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“Talking with Stakeholders About FDA Modernization”

Oral Presentation by Nancy Singer, special counsel for HIMA,
at FDA Stakeholders Meeting in Atlanta, Georgia

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Good afternoon. My name is Nancy Singer and I am special counsel for the Health Industry Manufacturers Association. The Health Industry Manufacturers Association (HIMA) is a Washington, D.C.-based trade association and the largest medical technology association in the world. HIMA represents more than 800 manufacturers of medical devices, diagnostic products, and medical information systems. HIMA's members manufacture nearly 90 percent of the \$62 billion of health care technology products purchased annually in the United States, and more than 50 percent of the \$147 billion purchased annually around the world.

I appreciate the opportunity to be here. Since this is the Office of Regulatory Affairs site, my remarks today will focus on the question, “What action do you propose to enable FDA’s Office of Regulatory Affairs to focus resources on areas of greatest risk to the public health.”

Working with device manufacturers, FDA has implemented many changes that have focused the agency’s resources, improved both the efficiency of FDA inspections, and made the enforcement process more equitable. These activities have a direct bearing on the public health. Cooperative efforts toward efficiency and fairness need to continue so that industry can work with FDA to enable patients to have timely access to safe and effective medical devices.

Medical device companies see themselves as innovators in the diagnosis, cure, or treatment of disease or injury. Their success depends on allowing patients early access to their technically advanced, safe, and effective devices. FDA officials see themselves as the guardians of the public health. Their mandate is to foster the introduction of new technology and to ensure that the devices designed to diagnose, cure, or treat disease or injuries do not inadvertently cause harm. One of the ways FDA accomplishes its mandate is through the inspection of device manufacturers. During the past few years, many FDA officials in the Office of Regulatory Affairs (ORA) and the Center for Devices and Radiological Health (CDRH) have begun to view industry as a partner rather than an adversary.

FDA Enforcement in the Early 1990s

In November 1990, David Kessler became the Commissioner of Food and Drugs. In speeches, he repeatedly stated that FDA enforcement “needed to be taken up a notch.”

One of his initiatives was to decentralize the power for enforcement actions and delegate authority to officials in FDA district offices to send warning letters. The district officials were instructed not to be predictable in their enforcement actions. They were to go into a firm, spot regulatory violations, and then go on to find different regulatory violations in other companies. These initiatives caused companies to be suspicious of FDA because they were fearful of unpredictable and inconsistent regulatory actions.

Stimuli to Change

In 1994, HIMA polled the industry regarding its concerns about FDA enforcement policies and developed recommendations to improve the inspection process. In meetings with officials from FDA's Office of Regulatory Affairs and CDRH, HIMA suggested items such as:

- Conducting preannounced inspections.
- Annotating the FDA 483 with completed or promised corrective actions
- Requiring that annotations be put in context (e.g., the investigator examined 50 complaints and found that 3 had not been reported as MDRs).
- Issuing close out letters after inspections.

A group of FDA officials received similar input from the Medical Device Industry Initiatives Grassroots Task Force, an industry group consisting of representatives of national and regional medical device associations.

Cognizant of its diminishing budgetary resources and of the reasonableness of the suggestions presented, FDA, in 1996, implemented a pilot program that included the items noted above. The agency subsequently surveyed the investigators and the companies being inspected, and found that the respondents in both groups believed that the pilot program improved the efficiency of inspections and the quality of communication between the investigator and the company. The program was so successful that, in March 1997, the features of the program became part of FDA's standard operating procedures for conducting medical device inspections. The program is currently being piloted in other centers.

To solicit additional ideas on how to further improve the inspection process, from 1996-1997, FDA met with industry officials from medical device companies in various cities, including Atlanta, Dallas, Nashville, Boston, Charlotte, and Orlando. Some of the suggestions coming out of these meetings included:

- Conducting joint training for industry and FDA investigators on the new requirements.
- Providing the establishment inspection reports (EIRs) automatically to companies after they have been inspected.

- Excluding from warning letters items that have been corrected or for which corrections have been promised.
- Increasing the time for companies to respond to FDA 483 observations, and acknowledging their response in the warning letter.

FDA Response to Industry Suggestions

Joint Training. In response to the industry suggestion on joint training, FDA's Southwest Region conducted joint training for FDA and industry personnel on how to comply with the MDR requirements. FDA also worked with the Food and Drug Law Institute and with national and regional device associations to present periodic teleconferences on FDA requirements for members of the industry and FDA officials. Additionally, the agency conducted joint training on how to comply with the design control portion of the new quality system regulation.

