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# The FDA Funding Crisis

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## Abstract

The role of the Food and Drug Administration (FDA) is to ensure the safety of prescription and nonprescription drugs, dietary supplements, and the food supply, representing more than 20% of US consumer spending. The increased need to monitor imported drugs, drug products and foods, drug shortages, and compounding pharmacies bring the adequacy of FDA funding into question. Performing even at status quo cannot be accomplished if responsibilities increase without equitable funding increases: both from the federal government and fees imposed on FDA-regulated industries. Additionally, scientific advancement, new legislation, and new industries are continually increasing the FDA workload, necessitating commensurate budget increases.

## Keywords

FDA, funding, drug compounding, safety, regulation, quality control

The Food and Drug Administration (FDA)–regulated products account for more than 20 cents of every dollar spent by US consumers, including approximately \$2 trillion of imported goods each year.<sup>1,2</sup> Although funding has been increasing over the past 10 years (Figure 1),<sup>3</sup> many factors, along with the 2013 sequestration, have led to tighter budget constraints and inadequacy in meeting its numerous responsibilities. The 2013 FDA budget is approximately \$4 billion combining congressional support and user fees, primarily pharmaceutical companies (including generic companies), but also from tobacco and device manufacturing companies. If sequestration reduces the 2014 budget by \$210 million as it has in 2013, the FDA will fall almost \$1 billion short of its \$4.7 billion 2014 budget request.<sup>1</sup>

Regarding the practice of pharmacy, the FDA protects patients by ensuring drug safety and efficacy, preventing drug shortages, monitoring dietary supplements, providing health education, and advancing medical countermeasures. Additionally, to meet stakeholder needs, funding expedites approval and improves postmarketing surveillance of generic drugs and biosimilars via generic drug manufacturer user fees. The United States is increasingly reliant on imported materials and drugs, yet only 1% of all imports are inspected, thus not keeping pace with this increased rate of imports (especially from China).<sup>2</sup> As it plays a major role in chemical, biological, radiological, and nuclear threat protection, the medical countermeasure programs can mitigate public health emergencies by providing drugs, vaccines, and diagnostic tests.<sup>1</sup>

The FDA's response to its budgetary challenges includes implementation of innovative, efficient clinical trial designs and better utilization of electronic health data, but these measures cannot replace needed funding for areas that will be negatively affected by a cut to the FDA budget,<sup>1</sup> specifically the following.

## Postmarketing Surveillance

Phase IV is crucial to the drug approval process. It detects side-effects not apparent during previous phases. Approximately 51% of adverse effects are not detected during the approval process.<sup>4</sup> While postmarketing surveillance and reporting of adverse effects is mandatory for pharmaceutical companies, it is voluntary for health care providers and consumers via the FDA's MedWatch and Sentinel Initiative, enabling reporting of adverse effects. It also provides consumer advisories of drug recalls and safety alerts. Compromises in phase IV surveillance may delay drug recalls or warnings with deleterious health outcomes.

