Executive Summary of the Food and Drug Administration's Consumer Roundtable on Consumer Protection Priorities

On December 13, 2000, the executive leadership of the Food and Drug Administration (FDA) joined with consumer leaders to discuss consumer protection priorities. The intent of this first-time Consumer Roundtable discussion was to strengthen consumer involvement in the Agency's processes for assessing how it is currently directing its consumer protection priorities and determining whether there is a need to redirect or shift priorities to better meet its consumer protection responsibilities. The Agency presented information on its current consumer protection priorities related to its statutory responsibilities and invited dialogue with consumers about their views and expectations related to those priorities.

Jane E. Henney, MD, Commissioner of the Food and Drug Administration, commenced the roundtable discussion by reviewing the methods that the FDA, one of the oldest consumer protection agencies in existence, has used to engage consumers in the business of the Agency. She stated that the FDA has opened the advisory committee process by inviting a public comment session, is one of the first Agencies to have an Office of Consumer Affairs, and utilizes a rulemaking process that includes public comment. She added that although the Agency has made strides to engage consumers and the public, it needs more and better ways to improve this process. The first method of doing so is to include consumers in the Agency's planning process.

Dr. Henney articulated that two of her priorities for the Agency include leveraging and strengthening the scientific base to ensure that the best science guides the critical decisions that need to be made. FDA has a vast number of products under its jurisdiction and with its mandate, it will always need others to help accomplish its work, even if unlimited resources were available. This can be realized through leveraging. Through the leveraging process, the Agency can reach groups that it would not ordinarily be able to reach, including those at the grassroots level.

Dr. Henney stated that the Agency is committed to the outcome of the roundtable discussion, in that it intends to incorporate consumers comments and suggestions into its planning session wherever possible. She added that today's roundtable discussion should be viewed as a plenary session and that follow-up discussions are on the horizon.

Center for Biologics Evaluation and Research (CBER)

Kathryn Zoon, PhD, Director, presented an overview of CBER's mission, vision, goals, and current and future activities. She described the range of CBER-regulated products—from blood to vaccines to allergenics to advanced gene therapy products.

She emphasized that a strong scientific base serves as the foundation for CBER's regulatory policies and activities. "A strong scientific base is critical to properly evaluate and ensure the safety of cutting edge products," said Dr. Zoon. She indicated that demand for greater access to new products is increasing while CBER's operating budget continues to decline.

Dr. Zoon talked about the critical challenges facing CBER, such as gene therapy, xenotransplantation, stem cell products, genomics, vaccine safety, tissue regulation, emerging infectious diseases, and bioterrorism. She also spoke of the importance of recruiting and retaining qualified staff, and of continuing in-house research, which helps staff keep abreast of advances in science and technology.

Dr. Zoon said that consumer outreach is a priority for CBER and that CBER presently has a number of services available. "We have a toll-free consumer hotline, the Vaccine Adverse Event Reporting System (VAERS), a fax information system, and several list servs for blood and plasma products," she said. Additional outreach activities include CBER exhibits at professional meetings and the distribution of informational materials to consumer and professional organizations. Dr. Zoon extended an invitation to the consumer groups present at the roundtable to meet with CBER on specific issues of concern.

Arthur Levin, Center for Medical Consumer & Health Care Information, provided the lead consumer response. He presented his organization's perspective on CBER operations. Mr. Levin remarked that consumers traditionally have not been involved in CBER's planning processes and need to be. "Consumers see themselves as clients of the FDA, not as stakeholders. The public is the big boss." He said that meetings such as today's, and the ones held with consumer groups in preparation for passage of the Prescription Drug User Fee Act (PDUFA), are an excellent mechanism to interact effectively with consumer organizations.

Mr. Levin asked if CBER was concerned about PDUFA III, and how the Center would build into its planning processes a way to address the increased workload, need for qualified staff, and shrinking operating budget. He also asked how gene therapy research would be funded.

Mr. Levin observed that decisions concerning cutting-edge products, such as gene therapy and xenotransplants, often transcend science and technology, and raise important ethical issues. He asked whether CBER had in-house ethicists to respond to these issues. He also remarked that FDA Advisory Committee members may not have the expertise to deal with advanced, biotechnology-based products. He asked how CBER would find the appropriate individuals to serve on its advisory committees. Further, he indicated that the current system for human subject

protection was inadequate and asked CBER to clarify its role in ensuring that proper safeguards were in place.

