Written by **Michael Tennant** on May 17, 2016

FDA: Popular Antibiotics Have Serious Side Effects

The Food and Drug Administration (FDA), the agency charged with preventing harmful drugs from coming to market, recently confessed that certain antibiotics it approved can have "serious side effects" that "generally outweigh the benefits" — an admission sure to give a shot in the arm to a lawsuit claiming that a former FDA commissioner suppressed information about these side effects for personal gain.

On May 12, the FDA issued a safety alert concerning fluoroquinolone antibacterial drugs. Such drugs "are associated with disabling and potentially permanent serious side effects that can occur together," reads the alert. "These side effects can involve the tendons, muscles, joints, nerves, and central nervous system." The agency is requiring changes to drug labels to reflect these potential side effects and asking physicians to stop treating patients with the drugs if they experience any of the side effects.

Many fluoroquinolones have been in use for years. Levaquin, a fluoroquinolone manufactured by Johnson & Johnson, was approved by the FDA in 1996.

Despite mounting evidence of the dangers of these drugs, however, the agency has been extremely slow to warn the public. Attorney Larry Klayman, a former federal prosecutor, thinks he knows why and has filed a federal racketeering lawsuit to prove it.

The suit, filed on behalf of several patients who were harmed by Levaquin, alleges that Dr. Margaret Hamburg, who served as FDA commissioner from 2009 to 2015, used her position of authority to suppress information about Levaquin's side effects in order to enrich herself, her husband, and Johnson & Johnson. The lawsuit names Hamburg; her husband, Peter Brown, a hedge-fund manager at New York-based Renaissance Technologies; Brown's partners; and Johnson & Johnson as co-defendants.

At the time of her appointment as FDA head by President Barack Obama, Hamburg and her husband were forced to divest themselves of most of their holdings in Renaissance Technologies and other drug-company stocks. However, as part of Renaissance's profit-sharing model, Brown continued to reap financial rewards from all the company's holdings, which included significant amounts of stock in both Johnson & Johnson and Alkermes, another pharmaceutical company Klayman accuses Hamburg of using her position to assist.

According to the complaint, during Hamburg's tenure as FDA commissioner, evidence of "debilitating, life-threatening, and deadly illnesses and effects" related to Levaquin poured into the FDA, but Hamburg refused to act on this evidence "because of her personal financial interest in maintaining Levaquin's branding as 'status quo'" so as not to harm Johnson & Johnson's stock price. The FDA's Adverse Event Reporting System recorded 8,000 injuries and 500 deaths associated with Levaquin during Hamburg's tenure, the complaint states. Since the agency estimates that only 10 percent of adverse events are actually reported, this could translate into as many as 85,000 Levaquin-related injuries or deaths over six years. Furthermore, plaintiffs say, numerous individuals, including elected officials and medical experts, petitioned the FDA to require additional side-effect warnings on

Levaquin's label. Also, "Hamburg received hundreds of emails from individuals who had severe Levaquin adverse effects" and did not act on the information, the lawsuit alleges.

The FDA did add some warning labels to Levaquin in 2013, but these only hinted at the dangers the drug presents, plaintiffs argue, noting that only in November 2015, eight months after Hamburg's resignation, did an FDA advisory committee finally recommend more comprehensive warnings. On the same day as that recommendation was issued, FDA employee Debra Boxwell "finally exposed to Plaintiffs, and the public at large, that Defendant Hamburg and the FDA had been aware that Levaquin may result in multi-system disability since 2013, but that it did nothing to add this information to the Levaquin label and instead conspired with the other Defendants to fraudulently withhold it," reads the complaint.

Hamburg's financial interest in Alkermes also led her to buck an FDA advisory board's overwhelming opinion that the company's painkiller Zohydro should not be approved, plaintiffs charge. Although the advisory board voted 11-2 not to approve the drug because of its potential for abuse, the agency nevertheless approved it. Shortly thereafter, 28 state attorneys general petitioned the FDA to rescind its approval, and Senator Joe Manchin (D-W.V.) introduced legislation to do so. Hamburg, however, defended the FDA's actions before a Senate committee.

That Hamburg, her husband, his partners, and the makers of Levaquin and Zohydro benefited from the Hamburg FDA's actions is beyond dispute. "Both Alkermes and Johnson & Johnson stock value increased significantly during Hamburg's tenure, according to Yahoo Finance historical data," reported the *Daily Caller*. In the months leading up to the FDA's approval of Zohydro — a move one would think unlikely given the advisory board's opinion — Renaissance vastly increased its holdings of Alkermes stock, the complaint claims. Brown and his partner Robert Mercer also did well for themselves, earning, by *Forbes*' estimate, $90 million each in 2012.

The question, then, is whether Hamburg acted as she did in order to profit or whether that was just a happy coincidence. As Qmed.com points out, "The complaint … lacks a smoking gun that ties the two together." Perhaps the legal process will uncover one; perhaps not.

Both Hamburg and Johnson & Johnson have repeatedly denied any wrongdoing. Hamburg's attorney has stated that Klayman's allegations are "patently false, reckless and offensive." Johnson & Johnson's boilerplate response: "We stand behind Levaquin and believe our actions regarding the medicine have been appropriate, responsible and in the best interests of patients."

Klayman, for his part, had this to say in a press release: "The alleged criminal … corruption we are seeking to remedy in this case is typical of … the sleazy politicians of both political parties that infest Washington, D.C. It helps explain why the political establishment and their lobbyist friends at companies like Johnson & Johnson are being shown the door by the voters during this year's election. By asking for over $120,000,000 in damages and $750,000,000 in punitive damages, if the victims are successful, they will put a chink in the sides of these alleged criminals and send a loud message that this misconduct will no longer be tolerated."

Another message that needs to be heard is that putting control of the pharmaceutical market into the hands of political appointees and bureaucrats is a recipe for corruption. The FDA regulates drug companies, who in turn supply employees to the FDA, and vice versa. Hamburg herself had served on the board of directors of a major healthcare corporation between her stints in government, she appointed former Johnson & Johnson officials to FDA posts, and at least one of her appointees went on

to work for the company.

In addition, the very existence of the FDA lulls many Americans into a false sense of security concerning drugs. If the FDA approves a drug, they reason, it must be safe; yet clearly that is not the case. Without the government giving its imprimatur to certain drugs, consumers would be far more wary and would seek out additional sources of information on those drugs before consuming them, as many already do.

As long as the FDA is here to stay, though, such abuses as alleged in Klayman's lawsuit, if they occurred, need to be rectified.