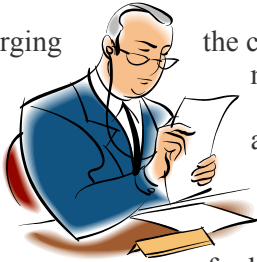


From the Political Front

A group of Democratic members of the House Energy and Commerce Committee sent a letter to Republican committee leaders Jan. 20, urging them to hold hearings to examine medical devices that have developed serious defects after being implanted in patients.

The members are also urging the committee to seek documents related to the Lap-Band weight loss device and urogynecologic surgical mesh.



This request follows an October request for hearings on two other medical devices that have caused serious problems: stents and metal-on-metal hip implants.

“The Committee has failed to schedule the hearing we requested in our October 12 letter, and we remain concerned that the Committee's previous hearings on medical devices have presented a skewed and inaccurate picture of the importance of appropriate medical device regulation,” the letter stated.

For example, in a Feb. 17, 2011, hearing, Energy and Commerce Committee Chairman Fred Upton (R-Mich.) said The Democrats said, “We hope you will reconsider your approach so that the Committee can have a fuller understanding of these critical issues as we prepare to reauthorize the Medical Device User Fees Act.”

The letter was signed by Energy and Commerce Ranking Member Henry A. Waxman (Calif.) and Reps. Diana DeGette (Colo.), and John D. Dingell (Mich.). The letter was sent to Upton; Joseph R. Pitts (Pa.), chairman of the Health Subcommittee; and Cliff Stearns (Fla.), chairman of the panel's Subcommittee on Oversight and Investigations.

The Democrats in the letter urged the committee to hold hearings “to examine whether FDA device regulation has been ineffective in protecting the public from dangerous medical devices like the Lap-Band and intravaginal mesh.”

The Lap-Band is a gastric band device that is surgically implanted and wrapped around

the upper portion of a patient's stomach to reduce its size. FDA approved the device for obese patients but has indicated that the device can pose serious risks, including erosion of the band through the stomach wall, stretching the esophagus, stretching the stomach pouch, stomach pain, gastroesophageal reflux disease, difficulty swallowing, nausea, and vomiting, the Democrats said in the letter.

According to the letter, Allergan, which manufactures the device, is seeking FDA approval to market the Lap-Band to children as young as 14, despite concerns among some physicians that the procedure is too drastic or extreme for a young person's developing body.

“The adverse public health consequences associated with use of this device are exacerbated by aggressive marketing and by the lack of a national registry of implanted medical devices, like those that exist in Europe, which would enable public health authorities to obtain more accurate data on the rates of adverse events and device failures,” the letter stated.

FDA in December sent warning letters to a California marketing company and several California surgical centers that sell the Lap-Band, telling them to immediately pull advertisements for the device that fail to adequately warn consumers about its risks.

Urogynecologic surgical mesh implant were permitted on the market under the 510(k) premarket notification process, meaning that the devices had to demonstrate that they were substantially equivalent to a device already on the market.

According to the House Democrats, beginning in October 2008, FDA started responding to rising reports of complications associated with the surgical mesh by issuing a Public Health Notification calling the transvaginal placement of the mesh “an area of continuing concern.”

FDA on Jan. 4 announced that it was requiring certain manufacturers to conduct studies of urogynecologic surgical mesh implants because of concerns over their safety and effectiveness. The agency also said it was considering reclassifying the devices from moderate-risk, or class II, to highest risk, or class III, which would require clinical data to be submitted for approval.

Device companies “are being forced to market their devices first in Europe because the EU countries have predictable and consistent regulatory processes.”

“It is unclear when the manufacturers of this device became aware of the serious health risks associated with the device,” the letter said. “It is also unclear if the manufacturers and the FDA have taken appropriate steps to protect patients.”

The Democrats further asked that the committee seek documents relevant to both the Lap-Band and intravaginal mesh devices. “In the case of the Lap-Band, we urge you to request documents from Allergan and the eight surgical centers named in the FDA’s warning letters to learn the degree to which these entities cooperated in the marketing of the Lap-Band, what steps were taken to minimize the risks the aggressive marketing campaign posed to patients and children in particular, and to obtain additional information regarding their knowledge of and response to device failures and adverse events,” the letter said.

In the case of the intravaginal mesh, “we ask that the Committee seek documents from the manufacturers of surgical mesh to ascertain when they first learned of the safety issues associated with certain uses of the device and what, if any, actions they took to limit risks for patients.”

