



December 6, 2017

Anna K. Abram  
Deputy Commissioner for Policy, Planning, Legislation, and Analysis  
Dockets Management Staff (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

RE: Docket No. FDA-2017-N-5093 for “Review of Existing General Regulatory and Information Collection Requirements of the Food and Drug Administration”

Dear Deputy Commissioner Abram:

On behalf of the American Academy of Family Physicians (AAFP), which represents 129,000 family physicians and medical students across the country, I write in response to the [request for comments](#) titled, “Review of Existing General Regulatory and Information Collection Requirements of the Food and Drug Administration (FDA)” as published by the FDA in the September 8, 2017 *Federal Register*.

The AAFP appreciates that the FDA seeks public comments to help identify existing regulations and related paperwork requirements that could be modified, repealed, or replaced to achieve meaningful burden reduction while also allowing the FDA to achieve its public health mission and fulfill statutory obligations. However, in the interest of public health and rather than suggesting FDA modify regulatory requirements, the AAFP encourages the FDA to enforce the following policies:

### **Enforce food labeling laws**

Per our October 16, 2017 [comment letter](#), the AAFP objects to any extension to the compliance date for final rules providing updated nutrition information food labels. We strongly urge the FDA to begin enforcement now.

The AAFP perceives sound nutrition as a cornerstone of health and we believe that food menu labeling requirements will help improve patient knowledge of nutritional choices. Furthermore, we believe that food menu labeling requirements will begin to help address the widespread prevalence of obesity in the United States. The AAFP is extremely concerned that the FDA yet again proposed to extend the compliance date for requiring disclosure of nutrition information for standard menu items in many restaurants. While nutrition labeling of menus alone will not eliminate the obesity crisis, the extent of the problem demands immediate action and this small but important step should be enforced now. We therefore urge the FDA to act and stop these needless and avoidable delays.

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### **Deem authority to regulate all nicotine delivery devices**

In a [letter](#) sent May 17, 2017, the AAFP and other public health leaders expressed concern that the Administration appears to be taking steps to reconsider the FDA “deeming rule” extending the agency’s regulatory jurisdiction to electronic cigarettes, cigars and other tobacco products not previously regulated. Any delay in implementation or enforcement of the rule would be to the detriment of public health.

The FDA announced on May 1 that it will defer enforcement of all future compliance deadlines for e-cigarettes, cigars and all other products affected by the deeming rule, for three months, to “allow new leadership at the FDA and the Department of Health and Human Services additional time to more fully consider issues raised by the final rule that are now the subject of multiple lawsuits in federal court.” The FDA announcement states that its action will extend compliance dates for fundamental requirements such as the submission of plans for implementation of cigar health warning labels, ingredient listings, the production of documents on the health effects of products, substantial equivalence and premarket tobacco applications, and the reporting of harmful and potentially harmful product constituents.

The deeming rule was the product of a multi-year rulemaking proceeding and is supported by overwhelming evidence. The public health justification for regulation is compelling and there is no basis for a reconsideration of the rule. Every day of delay in its full implementation subjects the public to the continuing public health threat of unregulated, highly addictive and dangerous tobacco products, many of which come in sweet or candy flavors which are designed and marketed to appeal to children.

There is no legal or policy reason to delay implementation of any provision of the deeming rule, or to reconsider the government’s strong legal defense of the rule. We therefore urge you to ensure that the deeming rule is implemented in accordance with its provisions, as well as to make certain that a strong defense of the rule is maintained against industry attack in court.

### **Promote the development of effective state prescription drug monitoring programs (PDMP)**

In a [comment letter](#) the AAFP sent July 10, 2017 in response to the FDA’s request for comments on training health care providers on pain management and safe use of opioid analgesics, the AAFP recognized the intertwined public health issues of chronic pain management and opioid misuse. The AAFP strives to protect the health of the public, and we are deeply aware of the critical and devastating problem of prescription drug abuse. At the same time, we need to address the ongoing need to provide adequate pain management.

The AAFP supports effective state prescription drug monitoring programs (PDMP) that facilitate the interstate exchange of registry information as called for under the *National All Schedules Prescription Electronic Reporting Act*. We advocate for physicians to use their state PDMP before prescribing any potentially abused pharmaceutical product. However, the success of such efforts depends on state reporting systems that are accessible, timely, and interoperable. We urge the FDA to work with physicians and states to make these systems more effective for the sake of the public health.

To help address opioid abuse and addiction, the AAFP recognizes the need for evidence-based physician education to ensure safe and effective use of extended-release and long-acting (ER/LA) opioids as well as short acting opioids. However, we maintain that mandating CME for individual

prescribers is not the solution for this public health crisis. It is AAFP [policy](#) to oppose actions that would require mandatory education of family physicians as a condition for prescribing opioids. The AAFP continues to believe educating physicians is an important tool, but to be impactful, the education must be designed to address needs and gaps of the learners. "One size fits all" education is not optimal. Requiring all physicians or "prescribers" in this case to complete the same education, regardless of whether a relevant performance gap in this area exists, would be a disservice to that physician and their patients since it will result in unnecessary time spent away from patient care. Mandated CME also impacts a family physician's ability to complete the most relevant education focused on specific needs and gaps.

The AAFP opposes limiting patient access to any physician-prescribed pharmaceutical without cause, as well as any actions that limit physicians' ability to prescribe these products based on the physician's medical specialty.

#### **Pursue safe and effective drugs and devices**

The AAFP fully supports the FDA's important public health mission to regulate and determine the safety and effectiveness of drugs and devices. This includes regulating foods, drugs, biologics including vaccines and blood products, medical devices, electronic products that give off radiation, cosmetics, veterinary products, and tobacco and nicotine delivering products. Approval of drugs and devices should be based on solid evidence and reduction of harm.

#### **About Family Medicine**

Family physicians are dedicated to treating the whole person. These residency-trained, primary care specialists provide a wide variety of clinical services. They treat babies with ear infections, adolescents with depression, adults with hypertension, and seniors with multiple chronic illnesses. With a focus on prevention, primary care, and overall care coordination, they treat illnesses early and, when necessary, refer their patients to the right specialist and advocate for their care.

One out of every five office visits in the United States are made with family physicians. More than 192 million office visits are made to family physicians each year. This is 66 million more than the next largest medical specialty. More Americans depend on family physicians than on any other medical specialty.

We appreciate the opportunity to nominate these two highly-qualified family physicians. Please contact Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or [rbennett@aafp.org](mailto:rbennett@aafp.org) with any questions or concerns.

Sincerely,

A handwritten signature in black ink, appearing to read "John Meigs, Jr.", with a stylized flourish at the end and the letters "MS" written below the signature.

John Meigs, Jr., MD, FFAFP  
Board Chair