A New Year's Resolution For The FDA, As Recommended By The GAO

FDA Needs To Restructure Its Staff In Order To Better Monitor Emerging Drug Safety Issues

(Posted by Tom Lamb at www.DrugInjuryWatch.com on December 23, 2009; see http://bit.ly/5JTQPU)

In mid-December 2009 the Government Accounting Agency (GAO) -- often referred to as the federal government's watchdog agency -- issued a report which was critical of the slow rate of change at the FDA as regards better monitoring of drug safety issues.

In preparing his December 9, 2009 article, "GAO: FDA yet to make safety changes post-Vioxx", *Associated Press* (*AP*) reporter Matthew Perrone reviewed a copy of this December 2009 GAO report.

From the December 9 *AP* article, here are this reporter's observations about some points raised in the GAO's December 2009 FDA report:

- Agency officials have made some changes to drug oversight, according to a Government Accountability Office report, but the FDA continues to give the bulk of its decision-making power to scientists who approve new drugs, rather than those who monitor the side effects of drugs on the market.

- The watchdog agency's report calls on the FDA to set a timetable for transferring new responsibilities to the surveillance office.

- The FDA said it intends to give the surveillance office more responsibilities, but only after its nearly 200 employees gain the experience and resources needed to take on those tasks. The Office of New Drugs has more than 900 employees.

- According to the GAO, the number of surveillance staffers would have to double in coming years to accommodate the additional work being assigned to the unit.

As pointed out by Perrone in his article, drug safety experts outside of the FDA contend that emerging drug safety issues should not be handled by the same FDA scientists who were involved with reviewing new drug applications -- that is, those who work in the FDA's Office of New Drugs.

Returning to the December 9 *AP* article:

> "There's this desire on the part of the people who first approved the drug to say, 'We predicted everything and it's fine,'" said Dr. Diana Zuckerman of the National Research Center for Women and Families in Washington.
>
> Zuckerman and others say such decisions should be made with equal input from the FDA's office for monitoring reports of side effects collected from across the country.
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> The GAO, the Institute of Medicine and other experts have long recommended that the so-called Office of Surveillance and Epidemiology be given equal authority on drug safety with the agency's Office of New Drugs. But GAO investigators report that FDA leaders still have not transferred key responsibilities to surveillance officials.

Hopefully, the FDA will adopt this drug safety-related recommendation from the GAO and others as its New Year's resolution for 2010.

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.
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