OIG Reports FDA Approved Drugs without Following Federal Safety Laws

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(NaturalNews) The Office of Inspector General (OIG) has just released a damning report on the FDA's drug approval process which provides clear evidence the FDA has approved drugs without following required legal procedures. Specifically, the Food and Drug Administration does almost nothing to police the financial conflicts of doctors who conduct clinical trials of drugs and medical devices in human subjects, government investigators report.

The OIG investigation of the FDA drug approval process found that in 2007 the FDA approved numerous new drugs without complete information; specifically conflict of financial interest information of clinical trial investigators.

The Office of Inspector General, as mandated by law, is the government agency responsible for making sure the FDA is abiding by Federal law and properly following procedure and protocol to assure the safety of human and animal drugs, medical devices and foods. A critical area of oversight is making sure there have been no financial conflicts of interest such as drug companies providing stock or other financial incentives to doctors to insure that their drugs are approved and rushed to market as soon as possible.

The report from the OIG provides clear cut evidence the FDA is NOT doing that job and not following proper protocol required by Federal law.

Here are some of the findings:

- Only one percent of clinical investigators disclose a financial interest.

- 42 percent of FDA-approved marketing applications were missing financial disclosures. Companies are required to disclose any financial interests with the companies they are conducting trials for, but the HHS report found that in 42 percent of the trials, the FDA did not receive the required forms.

- 23% of 2007's approved drugs and approved medical devices were missing required attachments.

- 31% of the 2007 FDA approved drugs and approved medical devices showed the FDA did not document any financial information.

When there were financial conflicts, in 20 percent of applications, the FDA reviewers did not take action.

In 1999, the FDA required drug and device makers to divulge any conflicting interests with doctors who oversee patients involved in clinical trials. The companies are supposed to disclose that information to the FDA, but the inspector general found there was almost no enforcement of those rules. The new report clearly shows that the The Food and Drug Administration (FDA) continue to have a hands-off policy over conflicts.

The New York Times reported that the FDA admitted that the efforts to try and protect patients from such conflicts is, "not worth the effort". FDA spokeswoman Karen Riley offered up the lame excuse that the agency opposed reviewing doctors' financial conflicts before trials because they represented just one possible source of bias.

Conflicting interests between drug companies and researchers conducting clinical drug/device trials is a story that makes the headlines almost weekly, especially since the research generated often dictates the prescriptions doctors write nationwide. The new federal inquiry feeds a growing debate and sense of outrage over the FDA's cozy relationship with the drug companies it is supposed to oversee and about how money that doctors collect from drug and device makers may hurt patients and skew studies.

The Department of Health and Human Services (HHS) inspector general report issued Monday reviewed 118 clinical trials marketing applications approved by the FDA in 2007.

To read the full Inspector General report: http://www.oig.hhs.gov/oei/reports/oei-...