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Food and Drug Administration  
Dockets Management Branch (HFA-305)  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

***Docket No. FDA 2009-N-0575: Incorporation of New Science Into Regulatory Decision-making Within the Center for Devices and Radiological Health; Public Meeting; Request for Comments***

Dear Sir/Madam:

On behalf of AdvaMed, the Advanced Medical Technology Association, I am pleased to submit these comments in response to the *Federal Register* notice of a public meeting and a request for comments on the incorporation of new science into regulatory decision-making within the Center for Devices and Radiological Health (CDRH).

AdvaMed represents manufacturers of medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed's members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent of the health care technology purchased annually around the world. AdvaMed members range from the smallest to the largest medical technology innovators and companies. Nearly 70 percent of our members have fewer than \$30 million in sales annually.

FDA asked for input on three areas with related questions: adapting to new scientific information, adapting to novel technologies or novel uses of existing technologies, and enhancing CDRH's technical competence and analytical capability. FDA has also asked for input on three case studies. AdvaMed has both general and specific comments below.

**General Comments**

The medical device market is diverse ranging from bandages, wheelchairs (motorized and non-motorized), diagnostic tests, magnetic resonance imaging and computerized tomography equipment, hip and knee implants to stents and defibrillators to name just a few. When considering "new science" in regulatory decision-making, FDA should bear

in mind the relative risks and benefits of devices to which a decision may apply. It is also important to remember that among manufacturers there are no identical devices, only similar devices, and that device design, materials, manufacturing processes or other factors may make “similar” devices quite different in fact.

The public notice on the incorporation of “new science” into regulatory decision-making within CDRH fails to define the term “new science” or scientific knowledge or scientific information and the terms are used inconsistently throughout the notice. As a result, the public notice leaves the impression that FDA may consider anecdotal information or observational information “new science.” AdvaMed believes that CDRH should clarify that “new science” and “scientific information” refer to existing regulatory and statutory definitions of valid scientific evidence. Valid scientific evidence already governs the device review, approval and post-market regulatory processes and should continue to do so. (Section 513 (a) of the Federal Food, Drug, and Cosmetic Act)

AdvaMed understands that there may be situations in which anecdotal or observational data (e.g., Medical Device Reports [MDRs]) may highlight potential critical safety issues that may require an expeditious response. In these instances, FDA should promptly perform a risk-benefit analysis to determine appropriate next steps. In general, however, FDA should confirm safety signals through scientific investigation as is planned with the FDA Sentinel Surveillance initiative.

In addition, in most instances (whether an expeditious response is required or not), there should be open communication with the sponsor(s) of the affected marketed devices to provide input, context and information regarding the complete clinical experience in order to assess the significance of the new scientific information.

As we indicate in greater detail in our specific response to Question 3, when FDA proposes to act upon valid new scientific information, the requirements for devices under review should not be modified unless FDA has determined that specific actions are required for devices that are already on the market. To change the rules without a corresponding change for devices already on the market creates a barrier for innovation.

As we indicate in our specific comments and in our case study comments, FDA should also take greater advantage of its Advisory Committees, utilizing them to recommend whether the new scientific information warrants a particular course of action. In this regard, FDA should endeavor to make sure that Advisory Committees have a full complement of members to ensure both a broad perspective and a fully considered response.

Finally, if FDA decides to pursue either changes in device specific clearance or approval requirements or more far-reaching regulatory changes, it is critically important for FDA to be transparent and to document device specific changes in requirements and make them generally available to all device manufacturers as quickly as possible via new or updated guidance, or in the latter case, via notice and comment rulemaking.

## **Specific Responses to Questions**

### **A. Adapting to New Scientific Information**

- 1. When CDRH gains new scientific information about a particular product or type of product, what should the criteria be for changing CDRH's expectations of the evidence necessary for pre- or postmarket regulatory decisions, keeping in mind our mission to protect and promote the public health, as well as our statutory and regulatory framework? What are potential “triggers” for making such changes?**

#### **AdvaMed Response**

As indicated in our general comment above, the criteria for changing premarket or postmarket regulatory requirements should be the same as FDA currently requires for premarket and postmarket submissions: valid scientific evidence. It would be inappropriate to change premarket and postmarket regulatory requirements based merely on anecdotal or incomplete or improperly derived observational data without further confirmation or validation of the safety issues. This is in part due to the nature of the industry, where small entrepreneurial companies could be irreparably harmed by unpredictable and changing pre and post market requirements. AdvaMed also believes that different thresholds for action exist depending on whether the new scientific information is related to either safety or effectiveness. In addition, any changes in clearance or approval requirements should be documented by FDA and made generally available to all device manufacturers as early and as quickly as possible, preferably via a new or updated guidance.