The lawmakers in the letter said holding hearings would provide important information for members to evaluate in the context of the reauthorization of medical device user fees, which are paid by device companies and help fund FDA, along with congressional appropriations.

“As the Committee approaches reauthorization of the Medical Device User Fee Act, we need to understand the safety of devices on the market, the tactics device manufacturers and others use to market these devices, and the extent to which these tactics may increase risks,” the lawmakers wrote. “It is also vital that we understand whether device manufacturers and the FDA are taking appropriate steps to keep hazardous devices from the market and to protect patients from marketed devices that are later discovered to be dangerous.”

The current legislative authority for the medical device user fee program, the Medical Device User Fee Amendments of 2007, will expire in September, and new legislation will be required for FDA to continue collecting user fees for the medical device program. FDA was required to submit final recommendations to Congress by Jan. 15, but they were not submitted by that deadline.

They never seem too made the dates they themselves set. The other problem is when politi-

cians become involved in FDA matters the outcome is always poor.

Off Label Use and other Zen Masters

Off-label promotion – just the words leave clients shivering. Pharmaceutical and medical device manufacturers walk a fine line between providing current, relevant, and accurate medical information to their clients (health care professionals) and being accused of violating FDA regulations against off-label promotion. Even the FDA admits that:

“FDA has long taken the position that firms can respond to unsolicited requests for information about FDA-regulated medical products by providing truthful, balanced, non-misleading, and non-promotional scientific or medical information that is responsive to the specific request, even if responding to the request requires a firm to provide information on unapproved or uncleared indications or conditions of use.”

Draft Guidance at 6. How to accomplish that scientific communication without running afoul of FDA regulations is the tricky part. And, the FDA is now admitting, technology has made it a bit trickier.

The FDA hasn’t said much about internet promotion in any context, so this guidance is interesting just for admitting the internet exists. Even more interesting is the recognition that there is a lot of information floating around on the internet and not all of it is good. For instance, a consumer recently prescribed a drug for an off-label indication can post a question on Yahoo! Answers and it can be answered by anyone – no medical degree, no pharmaceutical experience, no scientific background required. So, we were encouraged by the FDA’s admission that maybe the drug and device manufacturers might offer better answers than Aunt Millie or anonymous-knowitall@server.com: “Furthermore, as these firms are regulated by FDA and have robust and current information about their products, FDA recognizes that it can be in the best interest of public health for a firm to respond to unsolicited requests for information about off-label uses of the firm’s products that are addressed to a public forum, as other participants in the forum who offer responses may not provide or have access to the most accurate and up-to-date information about the firm’s products.”

Draft Guidance at 3. But, the FDA is still trying to hide the off-label ball; trying to force anything substantive to be non-public. Drug and device

manufacturers have long been aware of the FDA's rules regarding how it should respond to non-public requests (phone calls, direct emails, one-on-one communications) for off-label information about their products and those rules really haven't changed – the response has to be specifically tailored, truthful, non-misleading, accurate, balanced, and scientific. But what about those internet questions – those posted on product websites, chat rooms, discussion boards, etc. When Aunt Millie responds to those public questions, her response – no matter how inaccurate – is out there for the whole world to see. So, shouldn't the specifically tailored, truthful, non-misleading, accurate, balanced, and scientific response by the manufacturer get equal all-access status. Not according to the FDA.

“Because product information posted on websites and other public electronic forums is likely to be available to a broad audience and for an indefinite period of time, FDA is concerned that firms may post detailed public online responses to questions about off-label uses of their products in such a way that they are communicating unapproved or uncleared use information about FDA-regulated medical products to individuals who have not requested such information. In this circumstance, communications to persons who have not requested information may promote a product for a use or condition for which FDA has not approved or cleared. FDA is also concerned about the enduring nature of detailed public online responses to off-label questions because specific drug or device information may become outdated (e.g., new risk information may become available).” Draft Guidance at 10. So, anonymous know it all's response can linger forever to be discovered years later by someone searching at random for information about a product, but a drug manufacturer's informed medical response has to be hidden under a rock. Essentially, the manufacturer can respond to a public request for off-label information only by providing contact information where the requester can make a non-public request.

Draft Guidance at 11. “Therefore, any substantive communication about off-label uses for the



product, in response to the original unsolicited off-label question, should occur solely between the firm and the individual who made the request. Regardless of the fact that the original, unsolicited off-label question may have been available to a very broad audience, the firm should not make its detailed response with off-label information publicly available within the same forum.”

