PUBLICCITIZEN

215 Pennsylvania Avenue, SE • Washington, D.C. 20003 • 202/546-4996 • www.citizen.org

Public Citizen, a nationwide consumer protection organization with over 350,000 members and supporters, has the following priorities for FDA legislation in the 114th Congress:

1. **Mandatory drug recall authority**

The FDA lacks authority mandatory drug recall authority, while the agency has this authority over devices, biological products, tobacco, infant formula and food.[1] In several public scandals, a compounding pharmacy has delayed issuing a recall for months even after an FDA inspection detected severe problems.

2. **Antibiotics Research and Conservation**

The CDC estimates[2] that over two million Americans are infected with antibiotic-resistant bacteria each year and at least 23,000 die as a direct result. Antibiotic resistance is a serious public health concern that requires both: the development of new, safe and effective antibiotics; and conserving all antibiotics, whether new or old.

3. **Transparency in clinical trials data**

Congress should require the FDA to share data from clinical trials with the public. Sharing this data advances scientific knowledge, reduces duplication and costs for patients, companies and regulators, enhances clinical decision-making and minimizes conflicts of interest. A similar policy already exists in Europe.[3]

4. **Civil penalties for law-breakers**

The FDA currently lacks authority to impose civil penalties on drug companies that market adulterated or misbranded products. According to conversations with FDA officers, the FDA is reluctant to pursue criminal charges because of the resources required. Congress should therefore grant the FDA the authority to issue civil penalties similar to the existing fines for tobacco control violations. Since 2009, the FDA has initiated 1,877 civil actions for tobacco law violations.[4]

5. **Conflict of Interest and Gift Prohibitions for FDA Decision Makers**

The FDA Advisory Committee conflicts of interest policy is lax. Congress should require a cooling-off period before committee members can receive money or gifts from special interests within members' jurisdictions.

6. **Medical Device Regulation Based on Science, Not Assertions**

The current approval process relies on manufacturers' assertions that proposed products are "substantially equivalent." It does not generally require any clinical testing. An IOM report found that the FDA 510(k) process used to clear at least 95 percent of moderate- and high-risk medical devices is so deficient that it should be scuttled.[5]

---

[1] http://new.nationalaglawcenter.org/wp-content/uploads/assets/crs/RL34167.pdf
[2] http://www.cdc.gov/drugresistance/threat-report-2013/pdf/ar-threats-2013-508.pdf
[3] European Commission, Regulation No. 726/2004, Article 80.
[4] Compliance Check Inspections of Tobacco Product Retailers. http://www.accessdata.fda.gov/scripts/oce/inspections/oce_insp_searching.cfm.
[5] INSTITUTE OF MEDICINE, MEDICAL DEVICES AND THE PUBLIC'S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS 5 (National Academy of Sciences, 2011). (Brian Wolfman, former director of Public Citizen's Litigation Group, served on the committee that oversaw production of the IOM report.)