
**Statement of Ami Gadhia**

**Concerning Discussion Draft of "FDA Globalization Act"**

**Subcommittee on Health, Energy & Commerce Committee**

**U.S. House of Representatives**

**May 14, 2008**

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 Medical Device and Cosmetic Safety provisions of the Discussion Draft of the Food and Drug Administration (FDA) Globalization Act. Consumers Union applauds 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. INTRODUCTION

Some of the more high-profile failures of our medical device and cosmetics regulatory system are well known at this point: for example, 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. Other frightening stories of unsafe medical devices also serve as cautionary tales. Just a few examples of so-called "Class I" recalls of medical devices – those that pose a significant risk of injury or death – include balloon catheters that could fail to deflate and cause a heart attack, automatic external defibrillators that could fail to analyze

[1] Consumers Union (CU) 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.

a patient's electrocardiogram result, and heparin lock flush syringes that were contaminated with bacteria.

FDA is charged with overseeing these products. But due to a lack of resources – and political will – the agency has dropped the ball. There have not been enough inspections, enough authority, and enough enforcement of existing regulations, and consumers are paying the price.

Consider the ineffective oversight of cosmetics and personal care products. Like most drugs, they are often used on a daily basis, designed for frequent direct contact, in the mouth and on the skin. Many are also inhaled. Yet, consumers are almost always disturbed to learn that unlike for drugs, the safety of cosmetic ingredients and their production is not subject to FDA scrutiny before they enter the marketplace. [2] Further, many would be shocked to know that even the ingredients used in cosmetic products are not known to the FDA and sometimes even the Poison Control Centers, leaving both unprepared to act effectively when faced with reports of counterfeiting or contamination.

FDA maintains the Voluntary Cosmetic Registration Program, or VCRP, for cosmetic establishments and formulations. "As its name indicates, this program is voluntary. In contrast, it is mandatory for drug firms to register their establishments and list their drug products with FDA."[3]

Because of these important differences in FDA regulation of cosmetics – in contrast to its regulation of drugs - and the likely perception of consumers of the relative safety of cosmetics, it is very important particularly, in this era of increasing imports, that

[2] http://www.cfsan.fda.gov/~dms/cos-218.html
[3] http://www.cfsan.fda.gov/~dms/cos-218.html

the FDA be given the tools and resources to protect consumers from unsafe cosmetics, in addition to increased regulation and oversight of medical devices.

## 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. With regards to medical devices, CU supports the provisions of the bill that would require mandatory inspection of both domestic and foreign medical 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 device (e.g., tongue depressor facilities may be inspected less frequently than an establishment that manufactures cardiac pacemakers).

With regards to cosmetics, CU is in support of the provisions addressing the FDA's Cosmetic Adverse Event Reporting System (CAERS). However, there are two changes that we feel are necessary to this provision. Instead of requiring reporting of adverse events from each *facility*, the requirement should apply to *manufacturers*, since a facility can be a very small overseas shop that produces one ingredient in the product, and which may not adhere to the reporting requirement; the manufacturer should be responsible for all the ingredients/components of the product. In addition to mandatory

reporting of adverse events by manufacturers, it is important that FDA's processing and publicizing of these events occurs in a timely manner. We have reported on significant problems with this system. In the Winter 2007 issue of Consumer Reports' magazine *ShopSmart,* we reported the problems encountered by a health care provider when attempting to use CAERS. Dr. Amy Newberger, a dermatologist at St. Luke's-Roosevelt Hospital Center in New York City and a former member of the FDA's General and Plastic Surgery Devices Panel, reported a rash with blisters associated with the use of an anti-aging treatment, and she filed the report both over the phone and on the CAERS system. However, it wasn't until a year later, in November 2006, that the FDA sent her an email asking her to complete some forms. Such delays slow the availability of critical safety information to those who can protect the public health.