This is simply weird. The FDA admits that the information itself, properly vetted and hemmed in by mandatory disclosures and fair balance (not the Fox News kind, either) requirements is not misleading if done privately. How could it possibly be misleading when it's public? Especially when the alternative is so easy. If the FDA is worried about the information somehow going stale, the posting companies could be made to keep track of where they post and update the information accordingly. That's not hard.

The public/private distinction is just silly – the FDA is making a mockery of free speech yet again for its bureaucratic reasons. Equally silly is the FDA's solicited/unsolicited distinction. The same information that the FDA admits is truthful and beneficial in one context becomes illegal in another, for reasons having nothing to do with the content of the speech and everything to do with the FDA's seeming death wish to continue banning truthful off-label promotion. Well we have seen the future and it is Sorrell – we fervently hope.

Still, we guess it is better than nothing. Some people will get beneficial information for some of their medical problems. We can only hope that when someone requesting information about a drug gets a response from anonymous know it all claiming to “know it all” and a response from the drug's manufacturer saying “please call us,” they do the latter. But doesn't the FDA know that it's impossible to censor the Internet? We trust it will find out the hard way like every other would-be Savonarola or Breen Master of the Web before them. Before the Civil War, the Post Office censored the mail to remove abolitionist literature. May the FDA's attempt meet with the same historical fate.

In hopes of hastening that eventuality we'd like to point out – to any of you entrepreneurs out there – that the FDA's Draft Guidance creates the possibility for a wonderful online business opportunity. The partial censorship that the FDA is proposing practically cries out for some industrious on-line aggregator to defeat it, and make a buck doing it. Here's how:

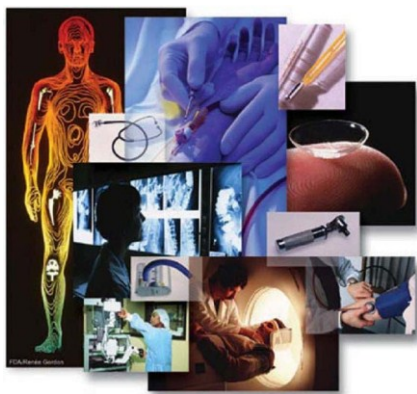
(1) There are lots of authoritative sources listing accepted off-label uses. There's a list in the Physicians' Desk Reference. There are the three compendia that Medicare uses in determining whether to reimburse off label uses. See 42U.S.C. §1396r-8(g)(1)(B)(i) (listing the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information, and the DRUGDEX Information System).

(2) Some enterprising soul – unaffiliated with any FDA regulated entity, of course – could send non-public emails, compliant with the Draft Guidance, to companies requesting information about all the off-label uses contained in these lists. We'd recommend a separate email for each off-label use. There's no business reason for the recipient companies not to respond with compliant replies, since sales are sales.

CDRH 2012 Strategic Priorities

CDRH has just published its wish list for the year. It contains a number of very interesting wants, and ideas. The entire publication is attached to this Oracle.

See page 3 for some very informative web links. The following are some of the priorities that we found to be very good ideas:



1.1.1. Strengthen Premarket Review

Goal 1.1.1.1. In 2012, CDRH will continue implementation of the action plan to improve our premarket programs.

By April 1, 2012, begin the Triage of Pre-market Submissions Pilot to increase submission review efficiency and better manage the pre-market review workload. By December 31, 2012, publish a proposed rule to clarify the circumstances under which CDRH could rely on clinical studies conducted in and for other countries. By December 31, 2012, finalize all guidance documents issued as part of the plan to improve our premarket programs. By December 31, 2012 conduct an evaluation of CDRH staffing, infrastructure, policies, and practices pertaining to medical software.

Goal 1.1.1.2. In 2012, CDRH will continue to take steps to address Class III device types currently

allowed to enter the market through the 510(k) process.

By December 31, 2012, clear within CDRH proposed rules for all remaining Class III pre-amendment medical devices.

Strategy 2.1. Enhance Communication and Transparency with Our Stakeholders

CDRH will develop and distribute timely information about medical device and radiation-emitting electronic products that is useful to our external constituencies, using methods that meet their needs, while giving them opportunities to engage in a dialogue with the Center about the issues important to them.

Goal 2.1.1. In 2012, CDRH will continue to take steps to strengthen information exchange and improve gathering feedback from our external constituencies.

By December 31, 2012, take steps towards establishing a national forum for engaging with patients, consumers and health care professionals in a dialogue about issues of interest to them.

