

January 16, 2007

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**Study finds 90 Percent of Actiq “Lollipop” Prescriptions are Off-label**

*Prime Therapeutics offers programs to help clients promote safe use of the drug*

ST. PAUL – A recent Prime Therapeutics (Prime) study found significant patterns of “off-label” prescribing for Actiq® among patients taking the powerful painkilling “lollipop.” Prescribing Actiq according to FDA guidelines is important for patient safety reasons because of the drug’s serious side effects, including its addictive nature.

The results of the Prime study confirm concerns about the drug, which have been highlighted recently by the national news media. Prime, a thought leader in pharmacy benefit management, provides programs that manage the use of Actiq and other dangerous drugs in an effort to promote health and safety while ensuring that patients get the treatment they need.

“The FDA has only approved Actiq for use by cancer patients who are already taking a long-acting, chronic painkiller but suffer from severe spikes in pain,” stated Pat Gleason, PharmD, Director of Medical and Pharmacy Integration Services for Prime. “The Prime study, however, found that only slightly more than 10 percent of the patients receiving the drug over a three-month period in 2005 met those guidelines. Nearly 90 percent of Actiq prescriptions in our study were off-label, or not prescribed according to the guidelines set forth by the FDA.”

Actiq contains fentanyl, a known potent synthetic opioid with a high potential for abuse and overdose. In addition, fentanyl has been linked to fatal respiratory complications. As a result, while physicians are allowed to prescribe medications for unapproved or “off-label” use, the FDA recommends strict adherence to Actiq’s prescribing guidelines.

Last year, in response to the safety concerns highlighted in the study, Prime began offering programs to promote Actiq’s safe use. These programs include a monthly limit of 120-doses of Actiq, or a newer related drug, Fentora®. Patients are also required to have prior authorization from their doctor and prescriptions are limited to a 12-month period. Prime’s

program also encourages members to take a long-acting opioid for chronic pain. The program guidelines follow FDA recommendations.

“There are serious safety issues regarding Actiq, so doctors need to be careful how it is prescribed,” said Gleason. “Prime integrates pharmacy and medical data to identify misuse of drugs such as Actiq and then develops programs to ensure patient safety. Our drug utilization programs not only keep members safe, but save health plans thousands of dollars a month.”

The study analyzed Actiq patient claims from a Midwestern commercial health plan from April through June 2005. Of the 95 patients who received prescriptions for the lollipop during that time, only 21 had a diagnosis of cancer or AIDS. In addition, only 11 of those 21 patients were taking a long-acting opioid painkiller. Overall, 84 of the 95 Actiq prescriptions, nearly 90 percent, were for off-label purposes. The study also found that more than 15 percent of Actiq prescriptions were for more than the FDA’s recommended 120 lollipops per month, suggesting that some patients may be overusing the drug.

**Prime Therapeutics LLC** is a pharmacy benefit management company dedicated to providing innovative, clinically based, cost-effective pharmacy solutions for clients and members. Providing pharmacy benefit services nationwide to approximately 10.5 million covered lives, its client base includes Blue Cross and Blue Shield Plans, employer and union groups, and third-party administrators. Headquartered in St. Paul, Minnesota, Prime Therapeutics is collectively owned by Blue Cross and Blue Shield Plans, subsidiaries or affiliates of those Plans. Learn more at [www.primetherapeutics.com](http://www.primetherapeutics.com).

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