As deaths from opioid overdose and admissions to treatment facilities for opioid addiction increase (1, 2), policymakers, researchers, and expert clinical societies agree that improved education on safe and appropriate opioid prescribing is a major priority (3). The U.S. Food and Drug Administration (FDA) has heard these calls. Its response includes mandating that pharmaceutical manufacturers develop risk evaluation and management strategies (REMS) for all extended-release and long-acting opioids, including a provision whereby industry will be required to establish goals for the number of prescribers trained and periodically report on reaching those goals (4). The REMS were also a focal point of a White House Office of National Drug Control Policy’s call to action, in which it sought to “require drug manufacturers to develop effective educational materials and initiatives to train practitioners on the appropriate use of opioid pain relievers” (5).

Most recently, in its Blueprint for Prescriber Continuing Education Program, available for public comment on 4 November 2011, the FDA stated that it expects the training to include some content provided by the pharmaceutical industry; to be free to prescribers; and to be conducted by accredited, independent continuing education providers with costs covered entirely by industry (6). Although the government’s move to enlist the pharmaceutical industry in helping address problems to which it has contributed (7) is understandable, this proposal misses opportunities to construct a system that avoids pharmaceutical industry influence, reaches an adequate number of prescribers, and includes competency-based prescribing. Data showing pharmaceutical company influence on physician behavior and a concern that this influence “could compromise clinical decision-making, adversely affecting health care delivery and undermining the reputation of the profession” has led some to call for a reduction of industry support for professional medical association activities to $0 (8). The Institute of Medicine and the American Medical Association have called for developing continuing education systems that are free from commercial influence and support (9, 10).

Aside from a substantial reliance on industry for content and funding of opioid prescriber education, the FDA’s plan has other weaknesses. For example, the Institute of Medicine recommends that when patterns of adverse events with medications are identified, the FDA should consider restricting the right to prescribe the medication to physicians with special training (11). However, the plan only mandates the creation of educational programming while stipulating that the pharmaceutical industry itself set goals for the number of prescribers trained. In contrast, the Office of National Drug Control Policy stated that it would “work with Congress to amend Federal law to require practitioners . . . who request DEA [Drug Enforcement Agency] registration to prescribe controlled substances to be trained on responsible opioid prescribing practices as a precondition of registration.”

This move would represent a sea change in the current regulatory environment and would put much-needed teeth behind the FDA’s efforts. However, if the current proposal is a preview of how a universal educational program would take shape, we have significant concerns. Namely, the current language used by the FDA is that it is an “expectation”—not a mandate—that training be done by accredited continuing education providers. Furthermore, there is no expectation or requirement that prescribers demonstrate understanding or mastery of content after receiving the training. Finally, although industry has estimated that adequate educational content to improve the safety of opioid prescribing could take up to 30 hours per trainee, the FDA proposed an initial training time of 2 to 3 hours, arguing that basic education for all prescribers was the most feasible goal (4).

In contrast to the FDA’s proposal, we believe that certain aspects of the Drug Addiction Treatment Act (DATA) of 2000 (12) and the subsequent federal support for training and ongoing prescriber guidance accompanying its implementation provide a useful framework upon which aspects of the REMS educational efforts could be based. This act established an 8-hour training requirement for physicians to prescribe schedule III to V opioids approved for treatment of opioid addiction, a practice previously banned by the Harrison Narcotic Act. To address these training requirements and to respond to mandates within DATA 2000, federal agencies orchestrated the creation of a practice guideline and training material by leading addiction medicine societies and academia (13), independent of industry. In addition, the federal Center for Substance Abuse Treatment subsidized prescriber participation in the trainings. The model, however, did not obligate competency-based prescribing. Since 2004, the Center for Substance Abuse Treatment has funded ongoing education and support for physicians prescribing buprenorphine (2004 to present) and methadone (2008 to 2011), with a new program covering all opioids recently initiated through its clinical support systems (14) (www.pcss-o.org).

The essential components of this model—required training before being permitted to prescribe; a federal–medical society collaboration to develop curriculum; and a federal–medical society collaboration to provide training
and support systems—are useful but would need substantial additional legislative and fiscal support to meet the goals of the FDA vis-à-vis REMS. Shortcomings of DATA 2000 are also instructive: Training and support services have not resulted in uniform exemplary practices, perhaps due to the absence of competency-based prescribing. Congress should provide federal agencies with the funding and authority to orchestrate a robust prescriber training and ongoing support system created and administered through a government–academia–medical society partnership similar to the one created in the wake of DATA 2000. This would be no small task: There were just over 1 million physicians registered with the DEA in 2009. Thus, training would need to be implemented in a gradual, rolling fashion, perhaps tied to renewal, so that access to needed medications would not be significantly compromised. Training should be of adequate content and scope—at least 8 hours of skills-based, interactive training—with recurring competency-based assessment (15). In addition to the worthwhile content outlined in the Blueprint, the scope should be expanded to include other controlled substances (e.g., short-acting opioids, benzodiazepines, and stimulants) that are often co-prescribed and have contributed to prescription drugs being more commonly abused than all illicit substances except marijuana. This would be entirely in keeping with the FDA’s authority to “require a manufacturer to develop a REMS when the FDA finds a REMS is necessary to ensure that the benefits of a drug outweigh its risks” (4).

If political will is lacking for the government to fund training entirely, funding could be required of industry, to be pooled and allocated for training developed and implemented by medical societies and academia. In such a scenario, federal agencies would need to ensure the presence of a “firewall” between training development and pharmaceutical industry influence and that accreditation standards for trainings were uniformly upheld, another substantial challenge that will require resources beyond what is currently proposed.

Opioid addiction, overdose, and death have reached epidemic levels exacting immeasurable personal tolls (1). The program described here would not guarantee safe and appropriate opioid prescribing in all circumstances, but it would take meaningful and much-needed steps in that direction.

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