Regarding recent CBER compliance actions concerning the American Red Cross, Mr. Levin noted that consumers have a stake in the outcome and asked what they could do to assist CBER in this matter. With respect to medical errors and the recent Institute of Medicine's report, Dr. Levin asked what CBER is doing to minimize medical errors, especially those that involve blood and blood component administration.

Mr. Levin concluded his presentation by stating that vaccines, particularly therapeutic vaccines, are a growing concern. "There is much that we do not know about these vaccines," he said. "We have concerns about under reporting to the Vaccine Adverse Event Reporting System (VAERS). Is CBER evaluating how effective VAERS is?"

CBER Action Items

Dr. Zoon responded to the questions and concerns raised by Mr. Levin during his presentation, with the following action steps:

Budget, Staffing, and PDUFA: CBER will continue to do its best to manage workload, recruit, train, and retain quality staff, and balance competing priorities within the Center, with limited resources. User fees gained from PDUFA will provide needed resources for new biologic product reviews and related activities.

Ethical issues: CBER is very much aware of the need to seek ethical input for Agency decisions. Presently, CBER Advisory Committees include representatives with expertise in medical ethics. CBER will continue to utilize these outside experts to advise on product issues and policies that have ethical implications.

Human Subject Protection: Human subject protection is a high priority for FDA and HHS. CBER is working with HHS on informed consent procedures and will continue to enforce strong safeguards to ensure that individuals participating in clinical studies are informed of any associated risks, and that clinical studies are designed to protect human subjects to the extent possible.

Blood Safety Action Plan: Maintaining the public's confidence in the safety of the blood supply largely rests with CBER. The blood supply is safer today than at any other time in history. CBER will continue to enforce strong standards for blood safety and will take action against blood establishments that are out of compliance with the law.

Vaccines: CBER will continue to focus on vaccine safety issues and to require vaccines to undergo a rigorous scientific and technical review. CBER also will explore ways to promote and publicize the VAERS program to health care providers, parents, and other consumers.

Center for Devices and Radiological Health (CDRH)

David W. Feigal, Jr., MD, MPH, Director, opened with the mission and vision of the Center for Devices and Radiological Health.

Mission:

CDRH promotes and protects the health of the public by ensuring the safety and effectiveness of medical devices and the safety of radiological products.

Vision:

Ensuring the health of the public through the Total Product Life Cycle – it's everybody's business.

He noted the scope of CDRH's work and provided a historical perspective on the level of staffing allocated to the products CDRH regulates and the laws involved:

- Medical devices, including implants, equipment and diagnostic devices
- Electronic products that emit radiation (other than nuclear radiation)
- Mammography quality
- Clinical Laboratory Improvement Act

Dr. Feigal outlined the methods CDRH uses to protect consumers, including risk management, science-based regulatory decisions making and enforcing integrity in manufacturing and clinical research. He discussed the role of the consumer, as members of the Center's advisory committees and focus groups, and as reporters of adverse experiences. He focused then on information-empowered consumers, and the Center's efforts to provide information, such as a new web page on LASIK eye surgery. Additional vehicles for consumer information and consumer feedback were provided.

Dr. Feigal closed his prepared remarks with a discussion of the concept of "total product life cycle," from the initial concept, through design, prototype, manufacturing, commercial use, and obsolescence.

Lee Richardson, **PhD**, Consumer Federation of America, provided the lead consumer response. He noted that CDRH has a large number of constituents, who are interested in both general information and information specific to a personal health need. Consumers want to know everything possible.

Dr. Richardson commented that people don't use devices as predicted. As an example, he discussed consumers who need products for hearing impairment, a common health problem. Many elderly patients find using hearing aids very difficult. He suggested that CDRH find ways to publicize hearing solutions, tell consumers about technological device developments early, and provide more referrals to other agencies.

Susan Cohen, consumer responder, commented that many people don't have health insurance much less a computer and FDA is relying too heavily on the Internet as a means of providing information to consumers. She suggested TV and radio public service announcements as an example of more far-reaching approaches.

Dr. Feigal noted that about 100,000 consumers down loaded one of CDRH's consumer information booklets, so the web can be a successful vehicle for consumer education. He agreed, however, that we should use other means in addition to the Internet to communicate with consumers. He noted that there are examples of the Center using the mass media. He recently had done radio interviews on the new LASIK website, appeared on *Larry King Live* on CNN to discuss cell phones, and had been interviewed for *Glamour* magazine on breast implants.

