

Institute for Safe Medication Practices
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**Latest ISMP QuarterWatch Report
Raises Safety Concerns**

Horsham, Pa--- The Institute for Safe Medication Practices (ISMP) has released its QuarterWatch™ report for the third quarter of 2010, which identifies possible new safety issues with varenicline (Chantix), Liraglutide (Victoza), and (QUetiapine) Seroquel.

The QuarterWatch program analyzes reported adverse drug event data to improve patient safety by identifying safety “signals” that are substantial enough to warrant further investigation.

Signals included in the latest report are:

Varenicline (CHANTIX) risks underestimated. It has recently come to light that hundreds of older serious psychiatric adverse event reports regarding Chantix were not initially entered into the FDA Adverse Event Reporting System (AERS), per usual procedure. Most notable were 150 cases of completed suicides, some dating back to 2007. These suicides were submitted amid hundreds of other less serious reports. Until July 2010, FDA safety analysts were not aware of more than half of the reported suicide cases in which Chantix was the primary suspect drug, and did not have available hundreds of other reported cases of serious psychiatric side effects. So much missing data could have led at the time to an underestimation of the risks of Chantix.

Liraglutide (VICTOZA) and pancreatitis. The QuarterWatch report notes possible signals for pancreatitis and other adverse effects within 9 months of the 2010 launch of Victoza. FDA approval of this drug was controversial because of uncertainty about its cardiovascular risks, and because animal studies showed an increased risk of thyroid cancer. Early adverse event reporting did not speak to these still unresolved issues, but did reveal a marked signal for pancreatitis.

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QUetiapine (SEROQUEL) and irreversible injury. QUetiapine shares with other antipsychotic drugs the risk that some of its most common side effects can be irreversible, notably some cases of diabetes and certain movement disorders. In the third quarter of 2010, hundreds of new reported cases of diabetes associated with QUetiapine appeared, together with a smaller number of reports of dyskinesia (involuntary muscle movements), dystonia (spasms or prolonged contractions), and parkinsonism (tremors or muscle rigidity).

More information and additional signals from other drugs are described in the full third Quarter 2010 QuarterWatch™ Report at: <http://www.ismp.org/quarterwatch/2010Q3.pdf>.

About ISMP: The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit charitable organization that works closely with healthcare practitioners and institutions, regulatory agencies, consumers, and professional organizations to provide education about medication errors and their prevention. ISMP represents more than 35 years of experience in helping healthcare practitioners keep patients safe, and continues to lead efforts to improve the medication use process. ISMP is a federally certified patient safety organization (PSO), providing healthcare practitioners and organizations with the highest level of legal protection and confidentiality for patient safety data and error reports they submit to the Institute. For more information on ISMP, or its medication safety alert newsletters and other tools for healthcare professionals and consumers, visit www.ismp.org.

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