Strategy 4.1. Foster the Development of Innovative Medical Devices

CDRH will work with our federal government partners and external constituencies to facilitate the development of innovative, safe and effective medical devices.

Goal 4.1.1. By September 30, 2012, CDRH will create processes and tools that will improve the pipeline for innovative medical devices and transform the way CDRH works with medical device innovators.

By March 31, 2012, using the Entrepreneurs in Residence Program, begin to pilot the Innovation Pathway 2.0.

By September 30, 2012, assess the implementation of the Innovation Pathway 2.0.

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Center for Devices and Radiological Health

CDRH 2012 Strategic Priorities



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INTRODUCTION

As we release our 2012 Strategic Priorities, we are proud to report on our accomplishments from 2011. We completed work on fifty action items in 2011. Highlights of the significant amount of work our staff accomplished in 2011 include:

- We released the [Plan of Action for Implementation of 510\(k\) and Science Recommendations](#) and completed many of actions in the Plan as well as undertook several additional efforts to improve our pre-market programs.
<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm276286.htm>
- We released a report, "Regulatory Science in FDA's Center for Devices and Radiological Health: A Vital Framework for Protecting and Promoting Public Health," to provide a broad overview of the many scientific activities in which our staff are currently engaged, as well as what we see as important regulatory science targets in the future as science and technology continue to evolve.
<http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM274162.pdf>
- We issued guidance on the Agency's regulatory expectations for in vitro diagnostic devices and therapeutic products that are developed together such that the therapeutic product depends on the diagnostic test to direct the use of the therapeutic product.
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm262292.htm>
- We played a critical role on the establishment of the International Medical Device Regulators Forum (IMDRF; see <http://www.imdrf.org/>), a voluntary group of medical device regulators from around the world who will charge future directions in medical device regulatory harmonization.
- We completed the pre-market reviewer competencies and began a Reviewer Certification Program (RCP) pilot.
<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm270858.htm>
- We launched an initiative to identify and promote best-quality device manufacturing practices. This includes a report, "Understanding Barriers to Medical Device Quality," that reviews the challenges that the FDA and industry face in supporting well-integrated, best-quality manufacturing practices and strategies that industry and the FDA can take to overcome these barriers.
<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm277272.htm>
- We completed database requirements and began the design and development phase of a unique device identification system. We also sent the draft rule to OMB.
<http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201104&RIN=0910-AG31>
- We launched the Innovation Initiative, which proposed actions the Agency could take to help accelerate and reduce the cost of development and regulatory evaluation of innovative medical devices in a way that maintains or improves patient safety and is based on sound science.
<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHInnovation/InnovationPathway/default.htm>

To complete this work our staff went above and beyond their already demanding workload. This is a remarkable achievement.

In 2012 we will focus on completing or continuing the work we already started in our four priority areas. This document identifies broad strategies that CDRH will implement in 2012 in alignment with those four priority areas: (1) Fully Implement a Total Product Life Cycle Approach, (2) Enhance Communication and Transparency, (3) Strengthen Our Workforce and Workplace, and (4) Proactively Facilitate Innovation to Address Unmet Public Health Needs. It includes timeframes associated with each strategy, and specific actions we will take to meet those goals or make significant progress towards achieving those goals.

Working together to achieve these goals we can take important steps to further our mission to protect and promote the public health.

PRIORITY I. FULLY IMPLEMENT A TOTAL PRODUCT LIFE CYCLE APPROACH

CDRH will make well-supported regulatory decisions that take into consideration all of the relevant information available to the Center, at any stage of a product's life cycle to assure the safety, effectiveness, and quality of medical devices, and the safety of non-device radiation-emitting products.

Strategy 1.1. Enhance and Integrate Premarket, Postmarket, and Compliance Information and Functions

CDRH will have in place strong, mutually reinforcing organizational components supported by integrated knowledge management systems, that work with a unity of effort toward our mission, and that are equipped to anticipate and address changes in the scientific and global-market landscape.

1.1.1. Strengthen Premarket Review

Goal 1.1.1.1. In 2012, CDRH will continue implementation of the action plan to improve our premarket programs.

- ❖ By April 1, 2012, begin the Triage of Pre-market Submissions Pilot to increase submission review efficiency and better manage the pre-market review workload.
- ❖ By December 31, 2012, publish a proposed rule to clarify the circumstances under which CDRH could rely on clinical studies conducted in and for other countries.
- ❖ By December 31, 2012, finalize all guidance documents issued as part of the plan to improve our premarket programs.
- ❖ By December 31, 2012 conduct an evaluation of CDRH staffing, infrastructure, policies, and practices pertaining to medical software.

