AMA
AMERICAN MEDICAL ASSOCIATION

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Margaret Hamburg, MD
Commissioner
U.S. Food and Drug Administration
Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

On behalf of the physician and medical student members of the American Medical Association (AMA), I urge the Food and Drug Administration (FDA) not take any action to reschedule hydrocodone combination products from Schedule III to Schedule II unless and until the Administration and Congress act to address existing access challenges to Schedule II pain medication for medically fragile patients in skilled nursing facilities (SNFs) and hospice care. The AMA agrees with the FDA and other stakeholders that there has been an alarming increase in diversion and abuse of prescription opioids, and we will continue to work closely with the FDA to address this epidemic, as we have recently in promoting your call to physicians for help in curtailing the U.S. opioid epidemic, for example. Rescheduling at this time would significantly limit appropriate pain treatment to patients in SNF and hospice care, a vulnerable population. We urge prompt attention to this access problem that impacts patient outcomes and contributes to human suffering. We would welcome the opportunity to work with the Administration and Congress in order to address the current barriers impeding access to Schedule II pain treatment options for this patient population.

Background on the Problem

For nearly four years, a cross-section of physician, pharmacist and long-term care organizations have engaged in an effort to address a major regulatory barrier to prompt dispensing of Schedule II drugs to SNF patients. During that time, long-term care (LTC) pharmacies have been reporting heightened enforcement action by the DEA due to the agency's interpretation of the Controlled Substances Act as precluding nurses in LTC and hospice facilities from acting as agents for an authorized prescriber of Schedule II drugs. As a result, a host of requirements must be met by the prescriber before an LTC pharmacy will fill and deliver a Schedule II drug.

These requirements create significant access challenges in these facilities, in contrast to a hospital or a physician's office, because the prescriber is often not on-site at the time a patient experiences an acute pain episode, when the medication would typically be initially ordered. Instead, such facilities are staffed by physicians who treat patients in multiple LTC facilities. As a result, they may not be on-site and may not be able to examine a patient face-to-face immediately when the need for these medications unexpectedly arises due to acute exacerbation of a painful condition near the end of life or when the patient is first admitted to the facility following a hospital stay. Also, these orders are

often given after hours or when the physician is traveling or otherwise in a location that is not amenable to writing and faxing a prescription. It is, therefore, not uncommon that prescribers are not able to immediately fulfill the paperwork requirements that a hard copy, practitioner-signed valid prescription be provided to the pharmacy before the drug is dispensed, particularly when a patient is suffering from acute pain. The foregoing is further complicated by the fact that this patient population is more likely than the general population to need relief from acute pain because of, for example, compromised health status, difficult to anticipate post-surgical pain profiles, and co-morbidities and complex health conditions.

The foregoing challenges are not theoretical. Physicians, nurses, pharmacists, patient groups, and others continue to report that the challenges associated with coordinating communications in order to meet the Drug Enforcement Administration's (DEA) requirements are substantial and onerous. Significantly, these hurdles have meant patients have faced hours, and in some cases nearly a full day, between the time that a physician determines the acute onset pain is so severe that a Schedule II pain medication is warranted and the provision of the pain medication to the patient. We are confident that these situations were not intended, but they are the result of current policies that interfere with physicians' ability to alleviate patients' pain in these settings.

How Rescheduling Would Exacerbate the SNF Problem

As LTC and hospice facilities struggle with difficulties obtaining Schedule II pain medication for their patients, the only viable alternative in many cases are Schedule III hydrocodone-containing pain medications such as Vicodin and Lortab, or transport to a hospital emergency department. Rescheduling these combination drugs from Schedule III to Schedule II without solving the LTC problem would leave health care providers with two options: use alternative analgesics that are considerably less potent and effective, or transport the patient to a hospital. Neither is acceptable medical care.

In the last Congress, many stakeholder discussions occurred and legislation was drafted in an effort to resolve this problem; however, no legislation has been enacted. We urge the FDA to join the effort to resolve the SNF issue and, at a minimum, we strongly recommend that the FDA suspend any consideration of rescheduling hydrocodone combination pain medications until after the SNF access problem is resolved.

If the AMA can provide any assistance to you in this matter, please do not hesitate to contact Sandy Marks in our Washington office at 202-789-4585 or sandy.marks@ama-assn.org.

Sincerely,

James L. Madara, MD