Implantable Medical Devices: Accelerating Standards Development to Streamline Regulation

Joshua Price | August 2, 2018
Are You Affected by Implantable Medical Devices?

Pacemakers

188,700
ew new pacemakers in the US every year

Artificial Hips and Knees

1.05 million
1.05 million new artificial hips and knees in the US every year
## Defining Implantable Medical Device

### Medical Device
- Instrument or machine
- Intended to diagnose, cure, treat, or prevent disease
- Non-chemical action

### Implantable Medical Device
- Inserted surgically or otherwise
- Remains for at least 30 days

<table>
<thead>
<tr>
<th>Artificial disc</th>
<th>Pacemaker</th>
<th>Hip prosthesis</th>
<th>Intrauterine Device</th>
<th>Neurostimulator</th>
</tr>
</thead>
</table>

Medical Device Regulation

The Players

The Goals

Safety

Performance

Clinical Efficacy
Balancing Device Safety and Innovation

- FDA reviews 2600 device proposals per year
- In 2011, US patients waited 3.5 years longer than patients in the EU for new medical devices
- For the past 20 years, companies have been moving R&D abroad due to regulatory imbalances
FDA Device Regulation is Complex
New Implant Regulation: The PMA Process

Investigational Device Exemption (IDE)
- Approval from FDA to run clinical trials
- Parallel to Investigational Review Board (IRB) review
- 2 mo. to 2 yrs

Clinical Trials
- Gold standard is double-blind, randomized, controlled Trial but most aren’t
- 3 yrs long on average
- 3 mo. to 7 yrs

Pre-Market Approval (PMA)
- Information on:
  1. Clinical Trials
  2. Production facilities
- 98% of PMAs approved
- 180 days

Post-Approval Studies (PAS)
- FDA can order PAS to confirm long-term safety and effectiveness
- FDA often does not enforce PAS
- No limit
Standards and Device Regulation

Technical Standard
A “set of technical definitions and guidelines... for designers, manufacturers, and users... that promote safety, reliability, productivity, and efficiency” (ASME)

Example: ASTM F2083-12
Standard Specification for Knee Replacement Prosthesis

Recommendations
1. National Academies to Review Standards Role

The Health and Medicine Division Should:
Publish a review report about the impact of technical standards on:
1. Time to approve new devices
2. IDE and PMA approval rates
3. Clinical trial success rates
4. Number of new device applications

Authorize and appropriate $1 million
2. NIST Medical Implant Standards Program

Example of NIST Program: Standards for Immuno-histochemical imaging

NIST Should:
- Establish a program to identify and promote the development of new medical device standards
- Emphasis on modeling, simulation, validation, and measurements

Authorize and appropriate $500,000 annually
3. NIST-CDRH Medical Implant Center of Excellence

Example of Center of Excellence:

Center for Hierarchical Materials and Design (CHiMaD)

Collaboration between NIST and selected research institutions to advance a specific research area.

NIST and CDRH Should:

Establish a Center of Excellence (CoE) to perform R&D necessary for medical implant standards in emerging areas utilizing CDRH data and domain expertise.

Authorize and appropriate $5 million annually
In Conclusion

Safety
Performance
Clinical Efficacy
Innovation
Thank You

Questions?

Joshua Price
jprice@berkeley.edu