Goal 1.1.1.2. In 2012, CDRH will continue to take steps to address Class III device types currently allowed to enter the market through the 510(k) process.

- ❖ By December 31, 2012, clear within CDRH proposed rules for all remaining Class III pre-amendment medical devices.

1.1.2. Address Challenges Associated with Globalization

Goal 1.1.2.1. By September 30, 2012, CDRH will have in place mechanisms to further harmonization efforts and exchange medical device information with foreign regulatory authorities.

- ❖ By March 31, 2012, hold the first meeting of the International Medical Device Regulators Forum.
- ❖ By September 30, 2012, participate in at least two harmonization activities with one or more foreign regulatory authorities.

1.1.3. Enhance Compliance Capability

Goal 1.1.3.1. By December 31, 2012, CDRH will begin to implement its business-case-for-quality initiative to address best-quality manufacturing practices, including mechanisms for FDA-industry engagement and increased transparency of device quality data.

- ❖ By June 30, 2012, select and begin to implement 2012 actions in support of the business-case-for-quality initiative.
- ❖ By December 31, 2012, select actions to be implemented in 2013 in support of the business-case-for-quality initiative.

Goal 1.1.3.2. By October 31, 2012, CDRH will take steps to enhance the efficiency and clarity of the medical device and radiation-emitting product recall processes.

- ❖ By September 30, 2012, develop methods and procedures for the systematic analysis and use of medical device recall information.
- ❖ By October 31, 2012, develop and begin to implement criteria for terminating recalls, including online posting of recall terminations.

1.1.4. Enhance Collaboration Through Reorganization

Goal 1.1.4.1. In 2012, CDRH will continue to implement its reorganization plan to enhance and integrate premarket, postmarket, and compliance information and functions.

- ❖ By December 31, 2012, provide at least two updates to staff on the status of the reorganization.

1.1.5. Implement a Knowledge Management Strategic Plan

Goal 1.1.5.1. By October 31, 2012, CDRH will develop and begin to implement a Knowledge Management Strategic Plan to make the best use of information collected or developed by CDRH.

- ❖ By March 31, 2012, hire a Knowledge Management Director.
- ❖ By October 31, 2012, finalize and begin to implement CDRH's Knowledge Management Strategic Plan.

1.1.6. Assess Real World Device Performance

Goal 1.1.6.1. By October 31, 2012, CDRH will develop a comprehensive strategy to assess real world device performance.

- ❖ By April 30, 2012, post on the web a proposed strategy to assess real world device performance and seek public input.
- ❖ By October 31, 2012, develop a comprehensive framework for the timely evaluation and management of significant postmarket signals.

1.1.7. Enhance CDRH's Quality Assurance Program

Goal 1.1.7.1. By December 31, 2012, strengthen CDRH quality assurance framework for periodically auditing the Center's regulatory programs and decisions and providing recommendations for improvement.

- ❖ By June 30, 2012, hire an Assistant Director for Quality Assurance.
- ❖ By December 31, 2012, implement a Center-wide quality assurance program.

PRIORITY 2. ENHANCE COMMUNICATION AND TRANSPARENCY

To improve public health and foster trust among our employees and with our constituencies, CDRH will provide meaningful and timely information about the products we regulate and the decisions we make, through strategic outreach and systems that support transparency and two-way communication.

Strategy 2.1. Enhance Communication and Transparency with Our Stakeholders

CDRH will develop and distribute timely information about medical device and radiation-emitting electronic products that is useful to our external constituencies, using methods that meet their needs, while giving them opportunities to engage in a dialogue with the Center about the issues important to them.

Goal 2.1.1. In 2012, CDRH will continue to take steps to strengthen information exchange and improve gathering feedback from our external constituencies.

- ❖ By December 31, 2012, take steps towards establishing a national forum for engaging with patients, consumers and health care professionals in a dialogue about issues of interest to them.

Strategy 2.2. Improve Internal Communications

CDRH staff will have access to timely information about what the Center is working on, completed projects, organizational information and will have opportunities to engage dialogue, share ideas and make suggestions to enhance CDRH's ability to successfully achieve our mission.

Goal 2.2.1. By December 31, 2012, CDRH will establish an internal communication program to improve communication of information and ideas to and from CDRH Staff.

