



New FDA Initiative Implies CDC Opioid Guidelines Are Not Evidence-Based

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On August 22, Food and Drug Commissioner Scott Gottlieb issued a [press release](#) announcing the FDA plans to contract with the National Academies of Sciences, Engineering, and Medicine (NASEM) to develop evidence-based guidelines for the appropriate prescribing of opioids for acute and post-surgical pain. The press release stated:

The primary scope of this work is to understand what evidence is needed to ensure that all current and future clinical practice guidelines for opioid analgesic prescribing are sufficient, and what research is needed to generate that evidence in a practical and feasible manner.

The FDA will ask NASEM to consult a “broad range of stakeholders” to contribute expert knowledge and opinions regarding existing guidelines and point out emerging evidence and public policy concerns related to the prescribing of opioids, utilizing the expertise within the various medical specialties.

Recognizing the work of the Centers for Disease Control and Prevention for having “taken an initial step in developing federal guidelines,” Commissioner Gottlieb diplomatically stated the FDA initiative intends to “build on that work by generating evidence-based guidelines where needed” that would differ from the CDC’s endeavor because it would be “indication-specific” and based on “prospectively gathered evidence drawn from evaluations of clinical practice and the treatment of pain.”

The CDC [guidelines](#) for prescribing opioids, released in early 2016 and [updated](#) in 2017, have been [criticized](#) by addiction and pain medicine specialists for not being evidence-based. Unfortunately, these guidelines have been [used](#) as the basis for many new prescribing regulations instituted at the state-level and proposed on the federal level. The American Medical Association and other medical specialty organizations have [spoken](#) out [against](#) proposed federal prescription limits that are based upon an inaccurate interpretation of the flawed CDC guidelines.

In May, Commissioner Gottlieb, in a blog post, mentioned he was [aware](#) of criticisms as well as complaints by patient and patient-advocacy groups and was interested in developing more “evidence-based information” on the matter of opioids and pain management.

Now it appears he is taking the next step. While the press release language was diplomatic and avoided any notion of disrespect for the CDC’s efforts, it is difficult not to infer that the Commissioner agrees with many who have been criticizing the CDC guidelines over the past couple of years.

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