Zithromax (Azithromycin) And Zmax Associated With Liver Failure And Pyloric Stenosis, Respectively

FDA Is Continuing To Evaluate These Emerging Drug-Safety Issues To Determine Whether Any Regulatory Action Is Needed

(Posted by Tom Lamb at www.DrugInjuryWatch.com on July 1, 2010; see http://bit.ly/bdEp8f)

In mid-May 2010 we wrote an article "Zithromax-Induced Liver Injury Case Report Where There Was No History Of Liver Problems".

It seems that Zithromax also had the attention of the FDA at about the same time.

On July 1, 2010 the FDA posted on its web site "Potential Signals of Serious Risks/New Safety Information Identified by the Adverse Event Reporting System (AERS) January - March 2010", which had listed, among other possibly unsafe drugs, Zithromax (azithromycin) and Zmax (azithromycin extended release 2 g). The side effect under scrutiny for Zithromax, according to this FDA document, is liver failure, while the side effect being looked at for Zmax is pyloric stenosis -- which is defined as "narrowing of the pyloric opening (as from congenital malformation or contraction of scar tissue)".

We point out that each Potential Signals list issued by the FDA -- which the agency describes as "showing newly identified potential signals of serious risks/new safety information identified from the [Adverse Event Reporting System (AERS)] database during the previous quarter" -- includes this important "disclaimer" language:

> The appearance of a drug on this list does not mean that FDA has concluded that the drug has this listed risk. It means that FDA has identified a //potential safety issue//, but does not mean that FDA has identified a causal relationship between the drug and the listed risk. If after further evaluation the FDA determines that the drug is associated with the risk, it may take a variety of actions including requiring changes to the labeling of the drug, requiring development of a Risk Evaluation and Mitigation Strategy (REMS), or gathering additional data to better characterize the risk.

Another antibiotic, Biaxin (clarithromycin), also appeared on the Potential Signals list issued by the FDA in July 2010, with the side effect being liver failure, also.

We will continue to monitor the safety profile of Zithromax and Zmax, as well as Biaxin, and will report significant developments, *e.g.*, any FDA regulatory action in the future, here on Drug Injury Watch.

Attorney Tom Lamb represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.
http://www.DrugInjuryWatch.com