFP certainly would go beyond these obligations.

Finally, AAFP believes that the length of the activity may still be made more attractive to learners, for example, if it were delivered in shorter modules or sessions. We also believe that the REMS education could be

incorporated into other CME programs, as appropriate. Specifically, we believe our members would have low uptake of a standalone REMS program. Therefore, a program that is combined with another CME program may be more successful at attracting more physicians. Finally, we suggest determining whether or not online programs would be feasible.

AAFP Understanding of the Public Health Implications and Importance of Education

The AAFP is deeply concerned about the public health consequences of undertreatment of pain, as well as opioid misuse. In the Institute of Medicine (IOM) report, "Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research," released on June 29, 2011, action items included enlisting various groups to reach multitudes of people with pain, suggesting a comprehensive plan to address the issue collectively. Careful review of the report suggests that many of its recommendations are consistent with AAFP policy and it clearly describes the need to involve family physicians and other primary care physicians in the care of people with pain.

Right now, nearly one in four of all health care office visits are made to family physicians. That is 208 million visits each year – nearly 83 million more than are made to the next largest medical specialty. And, for patients over age 20, family physicians prescribe more opioids than does any other specialty. As a result, family physicians have a high stake in ensuring that we get the most effective drug treatment for our patients. This accounts for our strong commitment to the effective education of our members. Furthermore, we have charged our Commission on Health of the Public and Science to develop a comprehensive strategy for pain management.

Following medical school, family physicians complete a rigorous three-year residency program that includes training in all medical specialties and drug prescribing. In addition, to remain members of the AAFP, family physicians are required to complete 150 credits of continuing medical education every three years.

Family physicians' scope of practice is quite broad, thus their learning needs are extensive. Pain management is one of many areas in which they are expected to remain proficient. Thus, the AAFP has offered nearly 90 CME activities related to pain since June 2009. Fifteen more activities took place during the AAFP Scientific Assembly this past September. In addition, the AAFP has developed a monograph for opioids that is based on guidelines from the American Pain Society and the American Academy of Pain Medicine. The monograph is designed to help our members properly treat patients with chronic pain.

To conclude, the AAFP would like to work with you on this critical and complex public health issue. We, too, wish to see the end the misuse of prescriptions drugs. The individuals who are affected are our patients and members of our communities. As a result, we would like the Blueprint to be as effective as possible.

Thank you for the opportunity to review this proposal.

Sincerely,

Roland Goertz, MD, FAAFP
Board Chair