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April 17, 2008

MEMORANDUM

TO: Members, Committee on Energy and Commerce

FROM: John D. Dingell, Chairman
Committee on Energy and Commerce

Frank Pallone, Jr., Chairman
Subcommittee on Health

Bart Stupak, Chairman
Subcommittee on Oversight and Investigations

SUBJECT: Discussion Draft of FDA Legislation

Attached is a Discussion Draft of the *Food and Drug Administration Globalization Act of 2008*. The Discussion Draft builds on H.R. 3610 (Rep. Dingell), H.R. 3624 (Rep. Pallone), H.R. 3115 (Rep. Stupak), and H.R. 3484 (Rep. DeGette) and the findings from investigations conducted by the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, the report of the Food and Drug Administration (FDA) Science Board's Subcommittee on Science and Technology, the Administration's Food Protection Plan and Import Safety Plan, and input from key stakeholders.

This Discussion Draft is meant to stimulate discussion about how to provide adequate funding and authority for FDA to ensure the safety of the Nation's food, drug, medical device, and cosmetic supply in an increasingly globalized marketplace. The intention is to hold legislative hearings on the draft over the next few weeks and to markup legislation shortly thereafter. The Discussion Draft contains language that would address specific problems in the following areas:

FOOD SAFETY

Create an up-to-date registry of all food facilities serving American consumers: Require all facilities operating within the U.S. or exporting food to the U.S. to register with FDA annually.

Generate resources to support FDA oversight of food safety: Registration would require payment of a $2,000 fee per facility that would generate approximately $600 million for food safety activities at FDA, more than doubling the agency's current food safety budget.

Prevent food safety problems before they occur: Require foreign and domestic food facilities to have safety plans in place to identify and mitigate hazards. Plans would be reviewed by FDA during mandatory inspections every four years. Refusing, impeding, or delaying an inspection would be cause for suspension of registration.

Incentivize food quality improvements through certification: Allow foreign and domestic food facilities to voluntarily seek certification from FDA-accredited certifying agents, which could include foreign governments. Certification would indicate that all applicable U.S. food safety requirements are being met. FDA would make public a list of certified facilities.

Restrict entry of non-certified food imports: After a phase-in period, foreign facilities not certified would be required to ship products only through ports of entry with Federal testing laboratories. Requires any non-certified foreign or domestic facility to be inspected by FDA every 2 years, as well as meet additional testing requirements.

Create fast-track import process for food meeting security standards: Directs FDA to develop voluntary security guidelines for imported foods. Importers meeting the guidelines would receive expedited processing.

Expand laboratory-testing capacity: Recognizing the significant increase in testing capacity that the requirements of the bill will generate, allow FDA to accredit third-party laboratories to perform testing to ensure food facilities' process controls are working and performance standards are being met. Accredited laboratories would be required to send any test results to FDA.

Require country-of-origin labeling and disclosure: Require all processed food labels to indicate the country in which final processing occurred. Require food manufacturers to identify the country of origin on their Web sites for all ingredients. Require country-of-origin labeling for all produce.

Provide strong, flexible enforcement tools: Provide FDA new authority to issue mandatory recalls of tainted foods. Strengthen fines imposed on food facilities that fail to comply with safety requirements.

Clarify consumer labeling for certain foods treated with carbon monoxide: Require meat, poultry, and seafood products to which carbon monoxide has been added to be labeled with a consumer notice that the freshness of the product should not be judged by color.

Advance the science of food safety: Direct the Secretary of Health and Human Services to fund research into testing techniques to identify contaminated food, with priority given to intentional adulteration.

Make GRAS determinations public: Require publication of the request for a "generally recognized as safe" (GRAS) decision and FDA's determination.

Allow fees for food export certificates: Allow FDA to charge U.S. food firms a fee for the issuance of export certificates in situations when exports are currently restricted without this type of certification. Such fees are currently collected by FDA for certificates for drugs and devices.

DRUG AND DEVICE SAFETY

Create an up-to-date registry of all drug and device facilities serving American consumers: Require all drug and device facilities operating within the U.S. or exporting products to the U.S. to register with FDA annually.

Generate resources to support inspections: Registration would require payment of a fee that covers the cost of drug and device inspections by FDA.

Require parity between foreign and domestic inspections: Require FDA to inspect foreign and domestic drug and device facilities every two years. Prohibit any manufacturer from introducing a drug, drug ingredient, or device into interstate commerce until an initial facility inspection has occurred. Refusing, impeding, or delaying an inspection would be cause for suspension of registration.

Restrict entry of imports lacking documentation of safety: After a phase-in period, require importers of drugs for commercial use who lack documentation of compliance with requirements related to identity, safety, and purity to ship products only through ports of entry with Federal testing laboratories.

Require verification of drug identity and purity: Require manufacturers of drugs and drug ingredients to test for contaminants.

Create strong new enforcement tools: Allow FDA to issue fines for violations of drug safety requirements. Extend current FDA authority to recall dangerous medical devices to include drugs. Extend current FDA authority to detain unsafe medical devices discovered during inspections to include drugs. Allow FDA to destroy counterfeit or adulterated commercial imports.

Require country-of-origin labeling: Require drug labels to identify the source of the active pharmaceutical ingredient and its place of manufacture. Require device labels to indicate the country of manufacture.

COSMETIC SAFETY

Create an up-to-date registry of all cosmetic facilities serving American consumers: Require all facilities operating within the U.S. or exporting cosmetics to the U.S. to register with FDA annually.

Generate resources to support FDA oversight of cosmetics: Registration would require payment of a $2,000 fee per facility.

Require adverse-event reporting: Require all cosmetic facilities to report adverse events resulting from the use of their products to FDA.

Require compliance with good manufacturing practices (GMPs): Require all cosmetic facilities to comply with good manufacturing practices established by the Secretary of Health and Human Services.

GENERAL PROVISIONS

Create an up-to-date registry of importers: Require all importers of drugs, devices, foods, and cosmetics to register with FDA annually and pay a registration fee.

Require unique identification numbers for facilities and importers: To improve the accuracy of data and the ability of FDA to identify more quickly parties involved in a crisis, would create unique identification numbers for all drug, device, food, and cosmetic facilities and importers.

Create a dedicated foreign inspectorate: Increase the capacity of FDA to monitor foreign facilities producing food, drugs, devices, and cosmetics for American consumers.

Continue operation of field laboratories: Prohibit FDA from closing or consolidating field laboratories or district offices.

Prohibit false or misleading reporting to FDA: Extend the current prohibition against making false or misleading reports related to devices to include food, drugs, and cosmetics.

This Discussion Draft raises challenging policy questions, and we anticipate a vigorous debate on these issues. We welcome comments and suggestions from all Members and look forward to continuing to work with you to address the safety of our Nation's food, drug, device, and cosmetic supply.

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For further information, please have your staff contact Jeanne Ireland or Jack Maniko with the Committee on Energy and Commerce staff at ext. 6-2424.