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A Note on Food and Drug Administration (FDA)

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Commentary

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DESCRIPTION

The Food and Drug Administration of the United States (FDA or USFDA) is a federal agency within the Department of Health and Human Services. Food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, Electromagnetic Radiation Emitting Devices (ERED), cosmetics, animal foods and feed and veterinary products are all under the FDA's control and supervision.

The FDA's major focus is on enforcing the Federal Food, Drug, and Cosmetic Act (FD&C), but it also enforces other laws and regulations, including Section 361 of the Public Health Service Act. Much of this regulatory effort is unrelated to food or medications, and includes items like regulating lasers, cell phones, and condoms, as well as disease control in settings ranging from domestic pets to human sperm donated for assisted conception. The types of products regulated, the hazards they pose, and the regulatory authorities assigned to the agency all influence the programmes. The FDA, for example, supervises practically every aspect of prescription medications, including testing, manufacturing, labelling, advertising, marketing, efficacy, and safety—yet the FDA only oversees labelling and safety in cosmetics. Most items are regulated by the FDA through a set of published standards that are enforced by a small number of facility inspections. Form 483 is used to record inspection findings.

The FDA also employs regulatory shaming measures, such as online disclosure of noncompliance, warning letters, and "shaming lists," to name a few. Companies' sensitivity to reputational damage is harnessed through shame regulation. For example, in 2018, the FDA produced an online "black list" in which it named hundreds of branded medicine companies that it claimed were using illegal or unethical tactics to stifle generic medication competition. Other federal agencies, such as the Department of Agriculture, the Drug Enforcement Administration, Customs and Border Protection, and the Consumer Product Safety Commission, frequently collaborate with the FDA. Regulatory inspections and enforcement measures are frequently performed in collaboration with municipal and state government authorities.

With the goal of resolving scientific and technical difficulties before they become barriers, the FDA conducts research and development to develop technologies and standards that support its regulatory mission. Biologics, medical devices, medicines, women's health, toxicology, food safety and applied nutrition, and veterinary medicine are among areas where the FDA conducts research. The widely publicised recall of Vioxx, a Non-Steroidal Anti-Inflammatory Medicine (NSAID) now suspected of contributing to thousands of fatal heart attacks in the United States, sparked a fresh wave of safety improvements at both the FDA rulemaking and statutory levels. Vioxx was approved by the FDA in 1999, and it was thought that it would be safer than other NSAIDs because of its lower risk of intestinal haemorrhage. However, results from the approve trial in 2004 firmly proved that Vioxx may raise the risk of myocardial infarction, as suggested by a number of pre- and post-marketing studies.

The Institute of Medicine appointed a Congressional committee in 2006 to study pharmaceutical safety regulation in the United States and make recommendations for improvements. The committee was made up of 16 experts from various fields, including clinical medicine, medical research, economics, biostatistics, law, public policy, public health, and allied health professions, as well as current and former executives from the pharmaceutical, hospital, and health insurance industries.

The FDA regulates a wide range of products that have an impact on people's health and lives in the United States. The existing FDA system for monitoring the safety of medications on the American market was deemed to have major flaws in a $1.8 million Institute of Medicine assessment on pharmaceutical regulation released in 2006. Overall, the authors advocated for the FDA's regulatory authority, budget, and independence to be increased.

The FDA has also been chastised for being overly severe on industry from the other side. According to a report published on the Mercatus Center's website, many people believe the FDA oversteps its regulatory authority and favours major corporations over small businesses and farms. The authors contend that the FDA is ill-equipped to regulate and inspect food in today's increasingly complex and diverse food market.

However, a 2011 study published in the Archives of Internal Medicine by Drs. Diana Zuckerman and Paul Brown of the National Research Center for Women and Families, and Dr. Steven Nissen of the Cleveland Clinic, found that most medical devices recalled in the last five years for "serious health problems or death" had previously been approved by the FDA using the less stringent "510(k)" approval process. In certain circumstances, the devices were found to be so low-risk that they did not require FDA approval. Due to the denial of PMTA applications, some businesses received a Marketing Denial Order (MDO). Some companies even argued that the FDA's choices were arbitrary.