FOIA and Drug Safety

FOIA has revealed disturbing problems involving drug-safety production, distribution, and administration involving federal agencies. This coverage has also revealed limits – which erode the public interest in having the safest healthcare system possible.

FOIA serves as an essential tool to uncover problems in government. Following are only a few examples:

- **A chemical being phased out of handsoap and other products remains in America's third-most-popular brand of toothpaste, seventeen years after the FDA accepted the manufacturer's claims that negative toxicology data in studies were unimportant.** ("Colgate Total Ingredient Linked to Hormones, Cancer Spotlights FDA Process," Bloomberg News, August 11, 2014; http://www.bloomberg.com/news/2014-08-11/in-35-pages-buried-at-fda-worries-over-colgate-s-total.html);

- **Drugmakers agreed to put "flow restrictor" valves on bottles of children's acetaminophen to reduce accidental overconsumption, but not on other medications, despite the safety benefits and minimal cost.** ("The Fix Isn't In: Why a Safety Device That Can Stop Overdoses by Kids Isn't Widely Used," ProPublica, December 30, 2013; http://www.propublica.org/article/why-a-safety-device-that-could-prevent-thousands-of-drug-accidents-by-kids);

- **Acetaminophen, commonly available in Tylenol and similar products, has been a popular pain-relief medication for decades – but for decades Tylenol's maker has opposed measures meant to insulate users from accidental overdoses, and for decades the FDA has failed to complete safety rules for the ubiquitous pain reliever.** ("Use Only as Directed," ProPublica, September 20, 2013; http://www.propublica.org/article/tylenol-mcneil-fda-use-only-as-directed);

- **A Houston research firm which tested drugs for a global array of companies was found to have distorted test results, casting the efficacy of about 100 drugs into doubt – but the FDA issued no public warnings and left some drugs on the market despite lacking additional independent confirmation of the drugs' safety.** ("FDA Let Drugs Approved on Faulty Research Stay on the Market," ProPublica, April 15, 2013; http://www.thewire.com/technology/2013/04/fda-let-drugs-approved-fraudulent-research-stay-market/64231/);

- **A drug designed to combat anemia was billed as safe, and more valuable, at higher dosages, but a trial revealed that patients receiving the higher dosage were dying or having heart attacks at higher rates; "quality-of-life" benefits were also not substantiated.** ("Anemia drugs made billions, but at what cost?" Washington Post, July 19, 2012; http://www.washingtonpost.com/business/economy/anemia-drug-made-billions-but-at-what-cost/2012/07/19/gJQAX5yqwW_story.html);

- **A whistleblower reported a North Carolina plant for unsanitary manufacturing conditions which contributed to five deaths and sickened hundreds, but an FDA inspector investigating the company for another complaint went to an abandoned facility and found nothing, and then a month later was led around the current facility by company leaders, and found only a labeling problem.** ("Records: Whistleblower at syringe plant warned FDA," Associated Press,

March 20, 2009; http://www.azcentral.com/news/articles/2009/03/20/20090320tainted-syringes0320-ON.html).

But FOIA has its limits.

- **Access to agency information does not guarantee timely agency action, or even reaction; the FDA began reviewing the risk of non-therapeutic use of antibiotics in 1970… and hopes to phase out the unnecessary drugs by 2017**. ("New Report Says FDA Allowed 'High Risk' Antibiotics to be Used on Farm Animals," Time (magazine), January 28, 2014; http://time.com/2825/new-report-claims-fda-allowed-high-risk-antibiotics-to-be-used-on-farm-animals/);

- **Despite federal oversight and regulation, and FOIA's disclosure requirements, a determined drugmaker deflected safety concerns for over four decades – and continues to do so**. ("Use Only as Directed," ProPublica, September 20, 2013; http://www.propublica.org/article/tylenol-mcneil-fda-use-only-as-directed);

- **The FDA took over three years to respond to a FOIA request for records of the actual results of a drug trial – giving a drugmaker-funded article a head start**. ("Anemia drugs made billions, but at what cost?" Washington Post, July 19, 2012; http://www.washingtonpost.com/business/economy/anemia-drug-made-billions-but-at-what-cost/2012/07/19/gJQAX5yqwW_story.html);

- **Even though the FDA released inspection reports regarding violations at a drug plant in consecutive years, culminating in a warning letter after the third year's inspection, the agency refused to voluntarily release the most recent inspection report without a FOIA request**. ("'Significant' offenses cited at Mylan plant," Pittsburgh Post-Gazette, November 23, 2011; http://www.post-gazette.com/pg/11327/1191924-28.stm).