#### ***Specific Comments on Case Study 1.a.***

With respect to Case Study 1.a.<sup>1</sup>, there are several relevant points to consider. The case study does not make clear whether “when used in the long-term for its cleared use” refers to long-term use in an individual patient (e.g., an implant that remains in a patient for 10 years or more) or to broad market use of the device over a long time period (e.g., equipment used on a regular basis on multiple patients over a long timeframe). Assuming the first interpretation, FDA should first work with the individual manufacturer to determine whether the problem is unique to the manufacturer’s particular device and to assess whether the issue is related to the device, user or condition and whether it is an issue with design, materials, manufacturing or labeling. The safety issue may, for example, be easily rectified via a labeling change or required warning (e.g., the device should not be used for periods of long duration). If the safety issue, for example, is related to a manufacturing issue, it may not be applicable to all devices in the category.

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<sup>1</sup> Case Study 1.a. -- CDRH clears Device X for marketing through the 510(k) process. Device X is cleared for a specific intended use. Several years later, a pattern of Medical Device Reports (MDRs) that have been submitted to CDRH calls into question the safety of the device when used in the long term for its cleared use. A number of other devices of the same type and with the same intended use as Device X are on the market when this new safety information comes to light. There is also a device of the same type, Device Y, under review through the 510(k) process. The 510(k) submission for Device Y cites Device X as a predicate.

Assuming the second interpretation (broad market use of the device over a long time period), FDA still needs to assess whether the concern is specific to a particular manufacturer's device as discussed above. If the issue affects a device category, FDA should as a first step conduct a risk analysis and take steps to validate or confirm the safety signals arising out of the MDRs. FDA should also contact the sponsor to obtain information from complaint files and complaint trending to help assess the validity of the MDRs. Then, if there is an unacceptably high risk/benefit ratio, FDA has a range of options to choose from including among others: post approval studies, a public health notification (PHN), a device category labeling change or warning, new clearance requirements or a combination of these. If the risk is sufficiently high, FDA could also order a recall of one or more of the products. It should be noted that not all of the devices that cite the predicate may share the specific cause of risk. A device type recall would only be necessary if it is clear that the risk is common to the device type. In all cases, FDA's actions should be commensurate with the level of risk posed. In addition, any changes in clearance requirements should be documented and made generally available to all device manufacturers as early and as quickly as possible, preferably via new or updated guidance.

***Specific Comments on Case Study 1.b.***

With respect to Case Study 1.b.<sup>2</sup>, the case study indicates that a single peer-reviewed study failed to replicate the clinical trial results of Device Z. In general, we believe it would be inappropriate to take regulatory action based on only one peer-reviewed study.<sup>3</sup> Despite its being published and peer-reviewed, it is not a certainty that the published trial is "more correct" than the pivotal trial associated with the approved product. There are many reasons clinical trial results may not be successfully replicated. It would for example, be important for FDA to understand what aspects of the trial were unable to be successfully repeated (e.g., higher incidence of adverse events). In addition, since the case study indicates there are other PMA products of the same type, FDA may be able to garner important information from a review of the associated pivotal trials. FDA should also consider the track record of the device(s) on the market. Affected PMA holders should be provided an opportunity to reconcile and/or critique the contradictory information presented in the single peer-reviewed study. The PMA holders should also be given an opportunity to provide complete information on post-approval experience with the device including the results of any post-approval studies. Finally, if the device(s) are safe and effective, then the only action needed may be revising trial requirements for future devices.

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<sup>2</sup> Case Study 1.b. -- CDRH approves Device Z for marketing through the PMA process on the basis of favorable results in a pivotal clinical trial. Several years later, a compelling peer-reviewed publication reports that an attempt to replicate these clinical trial results was unsuccessful. A number of other devices of the same type and with the same intended use as Device Z are PMA-approved and on the market when this article comes to light. There is also a device of the same type and for the same intended use, Device Q, under review through the PMA process.