A representative of the American Society of Radiological Technologists said that persons functioning as radiological technologists are often untrained, even though a minimum level of training is required for accreditation. He was critical that CDRH allows this situation to continue. The American College of Radiology, the American Cancer Society, and many other groups endorse training of radiological technologists. While the Mammography Quality Standards Act requires mammography technologists to have a certain level of training, mammography only represents 8% of medical imaging.
Dr. Feigal was sympathetic to the comment and said he would look into seeing if CDRH has a role in assuring better training.

A representative of the American Foundation of Maternal and Child Health expressed concern about the amount of ultrasound used during many pregnancies and during labor and delivery. She mentioned labeling of the dose given on the screen as one solution and concern about unknown long-term effects.
Dr. Feigal agreed that ultrasound should be used only when there is a medical need, and noted that CDRH had taken action to stop "ultrasound boutiques" which were set up in shopping malls to provide prenatal snap-shots for expectant mothers.

Another consumer participant expressed concern over FDA's independence and PDUFA.
Dr. Feigal explained how PDUFA works and the programs in CDER and CBER that it funds, pointing out that the MQSA program is completely funded by user fees and provides excellent State and Federal partnership to assure mammography quality.

CDRH Action Items

Lireka P. Joseph, DrPH, Director, Office of Health and Industry Program, CDRH, described the variety of mechanisms CDRH is using to provide consumer information. These include posting information on the consumer website at http://www.fda.gov/cdrh/consumer/index.shtml and working with consumer organizations and other multipliers, such as a service that will provide a consumer article to numerous magazines or local newspapers.

Dr. Joseph also mentioned the Center's current project to revitalize radiation issues. In light of the decreasing resources devoted to radiological health, the Center is evaluating the entire program to set priorities and determine how to best protect the public health under resource constraints.

Center for Food Safety and Applied Nutrition (CFSAN)

Joseph A. Levitt, Director, commented on a theme he has heard reiterated by several participants – i.e., the need for FDA to open-up its decision-making processes. On this point, Mr. Levitt noted that CFSAN is establishing a tradition of soliciting stakeholder input into key policy and program issues. In the past 18 months, for example, Mr. Levitt noted that comments from stakeholders were solicited on dietary supplements, food biotechnology, health claims on dietary supplements, development of on-farm egg safety standards, methyl mercury, and establishment of 2001 program priorities.

In his prepared remarks, Mr. Levitt addressed four topics: (1) Values; (2) priority-setting; (3) resources; and (4) long-term goals. Mr. Levitt talked about the core values of "CFSAN Pride" (**P**ublic Health and Safety; **R**espect; **I**ntegrity; **D**edication; **E**xcellence) as the foundation for the Center's public health mission to ensure the safety of our food supply. With respect to priority setting, he noted that on an annual basis, CFSAN reviews its programs in order to establish priorities. The priority-setting process focuses on the central question, "Where do we do the most good for consumers?" Mr. Levitt discussed the 2000 Program Priorities document and summarized the Center's accomplishments in four program areas: food safety; food additives; dietary supplements; and biotechnology.

After establishing priorities, it is important to communicate the priorities to stakeholders so expectations regarding CFSAN's performance will be in line with what the Center can reasonably deliver. On this point, Mr. Levitt presented CFSAN staffing charts that indicated a decline in resources between 1978 and 1998, with targeted increases received since then. The impact of a consistent pattern of declining resources over two decades is that some work is not going to get done, or it will get done slower.

Lastly, Mr. Levitt talked about three long-term goals: (1) strengthening the Center's science-based capacity for informed decision-making to improve public health; (2) enhancing the Center's operational capacity to implement decisions in a timely way; and (3) shifting to a culture within the Center of accountability, cooperation, and respect. Together, these will significantly strengthen CFSAN and build it into a truly world class organization.

Michael Jacobson, PhD, Center for Science in the Public Interest, provided the lead consumer response. He commented on two primary issues – i.e., the Center's diminishing resources and what he believes to be a lack of attention to several consumer concerns. With respect to resources, Dr. Jacobson opined that, to adequately do its job, CFSAN's resources need to be

doubled over the next four years. On the subject of consumer concerns, Dr. Jacobson recommended that CFSAN devote more attention to several issues: adequate implementation of seafood HACCP; consumer exposure to methyl mercury; foodborne illness from shellfish contaminated bacteria in the *Vibrio* species; requiring a mandatory, transparent review process of genetically modified foods; mandating disclosure in product labeling of trans fat and added sugars; and increased enforcement against misbranded labeling.