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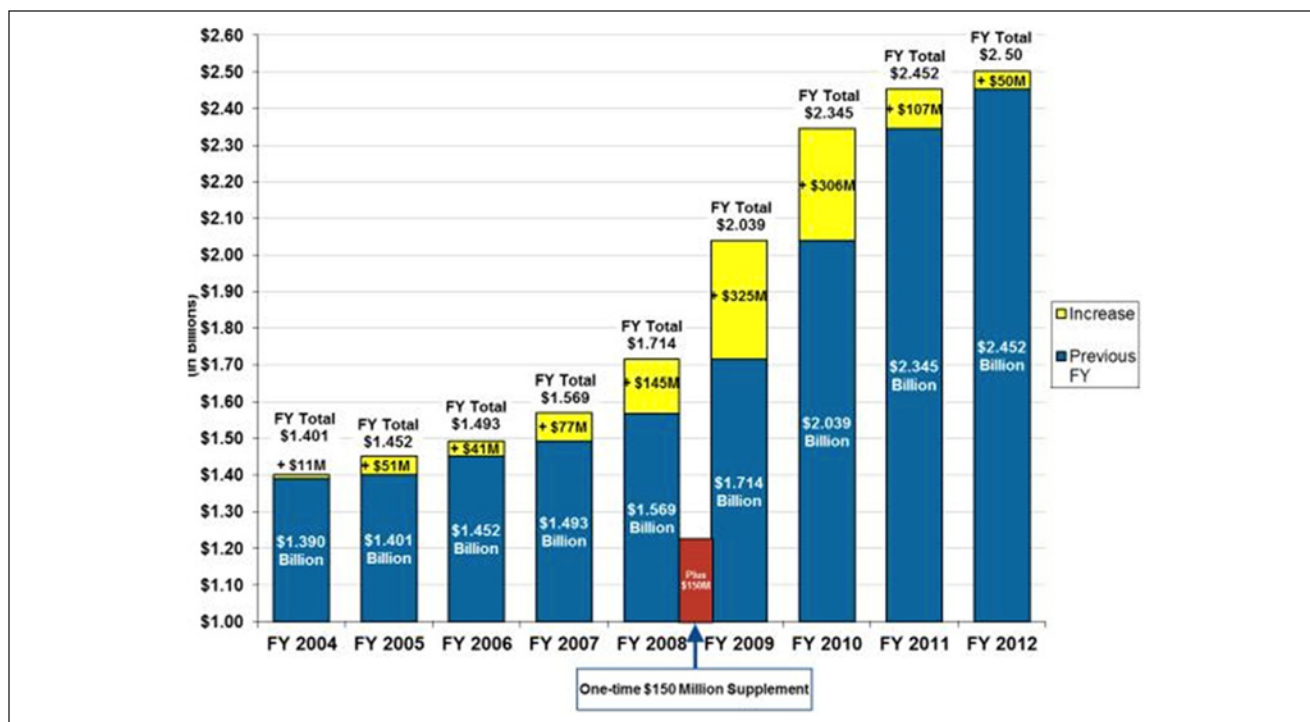


Figure 1. FDA appropriated funding, 2004-2012<sup>3</sup>.

## Dietary Supplements

Although dietary supplements are regulated differently than prescription and over-the-counter medications, the Dietary Supplement Health and Education Act of 1994 makes the FDA responsible for approving novel (post-1994) dietary supplement ingredients as well as removing harmful supplements from the marketplace. In 1994, this market was composed of ~4000 products. Today, there are ~55 000 products! However, since 1994, efficacy and safety evidence has been received for only 170 new products,<sup>5</sup> indicating efficacy and safety of most of the dietary supplements on the market today are unknown. If this is not complicated enough, there are also concerns of potential non-“natural” products being marketed as “natural,” with questionable safety profiles as seen in 2012 with dimethylamylamine.<sup>6,7</sup>

## Drug Import

Domestic drug shortages and rising health care costs are driving consumers, wholesalers, and manufacturers to foreign suppliers where concerns over drug adulteration and counterfeit drugs present a growing challenge.<sup>8</sup> Forty percent of US drug consumption and 80% of active pharmaceutical ingredients come from abroad,<sup>9</sup> yet the FDA’s limited budget only allowed for ~1200 foreign site inspections in 2009.<sup>2</sup> The imbalance between scarce resources and the plethora of overseas suppliers places consumer health at risk, as evident in the 2008 heparin contamination, when

oversulfated chondroitin sulfate was used in the manufacturing of heparin to lower production costs leading to scores of deaths.<sup>10</sup> Additionally, a vast portion of food and consumer products come from overseas, so these concerns are not limited to pharmaceuticals. The recent hepatitis A outbreak from an imported organic berry product exemplifies this concern.<sup>11</sup>