<sup>3</sup> The retraction by *The Lancet* of Andrew Wakefield's 1998 paper on an association between MMR vaccine and autism on Feb. 2, 2010 offers a potentially relevant cautionary tale.

In this case study scenario, we believe FDA should take a step-wise approach that includes careful monitoring of the literature and careful monitoring of MDRs and manufacturer complaint handling systems for these devices. Nevertheless, if FDA's device experience or literature monitoring reveal a compelling pattern or other substantial evidence (beyond one study) confirms safety concerns, FDA then has a range of options at its disposal (see response to Case Study 1.a.). Products under review should not be affected unless there is compelling evidence that there are issues either with study design or data for the devices under review. In addition, any changes in approval requirements should be documented and made generally available to all device manufacturers as early and as quickly as possible.

***Specific Comments on Case Study 2. a.- d.***

With respect to Case Study 2.a. thru d.<sup>4</sup>, one important difference to note (in contrast to Case Study 1.b.) is that the scenario indicates that *more than one* study exists i.e., “**other compelling peer-reviewed studies**” (emphasis added). This suggests that the surrogate's failure to reliably track the expected clinical outcome has, in effect, been validated by numerous studies. FDA should utilize the relevant Advisory Committee to assess whether the peer-reviewed studies indeed provide substantial evidence that the original surrogate is no longer valid.

In all the relevant variations, it will be important for FDA to communicate to all affected manufacturers as early as possible if the surrogate is no longer appropriate.

In variation b. FDA could consider post-market studies to assess the continued safety and efficacy of the cleared/approved devices and for the device still under review. In variation b. where products have already been cleared or approved using the surrogate endpoint, FDA should ask manufacturers for actual use data or for data from any condition or approval or Sec. 522 studies that may have been required to help validate the efficacy of the devices. FDA could also utilize validated Sentinel data to assess efficacy.

In variations c. and d., if information on actual use or other data demonstrate effectiveness and do not show lack of safety, FDA will have to take this into consideration for investigational devices and devices under review. There should also be prompt communication with the sponsors to determine if other data are available either from the IDE or other sources which address the clinical outcome in question. If not, every effort should be made to preserve the existing study data and to maximize its use in

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<sup>4</sup> Case Study 2. a. thru d. -- A company works with CDRH to design a three-year clinical trial to study an investigational device, Device J. The trial will assess the effect of Device J on a particular measurable variable, which is meant to be a surrogate for a specific clinical outcome. In year two of the trial, CDRH learns from other compelling peer-reviewed studies in publication that the surrogate does not reliably track the expected clinical outcome. Consider the following variations on the case above: a. Prior to this point, CDRH has not cleared or approved any other devices on the basis of clinical trials using this surrogate endpoint; b. Prior to this point, CDRH has cleared or approved a number of other devices on the basis of clinical trials using this surrogate endpoint; c. At this point, there are several other investigational devices that are being tested in clinical trials using this surrogate endpoint; d. At this point, CDRH is reviewing a PMA for an investigational device that was tested in a clinical trial using this surrogate endpoint.

determining whether the PMA should be approved. For example, a protocol modification that would collect additional data on a subset of the IDE subjects should be considered.

***Specific Comments on Case Study 3.a. – c.***

Case Study 3.a. – c.<sup>5</sup>, refers to a “new state of the art device with a significantly more favorable risk-benefit profile.” This term is undefined and AdvaMed believes that any attempt to include this concept in new regulatory policy should require a clear standard with clear criteria to guide FDA actions. It is also important to remember that per the Food, Drug, and Cosmetic Act, FDA’s mission is to assure that the devices FDA clears or approves are “reasonably safe and effective.” If products are unsafe or ineffective, FDA has the authority to remove those products from the market. Moreover, different device designs and approaches (including older device designs) are responsive to differing patient needs. Clinicians are in the best position to determine which devices are appropriate for their patients so long as they are receiving accurate and up-to-date information on the devices in question. Importantly, FDA does not remove older drugs from the market simply because newer drugs are approved. They are removed only if they are unsafe. Similarly, unless devices are determined to be unsafe or ineffective, there is no rationale for removing them from the market. Finally, FDA must be cautious in making determinations that would limit medical devices to only those that are in the Agency’s estimation the “newest and best” devices, potentially limiting patient access to care and placing many facilities and providers at a severe disadvantage. The lack of a medical device, even a first generation device, can be measured as a risk (compared to treatment with no device) just as easily as one can measure the risk presented by a medical device. See also our response to Question 3.

