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Science Board to the Food and Drug Administration
March 1, 2016

I have no financial conflicts of interest**.**

Over the past two decades, clinicians dramatically increased their prescribing of opioids for chronic non-cancer pain (CNCP). Unfortunately, this change in practice, which would ultimately lead to a public health crisis, was not driven by new evidence that opioids were safer or more effective than previously believed. Rather, it was a brilliant marketing campaign that led to a soaring increase in opioid prescribing.

In the six years following the release of OxyContin, Purdue Pharma sponsored more than 20,000 educational programs that minimized opioid risks, especially the risk of addiction, and exaggerated the benefits of using opioids long-term. Prescribers were given the false impression that opioids had been proven safe and effective for CNCP. The medical community was badly misinformed. The FDA permitted this to occur.

An evidence-based review, published last year by the Agency for Healthcare Research and Quality concluded: long-term opioids pose serious risks, especially at high doses and effectiveness has not been established. Or — in other words — the practice of treating chronic pain with long-term, daily opioids is dangerous and of questionable benefit.

In 2010, the FDA convened an advisory committee to review a proposal it had developed for an opioid risk evaluation and mitigation strategy (REMS) program. The advisory committee did not like the FDA's plan, which called for voluntary, industry-sponsored educational programs. The advisory committee voted 25 to 10 against the REMS, explaining that it rejected the proposal because it wanted *MANDATORY* training programs, it wanted strict firewalls to prevent industry bias, and it wanted immediate-release opioids to be part of the REMS. Despite the advisory committee's concerns, the FDA made no changes to its plan and went ahead with the REMS program as proposed.

In 2011, the FDA released a draft "blueprint" curriculum for the REMS programs. The curriculum was awful. It included no mention of the fact that opioids have NOT been proven safe and effective for long-term use or any mention that prescribing high doses is especially risky. Opioid manufacturers, I would imagine, were very pleased.

Concerns about the proposed curriculum were outlined in a letter to Dr. Janet Woodcock that was signed by 26 of our nation's top researchers and clinicians in the fields of pain, addiction, primary care, emergency medicine, public health, and other specialties. Despite the concerns

outlined in the letter, the FDA made no changes to the curriculum. REMS courses are now being taught all over the country. The courses are a comfortable revenue stream for the organizations that administer them and a source of free continuing medical education for the attendees. But they will not reduce harm to chronic pain patients caused by opioid overprescribing.

For fibromyalgia, low back pain, and chronic headache, there is an expert consensus that opioids should be avoided. There is agreement that opioids are more likely to harm these patients than help. But in the REMS, there is no mention of conditions for which opioids should be avoided. Prescribers are taught *HOW* to prescribe opioids to fibromyalgia patients instead of being taught *NOT* to start fibromyalgia patients on opioids. And prescribers are taught that close monitoring can prevent patients from becoming addicted, even though this is not true. Effective strategies for preventing addiction do not exist. Even with the closest monitoring, patients taking opioids exactly as prescribed can still become addicted.

The FDA proceeded with its REMS over the objection of its advisory committee. Similarly, the FDA ignored outside experts when concerns were raised about the REMS curriculum. If today's meeting is more than a public relations effort for the FDA to show that it is concerned about opioids, then maybe the FDA will listen to you, the Science Board. Please let the FDA know that the REMS programs for opioids require an overhaul. Prescriber education will be ineffective unless past misinformation is explicitly and forcefully corrected. Prescribers need to be able to weigh risks versus benefits before starting opioids. Education, like the existing REMS that continues to equate compassionate care for chronic pain with a prescription for opioids, will be more likely to worsen rather than improve the opioid addiction epidemic.