The FDA: Merging Innovation and Opportunity to Impact Public Health

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September 2009
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• This presentation should NOT be interpreted to imply or encourage inference that it reflects Guidance, Regulation or Statutes or the intent to develop such.

• The presentation and views expressed are not to be used as support for scientific, clinical or regulatory actions before FDA or any other regulatory agency.
Innovation Follows Recognition of Opportunity:
The Paths of Evolution and Revolution
Opportunities for Innovators

• Evolutionary
  • Based on communications from the Agency
  • Application of technology to improve safety, effectiveness, ease of use [and/or costs]

• Revolutionary
  • New Science
  • Disruptive advances
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⇒ Bridging technology across disciplines
Innovation Follows Recognition of an Opportunity
Paths for Innovation

Indicators  New Science
Paths for Innovation

Evolutionary Revolutionary
Evolutionary Innovation

Exploiting Life Cycle Management of Technology to Improve Safety, Effectiveness and Ease of Use
Infusion Pumps

- Ubiquitous in the hospital, increasing use in doctor offices and home care

- Perceived to be simple devices, but…
  - Software
  - Interface with disposables
  - Use in life sustaining settings
Infusion Pumps:  
An Opportunity Evident from Regulatory Activities

Multiple device recalls
- Company announcements
- DOJ involvement
- FDA’s searchable recall database:
  - Baxter Colleague ~300,000 units (global)
  - Cardinal Alaris ~300,000 units (global)
Infusion Pumps

Where Are the Innovations to Improve Safety, Reliability and Ease of Use?
“What I Want When I’m the Patient”

• Protection against being over or under dosed
• Proper warnings if there is problem, with robust diagnostics
• Reliable interface between disposables and reusables
• An interface that would make Apple jealous
Revolutionary Innovation

Nebulous, Risky and Disruptive: The Application of New Sciences
How is the FDA Preparing for New Science?
Platforms for Revolutionary Products
Opportunities for Bridging

- Nanotechnology
- Synthetic Biology
- Tissue Engineering
- Stem Cells
- Robotics
What is Nanotechnology?

- Size
- Properties
- Ingredient vs. Component
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⇒ If it’s small or may behave differently, let’s talk about it.
Chemists Can Make Novel Nanoscale Molecules

Shirai Nano Letters 2005
An Example of the Potential for the Tools: Nanocars Remotely Controlled
Robotics and Upper Extremity Prosthetics
Robotics and Upper Extremity Prosthetics
The Combination: A Miracle Ready to Happen?
Options to Prepare for Innovation

- Pass laws
- Establish regulations
- Publish Guidance Documents
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⇒ Each requires experience we don’t have
What Would Be Reasonable Messages From The FDA?

• Wouldn’t it makes sense to admit that there are more questions than answers?

• Given the novelty, shouldn’t we know if a product, includes or depends upon new science?

• Wouldn’t it be reasonable to treat *in vitro* diagnostics differently than implanted products?
Risk-Based Model for Nano-Products:
Scrutiny Increases with Greater Complexity and Risk

First Generation
• No nano-properties (predictable behavior)

Second Generation
• Nano-properties (unpredicted behavior)

Third Generation
• Mechanism of action via chemistry and physics (unpredictable behavior?)

Fourth Generation
• Nano-factories
How do we create consistent and transparent systems that welcome both evolutionary (incremental) and revolutionary innovations?
“The important thing is to not stop questioning.”

Albert Einstein
Are We Using Device Therapy Optimally for Treatment of Parkinson’s Disease?
The Neurosurgical Operating Room
Craniotomy Procedure
A Craniotomy Scar
Can We Explore an Approach Without a Craniotomy?
stimulus-isolator units

stimulation electrode

spinal cord
Which of You Will Be a Successful Innovator?