**2. When such changes are warranted, how should the center communicate them to industry, consumers, and other external constituencies? Should CDRH have a new regulatory paradigm for communicating with outside parties?**

**AdvaMed Response**

With respect to industry, FDA should communicate proposed new requirements based on new scientific information that affect particular categories of devices to *all* companies

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<sup>5</sup> Case Study 3.a. – c. CDRH clears Device W through the 510(k) process. At the time of clearance, it is considered to be state of the art. A number of other devices of the same type and with the same intended use as Device W soon come onto the market. Over the following years, devices of the same type and for the same intended use evolve through several generations, leading to a new state of the art device with a significantly more favorable risk-benefit profile than that of Device W and similar older devices. Device W and similar older devices are still in market use. There is also a device of the same type, Device R, under review through the 510(k) process. Device R has a similar risk-benefit profile to that of Device W, and the 510(k) submission for Device R cites Device W as a predicate. Consider the following variations on the case above: a. The newest devices are shown to be safer than Device W and similar older devices, but seem to have roughly the same level of effectiveness. b. The newest devices are shown to be more effective than Device W and similar older devices for their intended use, but seem to have roughly the same level of safety. c. The newest devices are shown to be both safer and more effective than Device W and similar older devices.

rather than in “one-off” communications to individual companies as is frequently done today. AdvaMed continues to believe that guidance, including updated guidance, is the most appropriate way to communicate new scientific or regulatory decisions across device categories. For fast-moving safety issues, letters or e-mails to companies remain appropriate and enable companies to move rapidly to address the issue. As indicated above, FDA can also consult with the affected industry to share concerns, obtain additional information and context and discuss the process.

With respect to providers, industry and other external constituencies, public health notifications (PHNs) that incorporate warnings are another mechanism FDA already uses. However, in the past, FDA has failed to discuss the issues involved in PHNs with all interested stakeholders (for example clinicians who may hold differing views) leading to biased notices. Although the severity of the safety issue must be considered and may require fast action, FDA should, whenever possible, consult with all affected stakeholders before releasing a PHN. Furthermore, for less risky issues that do not require a PHN, FDA should consider developing a new method of communication that might result in better solutions and better communications to the public. AdvaMed would be pleased to discuss this further with FDA. FDA should also take advantage of its standing Advisory Committees to share specific safety concerns and to help FDA assess the correct course of action. Advisory Committees would be especially useful in providing guidance to FDA on how to communicate the issue to patients.

In terms of communications to the public, FDA’s current communication methods are sufficient. Calibrating the appropriate tone and messaging to avoid alarming patients unnecessarily is critical. FDA’s Risk Communication Advisory Committee is in the process of evaluating appropriate communication methods for patients. FDA should also consider consulting this advisory committee in appropriate circumstances.

***Specific Comments on Case Study 2. a.- d.***

With respect to Case Study 2. a. – d. regarding use of surrogate endpoints in clinical trials that are later determined not to reliably track the expected clinical outcome, it is not clear to us why consumers and other external constituencies, other than the relevant clinical community and affected patients, need to be involved unless the device is posing risk to current patients. In that setting, FDA has many tools to use to communicate. Unless there is a specific risk, FDA does not currently apprise these groups of specific evidence expectations for specific trials and we are not aware of a convincing public health benefit that necessitates a change in this area.

**3. When such changes are warranted, how should CDRH apply them to devices currently under review?**

**AdvaMed Response**

It is important to recognize that not all changes should be applied to all products under review. FDA must first assess whether the problem is unique to one particular manufacturer’s device or applies across an entire device category. If it is the latter, FDA should first consider additional non-clinical testing that could be performed to confirm

