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Food and Drug Administration
Division of Dockets Management
(HFA–305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2017-D-2497—Draft Revisions to the FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioids

To Whom It May Concern:

On behalf of our 161,000 members, we are pleased to comment on the Food and Drug Administration's (FDA) draft Blueprint for Prescriber Education for Extended-Release and Long-Acting (ER/LA) Opioids. We offer these comments in response to your Federal Register notice of May 10, 2017 (82 FR 21818).

Opioid pain relievers—such as hydrocodone (Vicodin® and Norco®) and oxycodone (OxyContin® and Percocet®)—can be a safe and effective way to help dental patients manage moderate to severe post-operative pain. Unfortunately, the misuse and abuse of these potentially addictive pain medications has become a serious public health problem.

Drug companies are currently subject to a Risk Evaluation and Mitigation Strategy (REMS) to offer low or no cost continuing education on pain management and safe prescribing of ER/LA opioid pain medications. The Blueprint for Prescriber Education outlines the core messages to be communicated to prescribers of these drugs.

The revised Blueprint's emphasis on prescribing ER/LA opioids for chronic pain is not particularly relevant to dentistry. When indicated, a dentist may prescribe an immediate release and short acting (IR/SA) opioid to help manage *acute* pain following a one-time dental procedure (e.g., wisdom tooth extraction, etc.). But there is rarely, if ever, a need to manage *chronic* pain after dental surgery, much less to prescribe an ER/LA opioid.

Last year, the ADA submitted comments in response to a Department of Health and Human Services (HHS) request for information about how about how federal opioid prescriber education and training programs could be improved. We noted that most federal programs and activities have not sufficiently addressed the nuances of prescribing IR/SA opioids for *acute* pain versus ER/LA opioids for *chronic* pain. To help make the FDA's prescriber education and training content relevant for dentists, we urged the Department to:

- Direct the FDA to develop a blueprint for educating prescribers of IR/SA opioid analgesics.

- Direct FDA to expand its risk evaluation and mitigation strategy (REMS) to include educating prescribers of IR/SA opioid analgesics.

These recommendations are consistent with those developed at a joint meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee on May 3-4, 2016.

We were pleased by a recent statement from FDA Commissioner Scott Gottlieb suggesting that the agency will be revisiting its risk management program to ensure opioid prescribing is better tailored to the medical indication.[1] We are ready and willing to help you develop a risk management program that addresses the nuances of managing acute pain in dental settings.

We applaud your efforts to help curb the misuse and abuse of opioid pain medications and welcome the opportunity to discuss this further. If you have any questions, please contact Mr. Robert J. Burns at 202-789-5176 or burnsr@ada.org. Information is also available at ADA.org/opioids.

Sincerely,

/s/

Gary L. Roberts, D.D.S.
President

/s/

Kathleen T. O'Loughlin, D.M.D., M.P.H.
Executive Director

GLR:KTO:rjb
Enclosure

[1] Scott Gottlieb, M.D., "FDA Commissioner Asks Staff for 'More Forceful Steps' to Stem the Opioid Crisis," *FDA Voice*, May 23, 2017.