



Department of Health

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Dear Colleagues:

Welcome to my May letter. This month, I'd like to call your attention to new federal regulations regarding the use of codeine and tramadol in children and a rare disorder called Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS).

Codeine and tramadol: In April, the U.S. Food and Drug Administration (FDA) set new restrictions on the use of codeine and tramadol in children under 12 and in certain adolescent populations. The agency also strengthened its warnings against the use of these medications in breastfeeding mothers. These drugs can cause respiratory distress, and in extreme cases, death. The [new restrictions](#) establish single-ingredient codeine and tramadol as adult-only medications.

Under the new restrictions, codeine (for the treatment of cough and pain) and tramadol (for the treatment of pain) is contraindicated in children younger than 12, who appear to be at greatest risk. The FDA added a new warning against the use of both drugs in obese adolescents between the ages of 12 and 18, or teens who have obstructive sleep apnea or severe lung disease. All three conditions increase the risk for serious breathing problems. In addition, tramadol is now contraindicated for the treatment of pain in children under the age of 18 after having surgery to remove their tonsils and/or adenoids. The new labels include a stronger warning against taking either of these medications while breastfeeding. These medications can cause excessive sleepiness, respiratory distress and death in breastfed infants.

New York State has long considered these narcotic medications dangerous, given their high potential for abuse and addiction. In 2013, ahead of the federal government, New York made tramadol a Schedule IV controlled substance, which led to a decline in its prescription. New York is one of 22 states that does not allow products containing codeine to be sold over the counter. As controlled substances, codeine and tramadol are both on the state's Prescription Monitoring Program (PMP). Prescribers are required to consult the PMP whenever they prescribe controlled substances, such as codeine and tramadol. I urge all physicians to exercise caution when they prescribe opioids, to abide by the new restrictions from the FDA, and to adhere to New York State's five-day limit on new opioid prescriptions for acute pain and patient monitoring. Please remember that all licensed New York State physicians who have a DEA registration number to prescribe controlled substances must complete the new prescriber education requirement of Public Health Law §3309-a (3) by July 1, 2017. You can find guidance, FAQs, and a link to a free online course, sponsored by the Department and presented by the University of Buffalo, here:

http://www.health.ny.gov/professionals/narcotic/mandatory_prescriber_education/.

Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS): Next time a patient complains of long-standing and debilitating fatigue, I urge you to consider whether your patient has myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS), a multi-system

disease associated with neurological, immunological, and energy metabolism impairment. The hallmark of ME/CFS is post-exertional malaise (PEM), a delayed exacerbation of symptoms and loss of stamina following even minimal mental or physical function. In addition to PEM, patients may complain of other symptoms including cognitive dysfunction, sleep abnormalities, autonomic manifestations and, at times, pain. Sleep is typically unrefreshing. People with ME/CFS are unable to maintain their daily routines, one-quarter are housebound or bedbound and many are unable to work. In 2015, the National Academy of Medicine recommended new diagnostic criteria for ME/CFS that require a substantial impairment in activity that lasts six months or more and is accompanied by fatigue, post-exertional malaise, unrefreshing sleep, and either cognitive impairment or orthostatic intolerance. The patient may appear perfectly healthy and routine blood tests are typically normal.

ME/CFS is believed to impact approximately one million Americans, but the actual number may be much higher. The lack of biomarkers or a diagnostic test has made it difficult to diagnose ME/CFS. The disease is more common in women than men, and affects people of all racial and ethnic backgrounds. It can also impact children and adolescents. Experts believe ME/CFS is triggered by a viral infection, but the exact cause remains unknown. In the past, cognitive behavior therapy (CBT) and a graded exercise therapy (GET) were recommended as treatments. However, these recommendations were based on studies that included patients with other fatiguing conditions. Because of the hallmark intolerance to exertion of ME/CFS, exercise may actually worsen the health of those living with this disease. Currently, there are no FDA-approved treatments for ME/CFS.

Clearly more information is needed. The National Institutes of Health recently called for the creation of collaborative research centers to spur research into the cause and treatment of ME/CFS. The Centers for Disease Control and Prevention (CDC) published an article in the *Morbidity and Mortality Weekly Report (MMWR)* last December urging continued research into the science and epidemiology of ME/CFS. The CDC has also begun a new initiative to develop educational materials on ME/CFS, with input from patients, medical professional organizations, medical educators, clinical experts and government agencies.

As physicians, I hope you will make ME/CFS a part of your differential diagnosis when evaluating patients with these symptoms. Few things are as detrimental to a patient's health and wellbeing as not being taken seriously when presenting a problem to a health care provider. To learn more about ME/CFS from the patient perspective, consider watching this [TED talk by Jennifer Brea](#), who shares her journey with the disease and its impact on her life.

Thank you for your attention to these matters and for your commitment to health care in New York.

Sincerely,

A handwritten signature in black ink that reads "Howard Zucker M.D." in a cursive style.

Howard A. Zucker, M.D., J.D.