the new evidence. If clinical studies or trials have already been completed, FDA should rely on post approval study approaches wherever possible. For example, FDA and a manufacturer could agree that additional information could be supplied after clearance/approval within a specified timeframe or could agree to a distribution plan limited to a highly skilled subset of physicians. FDA could also consider requiring large simple real-world trials for the product type in question that are focused on the issue of concern. FDA should require a new study (utilizing least burdensome principles) only if it is the most appropriate way to demonstrate safety and effectiveness. This is especially true for smaller and start-up companies. New regulatory requirements for products under review for these companies will be especially deleterious. Clearly, when credible and valid scientific information raises serious questions of safety and efficacy, FDA may need to factor that into the review/approval process but should do so in a way that pending submissions are not held up indefinitely. FDA should rapidly assess whether the new information has a specific bearing on the safety and efficacy of a given product submission and should make every effort to avoid a situation in which decision-making about pending submissions is delayed while FDA awaits additional information that may never be forthcoming. In the latter instance, consultation with Advisory Panels may be useful. FDA should also document any new clearance or approval requirements and make them available to all device manufacturers as early and as quickly as possible.

***Specific Comments on Case Study 2. a.- d.***

With respect to Case Study 2 variation d. regarding use of surrogate endpoints in clinical trials that are later determined not to reliably track the expected clinical outcome, FDA should consider post market studies if FDA's risk-benefit analysis allows the device under review (when the valid scientific evidence is acquired) to be cleared/approved. Again, FDA should take advantage of the relevant Advisory Committee to assess whether the peer-reviewed studies indeed provide compelling evidence that the original surrogate is no longer valid.

**4. When such changes are warranted, how should CDRH apply them to products currently on the market? For example, how should CDRH treat "first-generation" products as new and improved versions are developed?**

**AdvaMed Response**

This question raises a number of issues. First, it is important to recognize that new devices that are more safe or more effective do not necessarily mean that older devices are "unsafe" or "not effective." Clearly, this will not be true in all cases. Second, it should be recognized that the new device does not automatically become the standard of care. In many cases, the older devices may be part of accepted clinical practice or the standard of care. Newer devices also may not be *both* more safe and more effective. FDA should also consider that some clinicians and their patients may prefer older, more basic models without added features and about which more is known. Diverse product models, including older products, also help respond to a diverse patient population. In short, diverse product models, including older products, also help respond to diverse patient populations as well as differing clinician and facility needs.

In fact, there are numerous decision-makers (hospitals, clinicians, group purchasing organizations) who assess how and when to purchase new products and equipment. For example, rural hospitals may retain older devices and equipment longer than urban academic medical centers. Providers and standards organization such as the Joint Commission on Accreditation of Healthcare Organizations also can and do structure remediation efforts around known issues (e.g., nurses may be required to double-check inputs for older infusion pumps without the latest computerized safety features). Should FDA decide to proceed with policy in this area, it should do so via notice and comment rulemaking and should proceed cautiously so as not to inadvertently deter innovation and product improvements that will ultimately benefit patients.

## **B. Adapting to Novel Technologies or Novel Uses of Existing Technologies**

- 1. Assessing the safety and effectiveness of a novel technology can be challenging because the extent of information on and the level of understanding of the technology's risk-benefit profile or manufacturing process is less mature than that of a technology for which there is extensive "real-world" experience. What steps should CDRH take to assure that novel technologies or novel uses of existing technologies are safe and effective, without creating barriers to innovation, keeping in mind our statutory and regulatory framework?**

### **AdvaMed Response**

As discussed below in more detail, where needed, FDA should take full advantage of its expert review contracting authority to access individuals with expertise in novel technologies. FDA should also acknowledge that companies who have researched and developed the products have considerable knowledge and should work with the manufacturer to determine a reasonable course of bench, animal and clinical testing. In short, FDA should take maximum advantage of expertise within the agency and available to it outside the agency from medical professionals, industry, and its Advisory committees to bring the best collection of minds to bear on the development of appropriate requirements for new technologies.

FDA should also take an explicit risk-benefit approach with respect to novel technologies. For example, for products with low safety risk that target diseases with significant mortality, FDA should be less risk-averse in evaluating novel technologies. Conversely, for products with high safety risks that target diseases with low mortality, FDA may want to consider a more conservative approach in evaluating novel technologies. FDA should also recognize and take into consideration the particular challenges associated with applying new science to new technologies whose risks and benefits may only be fully differentiated in the long-term. As a number of speakers pointed out at the public meeting, novel technologies may, in some cases, present unanticipated risks and FDA cannot be held to the impossible standard of accurately predicting every possibility. Importantly, FDA cannot be completely risk averse – it must be willing to utilize risk-benefit approaches to approve novel technologies and thus assure improved therapies and improved patient health outcomes.

