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Criminal Penalties for Off-Label Drug Marketing: Will They Make a Difference?

The Food and Drug Administration has unleashed a new tool for ensuring the regulation of foods and drugs. The FDA has begun using the "Park Doctrine" for the imposition of criminal sanctions against pharmaceutical companies for violations of FDA regulations.

The FDA is targeting the illegal promotion of products for unapproved uses. The practice is known as off-label marketing and is fairly widespread. The FDA has brought back the Park Doctrine after years of dormancy with the realization that civil penalties, no matter how steep, seem to have no deterrent effect on the practice.

The 1970's Supreme Court case of *United States v. Park* ruled that company executives may be held criminally liable for willful violations of FDA regulations. The criminal penalties typically include fines. However, the FDA has expressed the intention to also seek jail time for those executives responsible for the illegal acts.

The FDA recognizes that the profit motive overcomes the threat of fines, whether criminal or civil. The threat of actual prison time is hoped to be more of a deterrent. Off-label marketing is clearly profit driven and until the profit equation is tipped in favor of public safety, the practice will continue.

These practices are both widespread and widely accepted by pharmaceutical companies and doctors alike. There are numerous ongoing lawsuits, criminal cases and criminal investigations related to these practices. It remains to be seen whether the FDA will hold true to its threat of jail time for guilty executives. It also remains to be seen whether even a threat of a little jail time will tip the profit loss calculation sufficiently for these folks to stop skirting the law.

These cases are interesting for a number of reasons. First and foremost these practices risk the health and safety of patients. Related to this is the fact that both medical industry and the pharmaceutical industry are among the strongest proponents of caps on personal liability awards. They argue that it is trial lawyers that harm the public and threaten public health.

Even President Obama has jumped on the Tort Reform bandwagon suggesting support for medical malpractice caps. There is no disputing that medical malpractice is on the rise, while actual successful medical malpractice claims are

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on the decline. Neither is there a dispute that wrongful prescription of drugs for financial gain is commonplace. Finally, there is absolutely no disputing that medical malpractice and pharmaceutical company off-label marketing harm the public. So why the continued calls for personal injury liability caps?

Let's start over. It has become a widespread practice of pharmaceutical companies to actively market through financial incentives for cooperating doctors the use of their drugs beyond their FDA approved uses. The practice is called off-label marketing...

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