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Document: FDA-2010-N-0155-DRAFT-2248 Comment from JEAN PUBLIC, NA

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General Comment

THIS AGENCY LISTENS TO THEIR PAL STAKEHOLDERS. STAKEHOLDER IS A CODE WORD USED TO HIDE THE FACT THAT THEY ARE PALS OF THE AGENCY AND THAT THE AGENCY ONLY LISTENS TO THEM. THIS AGENCY TAXES THE ENTIRE AMERICAN PUBLIC FOR ITS OPERATIONS, BUT IT RSPONDS ONLY TO ITS PAL STAKEHOLDERS. THE CORRUPTION IN THE FDA IS BEYOND BELIEF THESE DAYS. GENERAL TAXPAYERS/CITIZENS ARE IGNORED ROUTINELY. THIS NEW REGULATIONS IS AS LOOSE AS CAN BE AND ENABLES ANIMALS TO BE DROWNED IN TOXIC CHEMICALS TO MAKE THEM GROW BIG AND QUICKLY, ALL TO THE DETRIMENT OF THE HEALTH OF BOTH THE ANIMNALS AND THE AMERICAN PUBLIC .THIS NEW RULE STINKS. IT HAS DONE LITTLE TO NOTHING TO CORRECT THE ABYSMAL ABUSIVE TREATMENT OF ANIMALS HEALTH. FDAI SI A PIMP FOR RICH CORPORATIONS. YOU CAN SEE HOW THE FOOD MFS PAY HUGE HUGE SUMS AND THEY GET THEIR WAY AT THE FDA. THIS WAS A RECENT REPORT ON THE FDA AND ITS MAKEUP: NaturalNews) It is now an undeniable fact that the pharmaceutical industry weaseled its way onto key U.S. Food and Drug Administration (FDA) advisory panels, which were instrumental in shaping the way drugs are safety tested and approved. According to The Washington Post (WP), a recent public records request has revealed that drug companies purchased special access onto these panels, where they were given the keys to the kingdom in swaying decision-makers about official drug policy.

Based on critical information gathered from leaked emails, pharmaceutical companies have doled out hundreds of thousands of dollars over the years to attend private meetings with the FDA, many of which were geared towards the regulation and approval of painkiller drugs. Drug companies would reportedly shell out upwards of \$25,000 or more per meeting to have their voices heard, a small price to pay for direct access to the \$9 billion American painkiller market.

According to the WP, officials from both the FDA and the U.S. NatL Institutes of Healthwould regularly meet with pharma representatives in private to discuss regulatory protocols, co-write scientific papers and collaborate on various ways to help streamline the drug approval process. And the only parties who actually paid to attend such meetings were the drug companies, a fact that one

official from the NIH expressed serious concerns about in an email, referring to the whole scheme as a "pay to play process."

Others who have since reviewed the emails agree, noting that, while the FDA did not necessarily benefit financially from these private meetings, many FDA officials went on to work as pharmaceutical consultants. In other words, FDA staff who agreed to grease the palms of the drug industry during these private meetings were later rewarded with high-paying positions in the drug industry. This is just one glaring example of how the line between the regulator (FDA) and the regulated (pharmaceutical companies) has been blurred beyond recognition.

"These e-mails help explain the disastrous decisions the FDA's analgesic division has made over the last 10 years," said Craig Mayton, the Columbus, Ohio, attorney who made the public records request to the University of Washington, to the WP. "Instead of protecting the public health, the FDA has been allowing the drug companies to pay for a seat at a small table where all the rules were written."

Big Pharma, FDA corruption runs deep

It is no longer a conspiracy theory, then, that the drug industry owns the FDA. In this particular case, it was two academics by the names of Robert Dworkin, from the University of Rochester, and Dennis Turk, from the University of Washington, who allegedly orchestrated the painkiller plot. But there have been many other plots with the same ultimate end, a fact that NaturalNews and many others in the so-called "alternative" media have been shouting from the rooftops for years, but that the mainstream media has ignored, until now.

"Shame on the FDA and NIH for sending representatives to this panel, cooked up by two unethical professors and their drug company cronies," wrote one WP commenter about the scandal. It should be noted that FDA officials actively participated in the painkiller scheme, all the while knowing full well that the private meetings they attended were hatched by Big Pharma. "Congress should come down hard on both agencies for participating in what was clearly pay-to-play, with awful consequences for the health of many suffering Americans."

Such consequences include a flood of dangerous analgesic drugs to the market that were approved based on questionable flawed safety studies. According to MedpageToday.com, the drug industry was successful during these meetings in convincing the FDA to adopt an "enriched enrollment" guidance for safety trials that eliminated patients who experienced adverse reactions. These and other modifications made it much easier for drugs to be declared safe and effective, and thus gain rapid

approval.http://www.washingtonpost.comhttp://www.medpagetoday.comhttp://seattletimes.com