Improving Patient Access Though Early Collaboration

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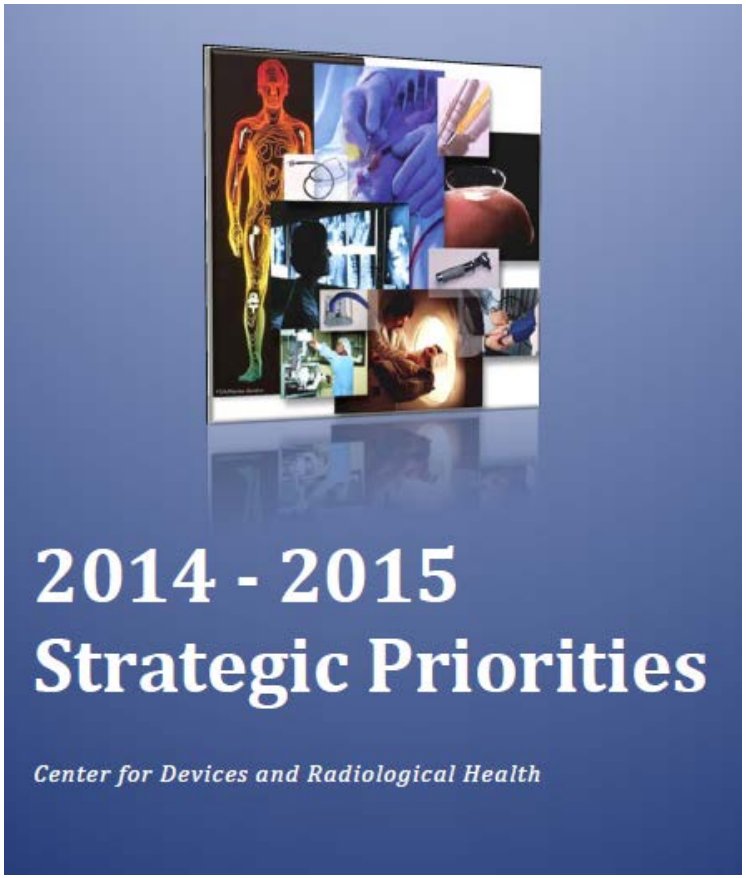


Vision: “Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world.”

We want our actions to improve the health, and enhance the quality of life of patients. If a device is safe and effective, we want patients to have access to it as quickly as possible.

Medical Device Development Process

Keys to Patient Access

Evidence

Value

Reimbursement

Market

Why is FDA talking about reimbursement?

"The success or failure of an innovative technology should be based on whether that technology works and fulfills a clinical need. However, the reality is that many other issues may cause the technology to fail, and one of those issues is reimbursement."

What is the real goal?

FDA understands the importance of gathering evidence required for 3rd party payer coverage, especially regarding innovative medical devices.

Three Critical Facts

- Margaret Hamburg, FDA Commissioner

  "Driving innovation is a key part of FDA's mission"

- Obtaining coverage and reimbursement are significant obstacles for innovative medical devices

- FDA interacts with medical device manufacturers early in the development process

How did we get here?

- FDA/CMS Memorandum of Understanding
- FDA/CMS Parallel Review
- CDRH 2013 Strategic Priorities
- Entrepreneurs in Residence Program
- Medical Device Reimbursement Task Force

FDA/CMS Parallel Review

- Current Projects
  - Exact Sciences: Cologuard colon cancer screening
  - Medtronic: renal denervation hypertension treatment
- CMS focus on Medicare beneficiaries
- National versus Local Coverage Decisions
- CMS decision making process is public
- Resources are limited

CDRH 2013 Strategic Priorities

Priority 1.

Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world.

Strategy 1.4. Strengthen the regulatory pathway from product concept to patient access

CDRH will work collaboratively with our federal government partners and external constituencies to reduce the time between pre-market approval and patient access to innovative medical devices.

Goal 1.4.1. By September 30, 2013, CDRH will take steps to streamline the pathway from FDA approval to reimbursement.

- By June 30, 2013, using the Entrepreneurs in Residence (EIR) program, begin a pilot project focused on ways to streamline the regulatory pathway from FDA approval to reimbursement.

