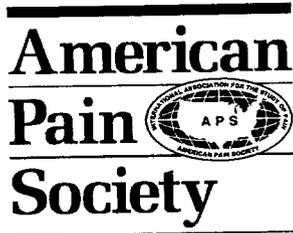


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NDAC Meeting on the Risks of APAP, NSAIDS, and ASA
Food and Drug Administration
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This statement from the American Pain Society is written to provide the Food and Drug Administration with information on the appropriate management of pain with over-the-counter (OTC) analgesic medications. The American Pain Society is an interdisciplinary professional society consisting of over 3,500 members. Membership includes basic science researchers, physicians from many specialties, psychologists, nurses, physical therapists, pharmacists, and other professionals interested in pain-related research, clinical care, and professional and public education.

Mild to moderate pain is a common human experience that can be treated effectively with OTC analgesics. Although the causes of pain are numerous, both acute and chronic pain of this intensity respond well to any one of a variety of OTC analgesic preparations. Therefore, OTC analgesics should be available to all Americans for use in the management of pain. The lack of availability of OTC analgesics would place extraordinary demands on an already

overtaxed health care system for the management of pain that can be well-controlled by OTC analgesics. Moreover, the lack of availability of OTC analgesics would deny appropriate analgesic treatment for pain to the millions of Americans who do not have health insurance.

At the same time that the American Pain Society believes that OTC analgesic medications should be readily available, we want to emphasize that the public needs better education about the appropriate use of OTC analgesic medications. The labeling of OTC analgesics should provide clear directions about the appropriate doses for and use of these medications, the most common side effects of these medications, information on the appropriate dose, and frequency of administration. The labels and package inserts should be at written in clear and simple terms and at the average reading level of most Americans [i.e., third to fifth grade reading level].

Another area that requires attention to ensure the safety of the American people is clear labeling of all OTC analgesic medications that are contained in combination products, including those that may not be viewed as analgesics themselves. Patients need to know the type of medication and the dose of the OTC analgesic in every combination product that is available over the counter. This information is critical to insure that these OTC analgesics are used safely and effectively.

Effective treatment of pain can be achieved with the appropriate use of OTC analgesics. The availability of OTC analgesics will insure that this goal is achieved in an appropriate and timely manner. Public education is the key to ensure that these analgesics are used in a safe and appropriate fashion.