Questions from consumer participants focused on the issue of the safety of bioengineered foods. Mr. Levitt reiterated that FDA held three public meetings to solicit comments from stakeholders on this issue. He also noted that FDA was in the process of developing two documents on bioengineered foods: (1) a proposed rule requiring the developers of bioengineered foods to notify the Agency before such products are marketed; and (2) a guidance to assist manufacturers who wish to voluntarily label their foods as manufactured with or without bionengineered ingredients. Lastly, Mr. Levitt noted that scientists with expertise in biotechnology are being added to the Food Advisory Committee.

CFSAN Action Items

Mr. Levitt noted that many of Dr. Jacobson's issues would be included in CFSAN's 2001 Program Priorities document that is currently being developed. Doing them all, however, is a function of time, attention, and priority. Mr. Levitt noted that when faced with budget limitations, his philosophy is to focus on fewer program areas or activities, but to accomplish those tasks both effectively and efficiently. He used the metaphor of FDA trying to push 100 pebbles up a mountain at one mile an hour. Using this method, after fifty years, the only accomplishment is that 100 pebbles are half-way up the mountain. A contrasting approach is to identify a few boulders (i.e., activities that are most important to accomplish) and get them up and over the mountain quickly. This approach focuses efforts, reaches closure, and provides concrete results. Mr. Levitt believes that CFSAN should work this way to best channel the Center's finite resources and fulfill its mission to protect the American consumer.

As a result of discussion at the meeting, Mr. Levitt noted increased awareness concerning the accessibility of outreach efforts to everyday *consumers*, not just consumer advocates. Noting that not all consumers have access to the Internet, Mr. Levitt identified as an action item exploring ways to reach consumers other than relying on web-based access. Lastly, Mr. Levitt noted that he intends to continue to solicit input from stakeholders in the development of key program and policy issues.

Center for Veterinary Medicine (CVM)

Stephen F. Sundlof, DVM, PhD, Director, discussed the Center for Veterinary Medicine's (CVM's) two-fold mission -- protecting human health and protecting animal health. He stated that CVM believes that healthy food animals will help produce wholesome food for people. Dr. Sundlof discussed the animal drug review process and CVM's top priority -- antimicrobial

resistance. He provided a brief overview of CVM's "Framework" document, open discussions the Center has had on the antimicrobial resistance issue, and monitoring under the National Antimicrobial Resistance Monitoring System (NARMS.) Dr. Sundlof also mentioned CVM's proposed withdrawal of approval of fluoroquinolones used in water for poultry, and CVM's support of the American Veterinary Medical Association's Judicious Use of Antimicrobials program. In addition, he discussed alternatives to antimicrobials, food additives, and bovine spongiform encephalopathy (BSE).

Dr. Sundlof concluded with a discussion of the challenges faced by FDA and the Center's goal to both protect public health and permit use of safe drugs to treat animals. He asked that consumers follow and engage in discussion of issues such as antimicrobial resistance and biotechnology and asserted that better informed consumers are better protected.

Richard Wood, M.Div., D.Min., Food Animal Concerns Trust (FACT), provided the lead consumer response. He stated that his group agreed that healthy animals help produce wholesome food for people. He applauded CVM's focus on the antimicrobial resistance issue. In particular, he noted the significance of CVM's Guidance Document #78 that addresses how CVM intends to consider the potential human health impact of the microbial effects associated with all uses of all classes of antimicrobial new animal drugs intended for use in food-producing animals when approving such drugs. He also thanked CVM for the Notice of Opportunity for Hearing (NOOH) to withdraw approval of the poultry fluoroquinolone drug, and urged Commissioner Henney to issue a summary action to ban these products from the market in a timely fashion.

While Dr. Wood felt CVM's "Framework" document on antimicrobials could be useful, he stated that it was not in place now. He also urged the Center to respond to a Citizen Petition filed by his group and others in March 1999 to rescind approval of non-therapeutic antimicrobial drugs.

He said that FACT had supported the addition of $3 million to CVM's budget to work on the antimicrobial resistance issue, and that they hoped the Center would use those funds to conduct safety reviews of antimicrobials approved in the past.

Dr. Wood pointed out that there was a lack of data on the sales of antimicrobials for food animals. We do not have this data that is important in making decisions on these products; he suggested that FDA require more data from the drug companies on this subject.

