To Whom It May Concern:

The American Dental Association (ADA) and the American Association of Oral and Maxillofacial Surgeons (AAOMS) are pleased to jointly comment on the public health impact of rescheduling hydrocodone-containing combination drug products (HCCs) from Schedule III (C-III) to Schedule II (C-II). We offer these comments in response to your Federal Register notice of June 8, 2012 (77 FR 34051).

The Drug Enforcement Administration (DEA) recently asked your agency for an advisory opinion about whether rescheduling HCCs from C-III to C-II would help curb their misuse, abuse and addiction. In response, the FDA is seeking comments for an advisory panel discussion about “the public health benefits and risks, including the potential for abuse, of drugs containing hydrocodone either combined with other analgesics or as an antitussive."

Our detailed comments are enclosed and may be summarized as follows:

- **Dentist impact.** It is unclear how rescheduling HCCs from C-III to C-II would alter dentist prescribing patterns. Prescribers might respond by treating pain less aggressively with C-III alternatives, perhaps to the detriment of patients with a legitimate need. Conversely, they might prescribe more doses of C-II drugs to help patients avoid the inconvenience of additional office visits, more dental office and pharmacy copays and the likelihood of an emergency room visit when a refill is not readily available. This could result in more unused medication being available in the household.

- **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. C-II refills require additional office visits, which would translate into more copays at the dental office and pharmacy. Patients may also choose to suffer through their pain, self-medicate with alcohol (or the medication of others) and/or go to the emergency room when a refill is not readily available.
Net public health impact. It is unclear whether additional barriers to obtaining HCCs from a prescriber would address the underlying public health problem, which is the demand for mind- and mood-altering drugs. For patients with a legitimate medical need, the likely cost would be inconvenience, suffering and higher out-of-pocket costs. To avoid that cost, prescribers may simply prescribe more doses, which could result in even more unused medication being available in the household. Moreover, those seeking illegal access to prescription opioids could easily modify their drug-seeking behavior or switch to another substance altogether.

We appreciate the DEA’s concern about how children and teens are unduly accessing prescription opioid medications. Fortunately, the current strategy of expanding prescription drug monitoring programs and educating patients and caregivers about how to properly secure, monitor and dispose of their unused, unwanted or expired prescription medications seems to be working.

The most 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 in the past month declined 14 percent between 2010 and 2011. This decline has driven an overall 12 percent drop in the number of Americans abusing prescription drugs.

As prescribers of opioid pain medications, dentists and oral surgeons are well positioned to counsel patients and caregivers about keeping prescription medications from becoming a source of harm. That is one reason the ADA and AAOMS have been collaborating with public and private stakeholders to educate dental practitioners about judicious opioid prescribing and counseling patients and caregivers about how to safely secure, monitor and dispose of unused, unwanted and expired medications. Information about these activities is available online at www.ada.org/rxabuse.

We welcome opportunities to continue working with the Food and Drug Administration (FDA), the White House Office of National Drug Control Policy (ONDCP) and other federal agencies to keep prescription drugs from becoming a source of harm. 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,

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The American Dental Association (ADA) and the American Association of Oral and Maxillofacial Surgeons (AAOMS) are pleased to jointly comment on the public health impact of rescheduling hydrocodone-containing combination drug products (HCCs) from Schedule III (C-III) to Schedule II (C-II). We offer these comments in response to your Federal Register notice of June 8, 2012 (77 FR 34051).

The ADA and AAOMS recognize the serious problem of drug diversion and subsequent abuse of hydrocodone combination drug products (HCCs) and other legally prescribed medications. In fact, our organizations are actively involved in a number of programs and initiatives to help educate dental practitioners, patients and caregivers about judicious prescribing and how to safely secure, monitor and dispose of unused, unwanted and expired medications. Information about this work is available online at www.ada.org/rxabuse.

Changing the controlled substance classification of HCCs from Schedule III (C-III) to Schedule II (C-II) will:

- Significantly impact patients suffering with acute pain (in several ways);
- Impact the ability of prescribers to effectively manage pre-operative and post-operative pain; and
- Produce little or no reduction in the availability and use of HCCs on the street.

The ADA and AAOMS prefer education and communication over regulatory changes that are likely to negatively impact dental patients in pain. As a strategy for keeping prescription drugs from being illegally diverted for non-medical use, we recommend against changing the controlled substance classification of HCCs from C-III to C-II.

**Dental Pain and Pain Management**

Acute dental pain may be categorized as mild, moderate or severe. Acute post-surgical pain and/or pain associated with a damaged dental pulp (pulpitis or pulp necrosis) is typically moderate or severe in nature. Procedures involving bone and dentin (and associated pain fibers) often cause severe pain.
The range of C-III opioid medications available to treat moderate to severe pain is limited to codeine combination products and HCCs. Nonsteroidal, anti-inflammatory drugs (NSAIDs) are also prescribed for acute oral/dental pain; however these medications lack the central nervous system effects of opioids. The "side effects" of sedation/drowsiness and mild euphoria are often desirable with moderate-severe oral/dental pain to help patients rest/sleep and to better manage severe pain.