FDA may also use its authority to require special labeling or warnings, establish specific clinician training programs, closely monitor MDRs, or use its post approval authorities to require additional studies once the product is approved. In fact, FDA's PMA CoA study authority envisions this scenario and enables FDA to calibrate pre and post market requirements based on device risk. If more information is needed, it can be captured post-market via a CoA study. Depending upon the need, FDA can closely monitor the CoA study, can require more frequent reports and can make the results public at Advisory panel meetings.

### **C. Enhancing CDRH's Technical Competence and Analytical Capability**

- 1. With current resources, what proactive steps should CDRH take to address gaps in staff-members' knowledge about new science and reduce uncertainty in science-based regulatory decision-making?**

#### **AdvaMed Response**

There are a number of authorities and programs FDA already has that help address gaps in staff knowledge about new science and which are designed to reduce uncertainty in science-based regulatory decision-making. These include authorities provided in Section 907 – Contracts for Expert Review in the Food and Drug Administration Modernization Act of 1997 (FDAMA) which explicitly authorize FDA to contract with scientific experts to assist in the review process. During congressional consideration of FDAMA, there was a great deal of dialogue about FDA's need for more scientific expertise, particularly in the review of cutting edge technologies in which only a handful of individuals may be expert nation-wide. If FDA is not doing so already, it should be taking full advantage of this authority.

FDA should also actively seek *Cooperative Research and Development Agreements (CRADAs)* with industry in identified areas of need. FDA also has a relatively new program, the *Commissioner's Fellowship Program*, to recruit high-level scientists and health professionals. The two-year program is restricted to doctoral level degree (e.g., M.D., D.O., D.V.M., D.D.S., D.P.M., Pharm. D., Ph.D. or a Bachelor's in engineering disciplines) individuals and provides those individuals with FDA training and experience in hopes they will join the permanent FDA workforce. The FDA Science Board has lauded the high quality of the individuals participating in this program.

In addition, FDA has the *Medical Device Fellowship Program (MDFP)* which enables FDA to collaborate with clinicians, scientists, researchers and academicians. If for some reason the Commissioner's Fellowship Program or the MDFP is not attracting sufficient or relevant expertise, FDA could collaborate with the pertinent clinical societies, industry or other stakeholder groups for advertising and recruitment purposes. The FDA Staff College is another mechanism FDA uses to address gaps in staff knowledge.

FDA should also actively seek *Cooperative Research and Development Agreements (CRADAs)* with industry in identified areas of need. FDA also has a relatively new program, the *Commissioner's Fellowship Program*, to recruit high-level scientists and health professionals. The two-year program is restricted to doctoral level degree (e.g., M.D., D.O., D.V.M., D.D.S., D.P.M., Pharm. D., Ph.D. or a Bachelor's in engineering disciplines) individuals and provides those individuals with FDA training and experience in hopes they will join the permanent FDA workforce. The FDA Science Board has lauded the high quality of the individuals participating in this program.

In addition, FDA has the *Medical Device Fellowship Program (MDFP)* which enables FDA to collaborate with clinicians, scientists, researchers and academicians. If for some reason the Commissioner's Fellowship Program or the MDFP is not attracting sufficient or relevant expertise, FDA could collaborate with the pertinent clinical societies, industry or other stakeholder groups for advertising and recruitment purposes. The FDA Staff College is another mechanism FDA uses to address gaps in staff knowledge.

FDA should formally consult with industry via AdvaMed to poll for and better understand gaps in staff knowledge for which staff college programs are needed or for specific areas of expertise the Commissioner's Fellowship program or the MDFP could supplement. FDA could also host additional Vendor Days to enable reviewers to see technologies of interest. Industry is also happy to host FDA staff at its facilities for educational sessions on specific technologies or to take information on new technologies to FDA.

Finally, FDA should formally consult with *all* relevant stakeholders to identify and assess areas where FDA is lacking in scientific expertise. Once FDA has identified gaps and has development plans in place to fill those gaps, industry and other stakeholders can assist in identifying and perhaps providing appropriate resources.

In closing, thank you for the opportunity to submit comments on the incorporation of new science into regulatory decision-making within CDRH.

Sincerely,



Janet Trunzo  
Executive Vice President  
Technology and Regulatory Affairs