Establishment Inspection Reports. FDA has instituted a program under which it automatically provides EIRs to companies after their FDA inspections. This program has proven to be very successful, with companies better able to understand FDA's conclusions about their firm's state of compliance.

Warning Letter Pilot. Prompted by one of the industry's pressing concerns about the impact that warning letters had on their corporate image and stock prices, a committee of the Medical Device Industry Initiatives Grassroots Task Force working with FDA officials designed an 18-month pilot program intended to preclude FDA from sending warning letters to companies who had corrected or were in the process of correcting deficiencies. The way the program works is as follows. Beginning March 29, 1999, after a domestic device investigation, a company with a good compliance record with FDA requirements will be given 15 working days to respond to deficiencies that would have previously triggered a warning letter. If the response is deemed to be satisfactory, then a warning letter will not be issued. Instead, FDA will issue a postinspectional notification letter. The letter will state that while the inspection found quality system deficiencies which, if not corrected, would warrant a warning letter, the company's written response has satisfied FDA that the company has taken or will take appropriate corrective actions. If, at a later time, FDA observes that the deviations from the quality system regulation have not been remedied, the agency may take regulatory action (seizure, injunction, and civil penalties) without notice.

The program also addresses situations that would have warranted a warning letter for failure to submit a 510(k) application or for labeling violations. Under this program, companies, in most instances, will receive an untitled letter within 30 working days of the FDA inspection.

Companies will have 15 days to respond to FDA. CDRH will then have 30 days to consider the firm's response. If the firm's response is satisfactory, FDA will send a postinspectional letter similar to the one discussed above. HIMA applauds the agency for this initiative as it provides the device industry with the opportunity to make corrections and forego the receipt of a warning letter without diminishing the agency's authority.

Inspection Evaluation Survey. For years, industry has made various allegations about the lack of uniformity in FDA inspections. In an attempt to get accurate data, a committee of the Medical Device Industry Initiatives Grassroots Task Force, in cooperation with University of California Irvine's Center for Statistical Consulting (UCI), designed a medical device inspection evaluation survey to provide a mechanism by which industry can provide anonymous feedback to ORA and members of the public regarding the FDA inspection process. The survey, which began on March 1, 1999, will be piloted for one year.

Upon completion of an FDA inspection, the investigator will fill out the top portion of the survey that contains background information about the company and the devices it manufactures, the name of the investigator, the FDA district, whether or not a 483 was issued, and the reason for the inspection. After completing the form, the investigator will give it to an official at the firm that is being inspected, ask him or her to complete it, and return it in the stamped envelope to UCI.

Data will be entered and analyzed at UCI, with specifics about companies and investigators kept confidential. UCI will analyze the data at the end of six months and at the end of one year. To show trends in satisfaction and perceived problems, a comparison of the responses both nationally and by individual districts will be made. HIMA believes that the evaluation will provide concrete data about what is going on during the FDA inspection process and where and how the process can be improved.

Quality System Inspection Technique (QSIT)

For years, members of the industry complained that FDA investigators inspecting their companies focused on individual deviations from the good manufacturing practice regulations rather than on whether their company had a quality system in place that was designed to manufacture safe and effective products. In 1998, an ad hoc group of FDA and industry officials developed recommendations to address these concerns.

Based on the group's recommendations, a CDRH team led by Tim Wells developed a new systems approach for FDA inspections, which they called the Quality System Inspection Technique (QSIT). QSIT is based on the premise that the quality system regulation has seven major subsystems whose requirements intersect. The subsystems are

Management controls.

Design controls.

Corrective and preventive actions.

Production and process controls.

Record/document/change controls.

Material controls.

Facility controls.

During an initial inspection, an FDA investigator will examine whether the company has the first four subsystems in place, and whether it is manufacturing products under the procedures required by those subsystems. If a company has an inspection following which no official action is indicated, subsequent inspections will be more limited. IIMA supports this program and predicts that it will result in focused and efficient inspections.

Conclusion

FDA officials working with industry have made tremendous progress in allowing FDA to focus its resources to improve the manner of conducting inspections and making the procedure for initiating regulatory action more equitable. This interactive exchange needs not only to continue, but also should be used as a model for how FDA can protect the public health by working with industry to improve all aspects of the regulatory process.