February 3, 2014

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
The Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Sebelius:

The undersigned organizations are concerned by the October 24 US Food and Drug Administration Center for Drug Evaluation and Research statement outlining the agency’s plan to formally recommend to the US Department of Health and Human Services later this year the reclassification of hydrocodone-containing combination drug products (HCCs) from Schedule III (C-III) to Schedule II (C-II). We respectfully ask that you direct the FDA to revisit any and all parts of the policy rationale it used to formulate this recommendation.

While narcotic analgesics—such as hydrocodone and oxycodone—have become a leading source of drug abuse among teens and young adults, rescheduling HCCs from C-III to C-II is not necessarily the best way in which to alleviate this problem. Rather, it is more likely that rescheduling would have negative implications for dental health providers trying to serve patients with legitimate clinical pain treatment needs.

While some statistical data may indicate to the contrary, we submit that, on public policy and public health levels, the reclassification of HCCs would not be in the best interest of the public good and thus, ought to be reevaluated. We respectfully offer the following comments in support of this contention:

- **Dentist impact.** If rescheduling were to occur, prescribers could easily respond by treating pain less aggressively with C-III alternatives, perhaps to the detriment of patients with a legitimate need. In lieu of treating pain less aggressively, they could also prescribe more doses of C-II pain medication to help patients avoid the inconvenience of additional office and pharmacy visits, corresponding copayments and the likelihood of an emergency room visit when a refill is not readily available. Certainly, this could result in even more unused medication being available in the household, perpetuating the exact opposite outcome of the intent behind reclassification.

- **Patient impact.** Rescheduling HCCs from C-III to C-II could cause inconvenience, unnecessary suffering and higher out-of-pocket costs for patients with a legitimate need. C-II drugs are usually more expensive than C-III drugs and not as readily available at all pharmacies. Patients unable to afford the additional copays or prescription costs may choose to suffer through their pain and/or self-medicate with alcohol (or the medication of others).

- **Net public health impact.** At this juncture, any concrete link between creating barriers to obtaining HCCs from a prescriber and addressing the underlying public health problem, i.e., the demand for mind- and mood-altering drugs, is still uncertain. And, regardless of any reclassification, those seeking illegal access to prescription opioids could easily just modify their drug-seeking behavior or switch to another substance
altogether. It should be noted that if this were to occur, the result of rescheduling HCCs would only be felt by prescribers and legitimate patients, not by those seeking to abuse, misuse, or divert pain medication.

As prescribers of C-II and C-III pain medications, dental practitioners have a key role to play in preventing their abuse, misuse, and diversion. For some time, our organizations have been collaborating with public and private stakeholders to educate dental practitioners about judicious opioid prescribing, as well as counseling patients and caregivers about how to safely secure, monitor and dispose of unused, unwanted and expired medications. And like you, we are pleased to know that these efforts seem to be working.

Recent data from the National Survey on Drug Use and Health (NSDUH) shows that the number of young adults (people aged 18 to 25) who used prescription drugs for non-medical purposes declined 14 percent between 2010 and 2011. This remarkable decrease has driven an overall 12 percent drop in the number of Americans abusing prescription drugs.

We welcome opportunities to continue working with your department, the White House Office of National Drug Control Policy (ONDCP), the Food and Drug Administration (FDA) and other federal agencies to keep prescription drugs from being a source of harm. In the meantime, we respectfully ask you to direct the FDA to revisit any and all parts of the policy rationale it used to formulate its recent recommendation to reclassify HCCs from C-III to C-II.

If you have any questions, please contact Mr. Robert J. Burns at the American Dental Association. Bob can be reached at 202-789-5176 or burnsr@ada.org.

Sincerely,

Academy of General Dentistry
American Association of Oral and Maxillofacial Surgeons
American College of Prosthodontists
American Dental Association