With regards to both device and cosmetic safety, we are pleased that under the draft legislation, FDA would track all registered establishments and, at least with regards to medical devices, have a firm number of establishments subject to inspection. Currently, the number of establishments the FDA should be inspecting is a ball-park figure, with many establishments completely off FDA's radar. However, although Sections 201 and 301 require drug, device and cosmetic establishments to register with FDA, the legislation does not provide (and FDA does not presently have) the authority to block products and ingredients from unregistered establishments at the border. In order to fix this loophole, importers should be required to prove at the border that the product's supply chain is composed of only registered establishments, and products that cannot document its supply chain should be refused entry. Although such a requirement may be

the intent of the Discussion Draft, we are concerned that such intent may need clarification in the actual bill language.

## III. AREAS OF CONCERN

The Discussion Draft would require destruction of adulterated, misbranded, or counterfeit drugs that a company attempts to import into the United States. However, a similar safeguard does not exist for unsafe medical devices. Such a provision is necessary to prevent importers from "shopping" until they find a port that will admit entry for their products, and will help to 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 countries outside U.S. borders – particularly those with lax regulation. The dangers from such devices are no less than those from adulterated, misbranded, or counterfeit drugs. We would therefore also recommend that the bill provide for a similar destruction of unsafe medical devices.

We support the provisions in the bill 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 affecting both medical devices and cosmetics that Consumers Union would urge the Committee to consider strengthening. We would recommend 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. 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 before the country-of-origin labeling requirement is enacted. In addition, there is a three-year delay in the requirement to produce documentation. These time intervals to implementation should be shortened.

Consumers Union supports the Discussion draft's provision creating a "user fees" schedule for various new FDA functions such as registration, certification, and inspection as a reasonable way to pay for FDA's increased inspections and enhanced oversight of both devices and cosmetics. However, CU urges 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 of both devices and cosmetics, 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 monetary civil penalties for violations of the medical device protections in the bill, in Section 210, are set too low.[4] 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

[4] Please note that the Discussion Draft does not create monetary civil penalties for violations of cosmetic safety provisions, so our concerns can pertain only to penalties for device safety violations.

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.

In addition, 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.

Finally, we have four concerns about cosmetic safety that they would also like to bring to the Committee's attention. These particular concerns are presented on behalf of CU and of the Consumer Federation of America (CFA). In the Winter 2007 issue of *ShopSmart* CU also reported that phthalates, a family of chemicals that may be linked to developmental and reproductive health risks, are found in many cosmetics, including perfumes and deodorants. CU tested eight perfumes – including five top sellers – and

found phthalates in all of them, *including* perfumes that the manufacturer stated were phthalate-free. However, companies are not required to list phthalates in their ingredient lists. What is more, there is currently only a voluntary program for manufacturers to report the ingredients in their cosmetics. Because of the voluntary nature of the program, many companies do not report their ingredients, and it is difficult for researchers to conduct thorough studies on the effects of chemicals in cosmetics upon humans. In order to advance our understanding of the effects of the various chemicals in cosmetic products upon our bodies, it should be made mandatory for companies to report the ingredients and their concentrations for all cosmetics to the FDA. Second, CU and CFA believe that the FDA needs to do a better job of enforcement with regards to cosmetic ingredients that are not approved as safe for use but that still exist in products. Companies that are using such non-approved ingredients in products must, by regulation, put a label on the product to inform the consumer of the ingredient's presence. However, such labeling is often missing. CU and CFA support giving FDA better enforcement authority to make sure that all cosmetics – both those manufactured domestically and abroad – bear such labels.

Third, CU and CFA feel that Discussion Draft should also contain, or direct the FDA to create by rulemaking, a definition of the word "safe" as used with regards to cosmetics. Finally, our organizations feel that FDA should be given the authority to regulate and oversee, in a comprehensive fashion, ingredients that appear across the various kinds of products that they regulate. Phthalates are a prime example of such an ingredient: they appear in medical devices, drug coatings, cosmetics, and in food packaging, for example.

## IV. CONCLUSION

We wholeheartedly support providing FDA with new authority and resources. We are pleased that this Discussion Draft gives FDA a number of new – and very necessary –powers to better ensure the safety of our medical devices and cosmetics. We also urge that manufacturers and others who profit from the sale of 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.