In addition, Dr. Wood stated that consumers need to be included in discussions on antimicrobials, including discussions of thresholds. He also stated that his group and others were concerned about expedited review of animal drugs because it is very difficult to remove drugs from the market once they have been approved.

Dr. Wood discussed CVM's enforcement of the "BSE feed rules." While he recognized CVM's educational and inspection efforts, he also mentioned a GAO report that indicates that CVM

needs to do much more work in this area. He stated that it was FACT's belief that the time had come for enforcing the rule and penalizing violators rather than just education.

Adam Goldberg, consumer responder, Consumers Union, asked Dr. Sundlof about the timeline for CVM's proposal to withdraw the approval of the poultry fluoroquinolones. Dr. Sundlof explained that the drug sponsor must supply data to FDA to show that the product approval should not be withdrawn. Next, FDA will review the data, and if it is determined that a hearing is warranted, a notice of hearing on the withdrawal will be issued by the Agency. The hearing would be held before an administrative law judge.

Brett Kay, consumer responder, National Consumers League, inquired what FDA is doing for follow-up on the "BSE" (ruminant feed) inspections.
Dr. Sundlof replied that 100% of all firms involved in rendering and feed manufacturing except for on-farm mixers were being inspected and that there would be re-inspection of those firms found out of compliance. He said that the Agency is very concerned about this issue because of the major health impact BSE has had in Europe.

CVM Action Items

Increase contacts with consumer groups so that they will be aware of the important issues the Center is facing and have an opportunity to share their opinions.

Publish a proposed rule to require drug sponsors to provide sales information for antimicrobial products.

Determine the best ways to ensure compliance with ruminant (BSE) feed rule by firms that have failed their inspections.

Center for Drug Evaluation and Research (CDER)

Janet Woodcock, MD, Director, began the CDER session with a presentation entitled, “Moving Forward: CDER”. The presentation covered the following five major issues related to what the public wants:

- Safe drugs
- Effective drugs
- Available, accessible drugs
- Low-cost drugs
- Good drug information

Dr. Woodcock discussed managing drug risks, assuring drug quality, pursuing health fraud, and appropriate advertising. Making useful information available to the public is one of CDER’s top

priorities. Recent efforts include: developing a drug product information page and up-to-date paperless labeling on CDER's Web Site; the new over-the-counter label; designing an easy to read prescription drug package insert; medguides; strategic use of regulations and guidance.

Cynthia Pearson, President, National Women's Health Network provided the lead consumer response. The following comments from Ms. Pearson and the audience were directed to CDER:

- Strive to increase consumer input.
- Public meetings should be held prior to most drug approvals.
- Improve the training for consumer representatives on advisory committees.
- Drug information needs to be available on CDER's Web Site prior to advisory committee meetings.
- FDA's information to consumers needs to reach a broader audience.
- Direct to consumer advertising (DTC) can be harmful. FDA should preapprove advertising information.

CDER Action Items

DTC Advertising: Dr. Woodcock stated that she agrees that the current brief summary that accompanies direct-to-consumer advertising isn't brief and does not adequately convey important consumer information. She recognizes the need to require a better format to accompany direct-to-consumer print ads to convey risk information in a format with language that is comprehensible to consumers.

Post-market Surveillance: Dr. Woodcock noted that there is not an active system which reports how drugs are used and misused. She added, the way drugs are prescribed and monitored definitely results in a lot of the side effects. FDA is working with a number of other Public Health Service agencies in a consortium, with HCFA, with ARC, and CDC to put data systems together, share information, and therefore, provide the best safety net as possible.

Consumer Outreach and Education: CDER will continue to seek out consumer grassroots and consumer advocacy groups by scheduling public meetings to learn consumer's concerns. Dr. Woodcock encouraged advocacy groups to formalize meetings with CDER. Consumer education remains a high priority and CDER recognizes it needs to reach more audiences. CDER will broaden its educational campaigns by using its limited resources strategically. Every effort will be made to improve consumer outreach and education.

Openness and Transparency

Margaret Jane Porter, Chief Counsel, Food and Drug Administration, discussed the importance the Agency places on providing consumers and other members of the public with useful information about the products FDA regulates and other FDA activities in an open and transparent manner. The openness and transparency of the Agency empowers consumers to

make informed choices concerning their health and also helps assure consumer confidence in the credibility of FDA's processes. As FDA is a regulatory agency, it must assure the integrity of its regulatory processes and protect the sensitive information regulated entities are required to submit to it. FDA attempted to balance these concerns by issuing procedural regulations before enactment of the Freedom of Information Act (FOIA). These FDA regulations have been a model for other government agencies for years.

