

# Acetaminophen Combination Products

## BACKGROUND

Earlier this year, the FDA issued a final rule mandating that manufacturers of nonprescription pain relievers must modify product labels to include information about potential adverse effects, such as increased bleeding risks and liver damage. Products containing acetaminophen and the non-steroidal anti-inflammatory drug (NSAID) class were the target of this new restriction.

Since 1998, the FDA has expressed concerns about the overutilization of over-the-counter (OTC) pain relievers as well as prescription pain relievers containing acetaminophen, specifically citing clinical studies that indicated that acetaminophen was a key player in acute liver failure in the United States. In 2007, the FDA's Center for Drug Evaluation and Research (CDER), in conjunction with a team of healthcare advisors, presented a range of recommendations to help mitigate public harm from the overutilization of acetaminophen products—final ruling on this matter was placed on hold pending public discussion and further review.

## NEW DEVELOPMENTS

On June 30, 2009, the FDA informed the public that an advisory panel had made final recommendations regarding the removal of Vicodin® (hydrocodone/acetaminophen) and Percocet® (oxycodone/acetaminophen) products from the market as well as reducing the maximum recommended total daily dose for acetaminophen—down from its current daily limit of 4,000 milligrams. A new maximum daily limit was not presented as part of the advisory panel's recommendations.

These actions stemmed from an April 2009 press release by the FDA restricting the labeling requirements for over-the-counter analgesic agents. In addition to the restrictions listed above, the advisory panel recommended lowering the maxi-

mum nonprescription dose of acetaminophen to 650 mg (two 325mg tablets) per dose and converting single doses of 1000 mg (two 500mg tablets) to prescription-only status.

## IMPACT IN WORKERS' COMPENSATION

Although the FDA typically heeds the recommendations of its advisory committees, it is not required to do so. For example, earlier this year a similar advisory committee urged the FDA to consider the removal of propoxyphene/acetaminophen (Darvocet®) products from the market, indicating that years of research had shown propoxyphene to be no better than acetaminophen alone. On July 7, 2009, the FDA decided that propoxyphene products would remain on the market despite the advisory panel's concerns; however, stronger language will be required on the drug's labeling.



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Currently, Vicodin and Percocet products continue to be available on the market. They are dispensed primarily in their generic formulation. Although it is unlikely that Vicodin and Percocet will be completely discontinued, it is possible that certain strength combinations (i.e., Vicodin ES®) may no longer be marketed. As a result, it is possible that patients may be transitioned to other short-acting opioid pain relievers should this occur.

## IMPACT TO PAYORS

Currently, Vicodin and Percocet account for 20% of in-network transactions and 8% of in-network spend—Vicodin products alone account for 15% of total pharmacy transactions. Furthermore, Vicodin products continue to be the number-one utilized analgesic agent in workers' compensation cases by transaction count. If the FDA bans or places limitations on available strengths of Vicodin and Percocet products, it is possible that

**If limitations are placed on available products, it is possible that there will be an increase in pharmacy cost.**

payors may see an increase in total pharmacy costs. This increase will likely be attributed to the conversion of these products to alternative agents, including higher-cost brand medications.

PMSI will continue to monitor this situation. Should a ban or limitations occur, our commitment is to ensure the highest level of generic utilization whenever possible in order to reduce the financial impact.

## REFERENCES

*FDA Requires Additional Labeling for Over-the-Counter Pain Relievers and Fever Reducers to Help Consumers Use Products Safely.* Food and Drug Administration. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm149573.htm>. <Accessed July 7, 2009>

*Joint Meeting of the Drug Safety and Risk Management Advisory Committee, Nonprescription Drugs Advisory Committee, and the Anesthetic and Life Support Drugs Advisory Committee.* June 29-30, 2009 meeting. Food and Drug Administration, Center for Drug Evaluation and Research. <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/DrugSafety-andRiskManagementAdvisoryCommittee/UCM170188.pdf>. <Accessed July 7, 2009>

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