Many Patients Mistakenly Believe That A Prescription Drug Must Be Safe If FDA-Approved

Safety Problems With New Medications Often Appear Only After Approval And Widespread Use

(Posted by Tom Lamb at www.DrugInjuryWatch.com on September 20, 2011; see http://bit.ly/qfacS6)

A medical journal article published in the September 12, 2011 edition of the *Archives of Internal Medicine* has given some profile to the myth that just because the FDA has approved a prescription drug it must be safe to use.

We start with a couple of brief excerpts from the Abstract for this article, "Communicating Uncertainties About Prescription Drugs to the Public":

> **Background** Many new drugs are aggressively promoted. The public may not realize that even with US Food and Drug Administration (FDA) approval, important uncertainties about the benefits and harms of these drugs remain....
>
> **Conclusions** A substantial proportion of the public mistakenly believes that the FDA approves only extremely effective drugs and drugs lacking serious side effects.

We move next to some comments and observations about this medical journal article which were presented in this September 12, 2011 news report, "Public Often Unaware of a Drug's Safety Record -- Or Lack of One", by *HealthDay* reporter Alan Mozes.

First, from Dr. Michael Carome, deputy director of Public Citizen's Health Research Group in Washington, D.C.:

> Patients need to be aware that almost any drug has potential side effects," he said. "And for newly approved drugs there's often insufficient information about serious risks, some of which may have gone undetected during the approval process and won't be detected until they're used in the real-world setting on a wide-scale basis.... Unless a new drug is a breakthrough medication for a condition for which there were no previously good options, we recommend that people not take it for at least seven years.

Second, Harvard University's Daniel Carpenter, a professor of government, weighs in:

> ...the term "FDA-approved" gives patients a mental and emotional security about a drug.... So I'm in sympathy with the policy recommendation that patients ought to be made aware, for example, that we know less about an FDA-approved drug that has been on the market for a day or a year than we do about drugs that have been on the market for five or 10 years.

Because this is the situation, doctors and patients have a role in helping the FDA identify emerging drug-safety issues. From the agency's "Reporting Serious Problems to FDA" page:

> In order to keep effective medical products available on the market, the FDA relies on the voluntary reporting of these events. FDA uses these data to maintain our safety surveillance of these products. Your report may be the critical action that prompts a modification in use or design of the product, improves its safety profile and leads to increased patient safety.

Here are links to two pages at our web site, Drug Injury Law, which will tell you more about the FDA's MedWatch program and how to submit a report:

http://www.druginjurylaw.com/drug-injury-reporting.html

http://www.druginjurylaw.com/medwatch-report.html

The September 12 *HealthDay* news reports concludes in this manner:

> Writing in the same [*Archives of Internal Medicine*] issue, Dr. Deborah Grady, of the department of medicine at the University of California, San Francisco, recommended that the job of selecting the safer, better drug be left to properly trained clinicians.

We agree wholeheartedly with that point.

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