As FDA continues to be one of the world's leading agencies in its emphasis on openness and transparency, it is aware that making even more information available to the public will further the Agency's mission to protect and promote public health and improve its credibility. For example, FDA has aggressively implemented the Electronic Freedom of Information Act and recently launched its redesigned website (www.fda.gov). The Electronic Freedom of Information Act quickly makes available in electronic form frequently requested and other publicly available documents so that requestors have this information without needing to file separate FOIA requests and waiting for responses to them. The redesigned website places more of the most important and popular information front and center on the home page. Also featured is regular updates on "hot topics" such as cell phones and breast implants; automated e-mail lists to which the public can subscribe, reports of safety alerts and product approvals; links to all of FDA Centers; special information for consumers, patients, women, and other audiences, and an improved search engine. The site also allows users to report problems with products regulated by FDA and to comment on proposed regulations.

As the Agency makes more information available, the challenges of ensuring that the information is accurate and complete increase, along with the potential for inadvertently disclosing legally protected information. In addition, finding the resources required to make the investments necessary in infrastructure, processes, and training, to improve transparency is a major challenge. The solutions to the current challenges lie in systematically redesigning the Agency's processes using available technology.

Although there is no way the Agency could or would make available all information, it wants to provide information to the public that is timely and useful, and welcomes suggestions for appropriate ways to become more open and transparent while maintaining its obligations.

Allison M. Zieve, Public Citizen Litigation Group, provided the lead consumer response. She acknowledged the efforts that FDA has made to provide consumers and other members of the public with more information via its website, and suggested areas that the Agency could promptly improve its openness and transparency and avoid further litigation. Specifically, those areas relate to the Freedom of Information Act and the Federal Advisory Committee Act (FACA). Under FOIA, Ms. Zieve opined that all protocols for postmarketing studies that are required by the FDA as a condition of approval for drugs should be released in response to FOIA requests. In addition, safety and effectiveness information and adverse event data should not be withheld from the public. Ms. Zieve also requested clarification on the methods the Agency applies for determination of whether a drug approval package is posted on its website.

With respect to FACA, Ms. Zieve said FDA should ensure that all Centers make advisory committee material available before or at the relevant meetings. She stated that only CDER abides by this practice. Ms. Zieve also stated that FDA consistently fails to fully disclose conflicts of interest of advisory committee members. She added that although a conflict of interest is disclosed, there is no information regarding the nature of the conflict and this should be provided. As an aside, but also related to advisory committees, she opined that FDA advisory committees do not adequately represent consumer interests. She urged the Agency to revisit its definition of those who represent consumer interests.

Deborah Hochanadel, consumer responder, also offered comments. She is Co-Director of the Massachusetts Breast Cancer Coalition and representative of the following organizations: Boston Women's Health Book Collective, Breast Cancer Action, Breast Cancer Action Montreal, Center for Medical Consumers, DES Action, Massachusetts Breast Cancer Coalition, National Women's Health Network, Women's Community Cancer Project, and Working Group on Women and Health Protection (Canada).

Ms. Hochanadel urged the FDA to strengthen its conflict of interest policies for advisory committees, specifically pertaining to consumer representatives. She recommended that all consumer representatives be required to disclose the percentage of annual funding their organization receives from industry and should never have a financial relationship with the industry being discussed by the committee. She also suggested that the FDA separate its public comment time during advisory committee meetings into industry-free and industry-support segments.

Action Items

Sharon Smith Holston, Deputy Commissioner for International and Constituent Relations, Food and Drug Administration, stated that with respect to consumer representatives, their role and conflict of interest, the Agency is currently addressing this issue. At this point in time, it cannot predict the outcome, but it will consider the recommendations put forth at this meeting.

Margaret Jane Porter stated that the Agency shares the overall goals of responsiveness and consistency does not want to spend unnecessary resources on litigation, but there are legitimate interests that FDA has a responsibility to protect and resolving issues related to those interests must be done carefully.

Dr. Henney closed the roundtable discussion by expressing her appreciation on behalf of the Agency for the candidness of the consumer participants. She also commended Mr. Mark Barnett of the FDA for moderating the roundtable. She added that she believes that the excellent discussions have provided a great starting point for future breakout sessions and the Agency welcomes any additional comments.