Statement of Ami Gadhia

Concerning Discussion Draft of "FDA Globalization Act"

Subcommittee on Health, Energy & Commerce Committee

U.S. House of Representatives

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Good morning, Chairman Dingell, Ranking Member Barton, Subcommittee Chairman Pallone, Subcommittee Ranking Member Deal, and members of the Subcommittee. My name is Ami Gadhia, and I am Policy Counsel with Consumers Union[1], the non-profit publisher of *Consumer Reports* magazine. I am here today to testify about the Drug, Device, and Cosmetic Safety provisions of the Discussion Draft of the Food and Drug Administration (FDA) Globalization Act. Consumers Union commends the Chairman for his leadership on the proposed legislation, and commends members of the Energy and Commerce Committee for holding today's hearing on this critical consumer safety issue.

I. FDA IS AN AGENCY IN DIRE NEED OF MAJOR REFORM

The FDA is the federal agency responsible for the regulation of myriad foods, drugs, devices, and cosmetics. The products regulated by this one agency represent about 25 cents of every consumer dollar spent, and are among the most intimate and important ones in our lives, including the drugs we take when we are sick and the medical devices implanted in our bodies to improve our lives. However, serious safety scares over the past few years have cast major doubt upon the ability of this beleaguered agency to adequately protect American consumers.

The call for a major overhaul of the FDA has now become a roar. According to a 1998 study by the Government Accountability Office (GAO), *ten years ago*, as much as

[1] Consumers Union is a nonprofit membership organization chartered in 1936 under the laws of the State of New York to provide consumers with information, education and counsel about goods, services, health, and personal finance. Consumers Union's income is solely derived from the sale of *Consumer Reports*, its other publications and from noncommercial contributions, grants and fees. In addition to reports on Consumers Union's own product testing, *Consumer Reports* and its other publications and websites have a total subscription of approximately 8.6 million. *Consumer Reports* regularly carries articles on health, product safety, marketplace economics and legislative, judicial and regulatory actions that affect consumer welfare. Consumers Union's publications carry no advertising and receive no commercial support.

80 percent of the bulk drug substances used by U.S. drug manufacturers was imported. No doubt this number has increased in the past ten years. A more recent GAO report, issued in November 2007, put the problem in stark relief: of all foreign plants, at most only seven percent of them are inspected in a year.[2] Of those that are inspected, these inspections are all announced to the plant owners in advance, despite FDA policy guidelines requiring that inspections be conducted without prior notification. In recent years we have seen a slide towards lax oversight and neglect of safety of imported products at the FDA. According to an April 2008 *New England Journal of Medicine* article, ". . .the evidence suggests that inspection needs have overwhelmed the agency's capacity."[3]

Some of the more high-profile failures of our drug, device, and cosmetics regulatory system are well known at this point: the import of contaminated heparin, a blood-thinning drug whose active pharmaceutical ingredient (API) was manufactured in China, and which is suspected to have been involved in the deaths of over 60 people; the 2006 recall of 183,000 packages of contact lens solution, manufactured in China, because of bacterial contamination; and a June 2007 import alert about toothpaste made in China that contained the very dangerous chemical Diethylene Glycol, which is used in antifreeze and as a solvent.

A September 2004 FDA report on the risk-based method of choosing foreign facilities for inspection indicated that the number of "registered human drug establishments" had increased by more than 400 percent during the previous 25 years, whereas the number of Good Manufacturing Practices inspections conducted dropped by more than 60 percent during that same time period. As FDA itself stated in that report,

[2] GAO, Drug Safety: Preliminary Findings Suggest Weaknesses in FDA's Program for Inspecting Foreign Drug Manufacturers, GAO-08-224T (Washington, D.C.: Nov. 1, 2007).
[3] Stuart O. Schweitzer, "Trying Times at the FDA – The Challenge of Ensuring the Safety of Imported Pharmaceuticals, *The New England Journal of Medicine*, April 24, 2008, p. 1776.

"it is impossible for FDA to achieve uniformly intensive [Current Good Manufacturing Practices] inspectional coverage for all registered drug facilities."[4]

II. PROVISIONS IN THE DISCUSSION DRAFT SUPPORTED BY CONSUMERS UNION

Consumers Union believes that the Discussion Draft of the FDA Globalization bill contains a number of strong provisions that will help make consumers safer. First, the bill would require mandatory inspection of both domestic and foreign drug and device facilities every two years. This inspection provision – if implemented with protections against conflicts of interest – should help improve compliance with existing FDA safety regulations. Consumers Union would respectfully recommend that this inspection occur annually (and more frequently, if there are problems), given the host of serious public health risks that have emerged from foreign facilities in particular. However, recognizing the time and resources involved in inspections, the annual inspection requirement could be modified to include a graduated inspection schedule depending on the category of product (e.g., tongue depressor facilities may be inspected less frequently than an establishment that manufactures heart medications).

