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Florida's Public Health Integrity Committee Addresses FDA's Inconsistent Drug Approval and Advertising Protocols

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Tallahassee, Fla.— Yesterday, Florida's Public Health Integrity Committee (PHIC), led by State Surgeon General Dr. Joseph A. Ladapo, held a meeting to discuss potential harms of the United States Food and Drug Administration's (FDA) inconsistent process for drug approval and lack of regulation of pharmaceutical advertising. Florida's PHIC members expressed concerns regarding the revolving door between the FDA and the pharmaceutical industry, the FDA's inadequate safety standards, and the lack of enforcement of pharmaceutical data requirements. Based on the PHIC's concerns, Florida is calling on the FDA to enforce greater oversight of the pharmaceutical industry and bring transparency to consumers on the lack of data within the current regulatory processes in place.

ISSUE #1: The FDA has a two-tier review process, allowing manufacturers to potentially skip clinical trial steps for some drugs.

When the Prescription Drug User Fee Act (Act) was passed in 1992, pharmaceutical developers were required to pay increased fees to the FDA for review of their applications, including requests for expedited review. "Accelerated Approval," "Breakthrough Therapy," "Fast Track Program," and "Priority Review" allow "earlier approval of drugs that treat serious diseases or drugs that fill an unmet need." The "Accelerated Approval" waives clinical trial requirements and allows FDA to approve the drug based on other data, such as blood testing or imaging. The "Fast Track" program allows the industry to submit information on a rolling basis rather than a complete application. Overall, nearly two thirds of the FDA's medical product budget come from industry and nearly half of the total FDA budget now comes from industry user fees. This has increased substantially over the last two decades, leading some critics to raise concerns that the agency prioritizes the pharmaceutical industry's agenda over the health and safety of patients.

While such opportunities seem altruistic, the FDA is approving more drugs than ever, and evidence shows it has allowed Big Pharma to cut corners on drug safety and efficacy. The opioid crisis exemplifies how Americans can experience the catastrophic effects of these risks. While the FDA typically requires at least two randomized controlled trials demonstrating clear effectiveness against specific conditions, extended-release oxycodone received approval based on only one two-week clinical trial among osteoarthritis patients. The FDA then allowed the labeling of this opioid to be prescribed broadly for many conditions resulting in Purdue Pharma promoting the drug for off-label treatment which is typically prohibited.

This pattern has also been observed among oncology therapeutics that are approved based on the apparent size of a tumor on a scan or image rather than how the medications affect the patients' survival or quality of life. At the same time, it can take nearly four years for accelerated cancer treatments to be withdrawn by the FDA when they are found to be harmful or ineffective.

The federal response to COVID-19 has further shed light on these regulatory errors and continued lack of transparency. Following the FDA's approval of the mRNA COVID-19 vaccine, both Pfizer and Moderna were instructed to conduct clinical trials investigating the effects of subclinical myocarditis. Neither Pfizer or Moderna have published or communicated to the public results from these studies nor do advertisements for the COVID-19 vaccines warn of the established risks of the products.

ISSUE #2: According to the FDA, there have been more than 15,000 drug recalls since 2012 – averaging more than three drug recalls per day.

Recently, the FDA recalled popular over-the-counter cold and allergy medications that contain oral phenylephrine as a nasal decongestant, nearly 50 years after its initial approval. At the time of approval, the FDA didn't use adequate clinical data on the drug. Now, the FDA has considered the drugs' clinical symptom scores that indicated ineffectiveness. For decades, families wasted time and money on ineffective medications based on "murky" evidence. Another example is, Makena, a drug approved to reduce the risk of preterm birth; however, the FDA finally removed it from the market 20 years after it had not only been repeatedly found to be ineffective but also carried increased risks of preterm birth and miscarriage.

ISSUE #3: Drug advertising is not reviewed for accuracy prior to public consumption.

The United States and New Zealand are the only two countries that allow drug manufacturers to market advertisements as "Direct-To-Consumer" (DTC). In 2015, a survey conducted by the FDA published that while "many DTC ads helped patients be more involved in their health care," the data indicated that about 75 percent of physicians believe that such ads cause patients to think that the drug works better than it does and pressure providers to prescribe something when patients mention such ads.

While the FDA requires prescription drug advertisements to include certain disclaimers, they do not see or approve drug advertisements prior to reaching consumers' televisions or phones. As soon as a drug receives approval, accelerated or not, manufacturers are able to advertise the drug. The FDA has acknowledged this unfortunate reality and states advertisements "may violate federal laws" as they are being viewed by the public until the ad is corrected or withdrawn.

In this spirit of transparency and integrity regarding American health care, the PHIC has developed infographics outlining the drug approval and the direct to consumer advertising processes – from initial development to your prescription cabinet and screen.

"I want to thank all of our PHIC members for joining us today and for their continued dedication to preserving the health and well-being of all people," **said State Surgeon General Dr. Joseph A. Ladapo.** "Florida will continue to fight for truth and scientific integrity."

“The primary problem that we are seeing with the FDA is that it’s moving away from science when approving medications,” **said Dr. Linda Wastila.** “Relying on application fees and surrogate end points only further enables the revolving door of the pharmaceutical industry self-regulating itself.”

“The United States is in desperate need of a regulatory agency which prioritizes human health over pharmaceutical industry profits. One critical step in achieving this will be increased transparency from the FDA,” **said Dr. Tracy Beth Høeg.** “Raw, de-identified data from vaccine and pharmaceutical trials should be made available to the public. Timely information should be provided to the public on post-marketing surveillance studies as well as vaccine and drug product side effects. Finally, prior to drug and vaccine approval by the FDA, clinical trials should determine if the benefits of the medical products outweigh the risks for the population they are intended to be used in.”

“We saw in the COVID-19 pandemic how some exceptions, when abused, led to the harm of patients rather than their health and well-being,” **said Dr. Jay Bhattacharya.** “Rather than allowing pharmaceutical companies to conduct their own safety assessments, the FDA should conduct very rigorous phase 4 clinical trials.”

“Surrogate end points allow Big Pharma to avoid conducting proper clinical trials indefinitely,” **said Dr. Joe Fraiman.** “By continuing to expedite the regulatory approval process, the FDA is robbing Americans of the health and well-being they deserve.”

“The federal government should place a much heavier emphasis on phase 4 clinical trials,” **said Dr. Christine Stabell Benn.** “By taking the safety analyses out of the pharmaceutical industry’s hands, the FDA will be able to conduct the proper rigorous standardized trials that are necessary.”

“Unfortunately, due to the FDA growing more lackadaisical, the pharmaceutical industry does not carry the same reputation that it used to,” **said Dr. Martin Kulldorff.** “The conflicts of interest at bay are directly linked to political influences and the incredible amount of money circulating within the industry, leading to a complete lack of accountability.”

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