Arnall Golden Gregory LLP

Client Alert

Contact Attorney Regarding This Matter:

William H. Kitchens
404.873.8644 - direct
404.873.8645 - fax
william.kitchens@agg.com

FDA Announces Strategies to Reduce the Misuse and Misprescribing of Long-Acting and Extended-Release Prescription Pain Medications

On April 19, 2011, the Obama administration announced a multi-agency plan to combat the "epidemic" of prescription drug abuse. The plan includes a Food and Drug Administration (FDA) education program that focuses on reducing the misuse and misprescribing of long-acting and extended-release opioids. The FDA's efforts will also include support for physician training of best practices for the safe use of these pain medications. Opioids are synthetic versions of opium that are used to treat moderate and severe pain. Over the past few decades, drug makers have developed extended-release opioid formulas to treat people in pain over a long period.

To reach those goals, the FDA wants manufacturers of these drugs to develop and implement risk evaluation and mitigation strategies (REMS) strategies for deterring abuse and misuse of these drugs. The FDA is now notifying opioid makers that they must propose a REMS plan within 120 days, with completion of the REMS expected by 2012.

Key elements of the White House plan—called "Epidemic: Responding to America's Prescription Drug Abuse Crisis"—include the following:

- expansion of state-based prescription drug monitoring programs;
- recommending convenient and environmentally responsible ways to remove unused medications from homes;
- supporting education for patients and healthcare providers; and
- reducing the number of "pill mills" and doctor-shopping through law enforcement.

FDA experts say extended-release and long-acting opioids—including OxyContin, Avinza, Dolophine, Duragesic and eight other brand names—are extensively misprescribed, misused and abused, leading to overdoses, addiction and even deaths across the United States. The FDA cited a 2007 survey that revealed more than half of opioid abusers got the drug from a friend or relative. The FDA estimates that more than 33 million Americans age 12 and older misused extended-release and long-acting opioids during 2007—up from 29 million just five years earlier. And in 2006, nearly 50,000 emergency room visits were related to opioids.

The new REMS plans are to be designed to improve pain management while preserving patient access to these needed medications. Toward that end, the FDA indicates that the new REMS plans should focus on the following:

1. Educating doctors about proper pain management;
2. Proper patient selection; and
3. Improving patient awareness about how to use these drugs safely.

Arnall Golden Gregory LLP
Attorneys at Law
171 17th Street NW
Suite 2100
Atlanta, GA 30363-1031
404.873.8500
www.agg.com

As part of the plan, the FDA wants companies to give patients education materials, including a medication guide that uses consumer-friendly language to explain safe use and disposal.

Doctor training, patient counseling and other risk reduction measures developed by opioid makers as part of the REMS are expected to become effective by early 2012. They will be required for various brand name and generic products known under the generic names:

- Hydromorphone;
- Oxycodone;
- Morphine;
- Oxymorphone;
- Methadone;
- Transdermal fentanyl; and
- Transdermal buprenorphine.

At this time, the opioid REMS education program will not include a mandatory physician training requirement linked to the ability of healthcare professionals to prescribe long-acting and extended-release opioids. The FDA is concerned that such a system at this time would be overly burdensome on the healthcare system and could negatively impact access to these necessary medications. In addition, it would require the establishment of a new system for registering prescribers of long-acting and extended-release opioids that would duplicate the existing Drug Enforcement Administration (DEA) registration system. However, as part of the long-term comprehensive action plan to address the national prescription drug abuse epidemic, the Obama administration intends to seek legislation to require prescriber education as a condition of obtaining DEA registration.

If this legislation is enacted, it will require mandatory education without requiring the manufacturers to create a duplicative registration system. The FDA intends to work with other federal agencies, including the Departments of Justice, Health and Human Services, Veterans Affairs and Defense to support such legislation. As an interim step, the FDA will require manufacturers of long-acting and extended-release opioids to monitor their REMS plans to determine how many prescribers are completing the educational programs and whether the REMS is adversely affecting patient access to necessary pain medications. If the FDA determines that the REMS plan is not meeting expectations, the agency will reevaluate the program.

As part of the announcement, the FDA published a list of the brand name and generic opioid products that will be required to have a REMS (please click here to see the list)[1] and a summary regarding the REMS requirements for long-acting and extended-release opioids in question and answer format (please click here to view the summary).[2]

1 http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm251735.htm

2 http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm251752.htm