Second, the Discussion Draft would require destruction of adulterated, misbranded, or counterfeit drugs that a company attempts to import into the United States. This provision is necessary to prevent importers from "shopping" until they find a port that will admit entry for their products, and will therefore keep dangerous products out of the U.S. The destruction of these unsafe drugs will also prevent importers from simply "dumping" them on the citizens of other countries – particularly those with lax

[4] "Risk-Based Method for Prioritizing CGMP Inspections of Pharmaceutical Manufacturing Sites – A Pilot Risk Ranking Model," Dept. of Health and Human Services, U.S. Food and Drug Administration, September 2004, pg. 4.

regulation. We would also recommend that the bill provide for a similar destruction of unsafe medical devices.

Third, the Discussion Draft would give the FDA the authority to recall seriously unsafe drugs – an authority that the agency currently has for dangerous devices, but which has been sorely lacking with regards to drugs. We strongly support this provision.

We also applaud members of the Committee for including in this Draft a provision requiring a label with the country of origin of active pharmaceutical ingredients and biologics, and a label with the country of manufacture for devices, known as Country of Origin Labeling (COOL). We believe that consumers and their health care professionals are better served by more information, rather than less. In addition, the draft bill would keep FDA from closing any of its 13 labs without Congressional review of its reorganization plan, which we support. (FDA originally indicated it would close 7 of the 13 labs, but has suspended that decision.)

We are also glad that the bill includes provisions addressing the safety of cosmetics. As mentioned above, in June 2007, FDA issued an import alert against imported toothpaste that contained Diethylene Glycol. Other cosmetics may also contain this or other harmful chemicals. It is not sufficient for FDA's inspection resources to stay at their current extremely inadequate level with regard to imported cosmetics. Creating a fee requirement for importers of cosmetics is one step towards addressing this problem.

There are, however, some provisions in the Discussion Draft that Consumers Union would urge the Committee to consider shortening the timeframes for implementation. It appears that the effective dates of a number of the bill's provisions are too far out into the future. For example: there is a two-year delay after enactment of

the Act before foreign producers are required to undergo inspection of their facilities as a pre-condition to importation, and a similar delay in the implementation of the COOL provisions. There is a *three*-year delay after the enactment of the Act before importers are required to produce documentation demonstrating compliance with drug and device safety requirements as a pre-condition of entry. These implementation dates, particularly the three-year delay in the requirement to produce documentation, should be shortened.

III. AREAS OF CONCERN

We support the Discussion draft's provision creating a "user fees" regime for various new FDA functions such as registration, certification, and inspection as a reasonable way to pay for the numerous new functions that FDA must incorporate. However, we urge the Committee to ensure that the user fees do not turn into a "pay-for-play" scenario. That is, we would not want to see regulated entities have the ability, through the user fee program, to exert undue influence over the FDA in its decision-making or other functions.

We are also concerned that the fees for registration of importers as established by Section 401(c) of the Draft are not indexed for inflation. Like the user fees for food safety importation, the drug and device importer fees should be indexed.

Consumers Union also believes the civil money penalties for violations of the bill, in Section 210, are set too low. For a large manufacturer, producer, or other multi-national, a penalty of $100,000 is simply a cost of doing business. The drug and device industry is a multi-billion dollar industry, and a $100,000 fine may simply be a few hours' worth of profit for some companies. For the penalties to serve as a true deterrent against unsafe or illegal actions, they should be set higher.

We also urge inclusion of one particular GAO recommendation from its November 2007 report that is not currently in the Discussion Draft: FDA must have the ability to perform unannounced inspections of foreign facilities. Currently, since FDA gives foreign manufacturers advanced warning of inspections, these manufacturers – unlike domestic companies – are able to "clean up" to ensure they pass inspection, even if they are not in compliance every other day of the year. A dedicated foreign inspectorate (which the bill provides for) and regular FDA presence overseas, as well as adequate resources to staff these overseas offices, may be the best way to ensure random inspections.

Finally, any provisions in the final bill that permit FDA to outsource inspection, certification, registration, or any other agency tasks to a third party should include protections against such tasks being performed by entities with a conflict of interest. That is, any third party entities engaged by FDA to conduct safety and quality tasks should not be in any way connected with, related to, or otherwise influenced by any company within the supply chain.

IV. CONCLUSION

We wholeheartedly support providing FDA with new authorities and resources. We are pleased that this Discussion Draft gives FDA a number of new – and very necessary – additional powers to better ensure the safety of our drugs, devices, and cosmetics. We also urge that manufacturers and others who profit off of the sale of drugs, medical devices, and cosmetics to American consumers fairly shoulder their full responsibility for improving the safety and quality of the products they sell.

I thank the Committee for the opportunity to testify today, and we at Consumers Union look forward to working with the Committee to help move forward on the strongest FDA reform bill possible.