

March 27, 2014

Drug Enforcement Administration  
Attention: DEA Federal Register Representative  
ODW, 8701 Morrisette Drive  
Springfield, Virginia 22152

Re: Docket No. DEA-389

To Whom It May Concern:

The undersigned organizations are concerned by the Drug Enforcement Administration's recent notice of proposed rulemaking to reclassify hydrocodone-containing combination drug products (HCCs) from Schedule III (C-III) to Schedule II (C-II). We respectfully ask that you revisit any and all parts of the policy rationale used to justify this action and we offer these comments in response to the Federal Register notice of February 27, 2014 (79 FR 04333).

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.

We submitted detailed technical comments in support of this position to the Food and Drug Administration in 2012. Those detailed comments are enclosed and may be summarized as follows:

- ***Dentist impact.*** If rescheduling were to occur, prescribers might 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 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 might also translate into more copays at the dental office and pharmacy. 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) and/or go to the emergency room when a refill is not readily available.
- ***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

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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 agency, 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 revisit any and all parts of the policy rationale used to justify your agency's notice of proposed rulemaking.

If you have any questions, please contact Ms. Jeanne Tuerk at the American Association of Oral and Maxillofacial Surgeons. Jeanne can be reached at 847-233-4321 or [jtuerk@aaoms.org](mailto:jtuerk@aaoms.org).

Sincerely,

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

Technical Comments from the  
American Dental Association  
American Association of Oral and Maxillofacial Surgeons  
to the  
Drug Safety and Risk Management Advisory Committee  
Docket No. FDA-2012-N-0548  
October 15, 2012

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](http://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.