Acetaminophen, aspirin and NSAIDs are often combined with opioid analgesic drugs (e.g., HCCs) in order to achieve pain relief via both central and peripheral pathways. The intent is to increase pain relief and decrease the likelihood of break-through pain, which can negatively impact effective pain management. Single agent NSAIDs are capable of relieving moderate and even severe pain in some patients, though these agents are contraindicated in many patients due to gastrointestinal side effects. In recent years, the potential for serious cardiovascular side effects with NSAIDs has also come to light.

Since soon after their introduction, HCCs have been the drug of choice for moderate to severe oral/dental pain. HCC’s have improved pain management and reduced adverse effects generally for dental patients versus the current combination product alternative, codeine combination products. (Codeine is a pro-drug, undergoing metabolism to the active compound, morphine.)

Codeine is typically less effective than hydrocodone at controlling pain for dental patients at commonly prescribed doses. Less effective pain management may be partly explained by variations in an individual’s ability to metabolize codeine. Segments of the population may have more or less of the enzyme needed to produce the active form of the drug. Poor metabolizers (2-10% of the population) may have poor pain management. They may then be prescribed (or take on their own) higher doses of a codeine combination product. This may have serious implications related to adverse effects from the opioid or non-opioid component of a codeine combination product, such as acetaminophen liver toxicity. High metabolizers (0.5-2%) may be prone to more adverse effects at typical recommended doses.

Potential Impact on Dental Patients

Rescheduling HCCs to C-II would require patients with legitimate pain to return to the dental office to be seen and to obtain the appropriate prescription. Patients may elect to use alcohol or the medication of others to control pain rather than go through the process of returning to the dental office, either because of time and distance constraints or because they fear additional costs associated with the visit.

Patients with medical insurance may find that they can reduce their out of pocket costs for a new prescription by going to the hospital emergency room. An emergency room visit may also be the only alternative for effective pain management in some cases in after-hours situations due to limitations on phone orders. These scenarios and others may result in greater overall health care costs.

For the group of patients suffering from chronic orofacial pain who are managed in dental practices that focus on those problems, the change in Schedule will mean either that the managing doctor will need to write for larger quantities of medication when the
patient is seen or more frequent visits to the clinic with the resultant increase in health care costs and time lost to work. The alternative will be that pain levels rise and the social and financial impact of the chronic pain increased by reducing the ability of the patient to work and function within their community. Ineffective pain control in acute and chronic pain is a major factor in work time loss and a change in Schedule of HCCs will likely increase the negative impact of pain on functional status.

Prescribing larger quantities of medication caused by a Schedule change could increase the amount of medication available for inappropriate use. The Schedule change may cause patients who understand the implications of the change to more forcefully request the C-II medication while in the dental office rather than accept a C-III or other lower class of analgesic medication because they understand that accepting a less effective medication and experiencing ineffective pain control will result in the need to be seen again by the dentist, resulting in added cost (travel; time; drug costs; and office visit).

**Potential Impact on Dentists**

It is unclear how rescheduling HCCs from C-III to C-II would alter dentist prescribing patterns. Prescribers might respond by treating pain less aggressively with C-III alternatives, perhaps to the detriment of patients with a legitimate need. Conversely, they might prescribe more doses of C-II drugs to help patients avoid the inconvenience of additional office visits, more dental office and pharmacy copays and the likelihood of an emergency room visit when a refill is not readily available. This could result in even more unused medication being available in the household.

**Impact on Diversion/Abuse**

It is not clear whether changing the Schedule for HCCs from C-III to C-II will significantly reduce the volume of HCCs used for non-medical purposes. If pain is not effectively managed with alternative C-III or non-controlled analgesic alternatives, the number of HCC doses may actually increase. Prescribers may write for a codeine combination product with refills. If that is not effective, a C-II HCC may be prescribed. The number of doses prescribed may be higher than for the same drug if it were C-III. Because the C-II is not refillable, the prescriber may wish to decrease the potential added cost and inconvenience of follow up office visit or emergency room visit for additional pain medication. The original codeine prescription (and refills) may also be diverted.

In the end, it is doubtful that changing the controlled substance classification of HCCs from C-III to C-II will address the underlying public health problem, which is the demand for mind- and mood-altering drugs. The likely cost would be inconvenience, suffering and higher out-of-pocket costs for patients with a legitimate medical need. To avoid that cost, prescribers may simply prescribe higher quantities, which could result in even more unused medication being available in the household. Moreover, those seeking illegal access to prescription opioids could easily modify their drug-seeking behavior or switch to another substance altogether.