## Drug Shortages

The new norm for health care professionals is finding solutions to daily drug shortages. They have increased by 300% since 2005. More than half of drugs in short supply are critical (ie, no alternative drug therapy).<sup>12</sup> A variety of causes leading to drug shortages including unavailability of raw and bulk materials, problems at manufacturing facilities, recalls, change in formulation or manufacturer, industry consolidations, and economic decisions not to develop or continue product manufacturing. Additionally, drug shortages arise because only a small number of companies make most drugs. If one of these companies stops production, there is no backup.<sup>13,14</sup> Although the FDA has successfully prevented 137 drug shortages since 2010, they are increasing in frequency and adversely affecting patient care.<sup>12</sup> Thus, the FDA must balance safeguarding drug therapy with guaranteeing the nation’s adequate supply. A solution to this crisis is early notification of any impending shortages between manufacturers and the FDA. Additionally, the

Prescription Drug User Fee Act (PDUFA) helps by expediting drug review process of scarce critical medication replacements. It also requires early notification of anticipated production interruption, enabling the FDA to respond proactively. PDUFA also allows the FDA to ask other companies to increase production; import safe, efficacious medications from other countries; and expedite regulatory drug applications (ie, extending expiration dates, using new raw materials, licensing new manufacturers, allowing product specification changes). Further taxing the FDA's budget, implementation of PDUFA will require additional staffing. In contrast, the Affordable Care Act has provisions for branded prescription drug fees, which are not allocated to the functions of the FDA, but are credited to the Medicare Part B trust fund.<sup>15</sup> Looking forward, there is a critical need for development and approval of new antibiotics to control emerging strains of pathogens that are resistant to present-day antibiotics.<sup>16</sup>

## Compounding

Recently, local and federal government, patients, physicians, and, most important, pharmacists have been troubled by limited oversight of pharmacies compounding drugs in bulk, distributing across state lines.<sup>17-19</sup> As these compounding pharmacies are regulated by state boards of pharmacy, their oversight became concerning in 2012 when mass quantities of compounded contaminated injectable methylprednisone acetate caused 741 cases of meningitis and 55 deaths across 20 states.<sup>20</sup>

As a result, the public looks to the FDA for change to the current regulation of compounding pharmacies. Recently, the US Senate approved a bill seeking to make the FDA responsible for oversight of compounding manufacturers making them subject to safety inspections and accountable for standards similar to those of drug manufacturers.<sup>17-19</sup> Pharmacies that are not mass-producing will continue to be regulated by state boards of pharmacy. If this bill becomes law, the duties of the FDA will once again expand along with its financial need.

## Conclusion

Each day, the FDA is responsible for safeguarding and also promoting the availability of prescription and nonprescription drugs, medical devices, dietary supplements, and the nation's food supply. Our review of FDA responsibilities makes it abundantly clear that the FDA budget is being burdened with increased contemporary demands beyond traditional safeguards and approvals laws, executive directives, and public expectations. Each of these issues are interrelated as drug shortages compel overseas acquisition of products and raw materials, need for commercially unavailable compounded products, and expedited approval processes,

potentially increasing the incidence of undetected adverse events during initial drug approval phases.

An increase in the FDA's budget can substantially increase its performance level, but this cannot be advantageous unless efficiency measures are also adopted. Before renewal of the PDUFA in 2012, which provides an additional \$6 billion in funding to the FDA in the next 5 years, it took 30 months to review new drug applications. Postimplementation, the FDA has reduced the average new drug review time to 6 months. Over time, funding from manufacturer fees has also exponentially increased. Additional funding increases via application fees from companies seeking approval for generic and biosimilar drugs will better enable the FDA to fulfill its mission. Since the government, in contrast to the pharmaceutical industry, is not in a position to adequately fund the FDA, increased user fees will provide resources needed to better promote development of new drugs, both domestic and imported, while increasing safeguards. Although the FDA is receiving more funds by requiring new industries to contribute fees, the FDA is being asked to take on contemporary issues that are not funded by the PDUFA, begging the question whether these fees are sufficient in protecting our patients at the highest level possible without additional congressional support.

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