Medical Device Reimbursement Task Force

Mission

Streamline the pathway from regulatory clearance or approval to reimbursement to support patient access to innovative medical devices

Plan

Develop a voluntary process that facilitates earlier interactions with payers, including private 3rd party payers about evidence to support coverage and reimbursement

> *"Winning coverage and payment has become a steeper challenge than gaining FDA approval for small device firms in recent years."*
>
> Mike Carusi on behalf of NVCA, AdvaMed and MDMA

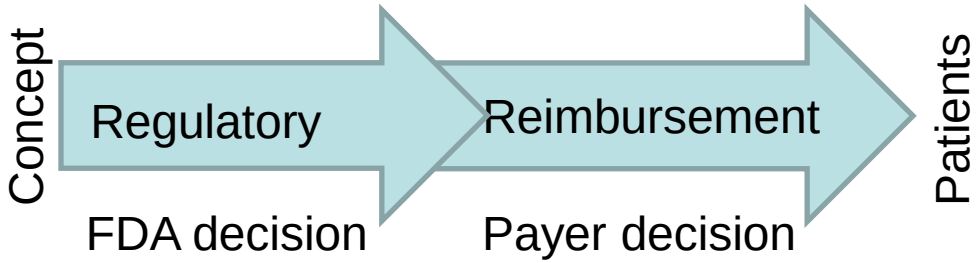
MDRTF Goals

1. Develop a voluntary process that facilitates earlier interactions with payers about evidence to support coverage.
2. Identify opportunities to share data to support coverage and reimbursement decision making.
3. Develop strategic partnerships with payers, trade organizations, and other stakeholders.
4. Establish a process to incorporate coverage related considerations into leap-frog guidance.

What is our future vision?

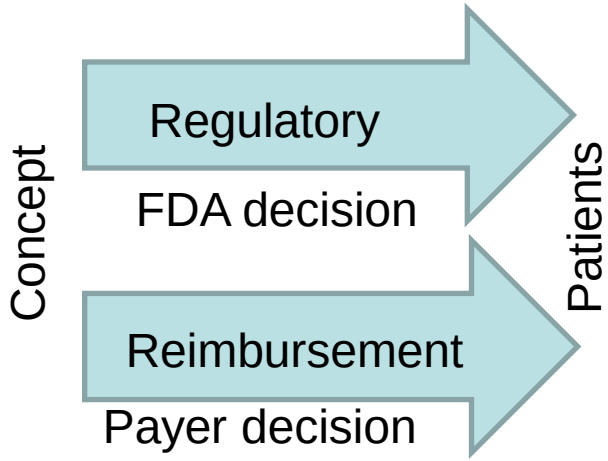
Now

- Steps in series
- Coverage/Reimbursement considered late
- Long gap between FDA decision and patient access



Future

- Steps in parallel or simultaneous
- Coverage/Reimbursement considered early
- Shorter gap between FDA decision and patient access



What are we proposing?

FDA Review Team

Manufacturer

Payer

Provide a process to enable manufacturers to include and engage payers during meetings with FDA using the Pre-Submission program.

What is FDA not doing?

- Creating a new formal program
- Becoming coverage or reimbursement experts
- Promoting specific devices or manufacturers
- Promoting specific payers
- Considering reimbursement or costs for approvals
- Modifying FDA review or decision processes
- Sharing documents or information
- Suggesting that payers use FDA's evidentiary requirements or alter our standards

Important Clarifications

- FDA evaluates Safety and Effectiveness in the same way using the same tools
- Manufacturers will opt-in
- Payers/providers will opt-in
- Manufacturers will invite payers/providers
- Discussions remain confidential
- Use existing FDA processes

What's in it for you?

Patient

- Earlier access to innovative technologies

Payer

- Learn more about new technologies beyond current horizon scanning
- Provide suggestions about what data and analyses would be useful for evaluation
- Learn more about FDA review process and public information

Manufacturer

- Engage payers in discussion about evidentiary needs
- Consider and address coverage-related issues earlier in the process
- Potential for earlier reimbursement through earlier engagement

FDA

- Improve public health by shortening the time for patients to access innovative medical devices

References

CDRH 2014-2015 Strategic Priorities

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FDA/CMS Parallel Review

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm255678.htm

Pre-Submission Program Guidance

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm310375.htm

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