- ❖ By September 30, 2012, issue standard operating procedures (SOPs) for sharing information with CDRH Staff.
- ❖ By December 31, 2012, with input from staff, develop and begin to implement a plan to improve internal communication.

PRIORITY 3. STRENGTHEN OUR WORKFORCE AND WORKPLACE

CDRH will be a thriving organization with the knowledge, skills, and technical expertise we need to fulfill our mission; a collaborative employee culture; efficient administration of CDRH programs; and a workplace environment that supports productivity.

Strategy 3.1. Continue to support the Life Cycle Approach to CDRH Employee Education

CDRH employees will have access to high quality educational tools and programs, assuring that we accomplish our mission and meet the anticipated demands of the future.

Goal 3.1.1. By December 31, 2012, CDRH will launch the Experiential Learning Program (ELP) to enhance premarket reviewer knowledge of how medical devices are designed, manufactured, and utilized by providing real-world learning opportunities.

- ❖ By March 31, 2012, begin the ELP pilot.
- ❖ By December 31, 2012, fully implement the ELP.

Goal 3.1.2. By December 31, 2012, CDRH will launch the CDRH Leadership Enhancement and Development Program (LEAD) to provide CDRH managers and supervisors information and tools to assure effective leadership.

- ❖ By March 31, 2012, begin the LEAD pilot.
- ❖ By December 31, 2012, fully implement LEAD.

Strategy 3.2. Enhance Employee Satisfaction

CDRH will recognize the value of our employees and provide a workplace environment that supports productivity.

Goal 3.2.1. By September 30, 2012, CDRH will make recommendations on how to adequately recognize good employee performance and address poor performance.

- ❖ By February 28, 2012, form an internal, cross-Center, staff-led work group to develop recommendations.
- ❖ By September 30, 2012, share with Center staff the work group's recommendations and seek their input.

Goal 3.2.2. By September 30, 2012, CDRH Offices will make recommendations on what resources are necessary to ensure staff are successful in performing their work.

- ❖ By May 31, 2012, Offices will solicit recommendations from staff on what resources are necessary to ensure staff are successful in performing their work.
- ❖ By September 30, 2012, Offices will share their recommendations and an action plan for implementation with staff.

PRIORITY 4. PROACTIVELY FACILITATE INNOVATION TO ADDRESS UNMET PUBLIC HEALTH NEEDS

CDRH will further enhance our efforts to anticipate emerging technological trends and public health challenges and partner with federal and external stakeholders to facilitate the development of innovative, safe and effective medical devices and advance regulatory science.

Strategy 4.1. Foster the Development of Innovative Medical Devices

CDRH will work with our federal government partners and external constituencies to facilitate the development of innovative, safe and effective medical devices.

Goal 4.1.1. By September 30, 2012, CDRH will create processes and tools that will improve the pipeline for innovative medical devices and transform the way CDRH works with medical device innovators.

- ❖ By March 31, 2012, using the Entrepreneurs in Residence Program, begin to pilot the Innovation Pathway 2.0.
- ❖ By September 30, 2012, assess the implementation of the Innovation Pathway 2.0.

Strategy 4.2. Further Develop a Personalized Medicine Program

CDRH will work collaboratively with our federal government partners and external constituencies to assure the appropriate regulatory oversight of therapeutics and diagnostics when their safety and effectiveness are intimately tied to one another.

Goal 4.2.1. By September 30, 2012, CDRH will continue to develop policies and procedures to assure that safe and effective diagnostic products that are either innovative themselves or provide innovative uses reach the public.

- ❖ By June 30, 2012, clear within CDRH the final guidance on Companion Diagnostics.
- ❖ By December 31, 2012, clear within CDRH draft guidance on co-development of drugs or biologics and devices.

Strategy 4.3. Strengthen Regulatory Science

CDRH will work collaboratively with our federal government partners and external constituencies to advance medical device regulatory science.

Goal 4.3.1. By December 31, 2012, CDRH will have in place mechanisms to enable collaborative work between FDA, our federal government partners and external constituencies to advance medical device regulatory science.

- ❖ By December 31, 2012, establish a public-private partnership between industry, the FDA, and academia to advance regulatory science.

Goal 4.3.2. By September 30, 2012, CDRH will expand computer modeling and simulation efforts to support regulatory science.

- ❖ By September 30, 2012, finalize a strategy for validating and incorporating computer models that are part of the Virtual Physiological Patient Project into a publicly accessible library that can be used in device development and regulatory applications.