Future of Drug Development

Janet Woodcock
Director, CDER, FDA
THESIS
Multiple Forces Are Driving the Shape of the Future

- International regulatory convergence
- Advanced manufacturing
- Rise of biosimilars
- New science and technology
- Digital revolution
- Drug costs

THE GENERIC INDUSTRY AND ITS REGULATORS NEED TO BE AHEAD OF THESE TRENDS
International Regulatory Convergence

• This is a good thing
• Too many repetitive submissions in too many regions, too many inspection visits—leads to errors, increase costs
• Convergence of regulators:
  – Mutual reliance initiative between EU and US
  – At the end, only EU inspectors inspect in Europe and only US inspectors in USA
  – Must go through a process, currently just for surveillance inspections, but making progress
  – Other regulators could join
  – FDA interacts closely with other regulators via foreign offices
International Regulatory Convergence: Convergence of Standards

• ICH
  – Revitalized
  – Hope for and expect substantive industry participation
  – Continue to harmonize technical requirements

• Inspection reports
  – Need to be able to read each other’s reports (e.g., different languages, formats)
  – US: piloting NIP (“new inspection protocol”), procedures and standardized, quantified assessment
  – Ultimate goal—regulators use same tool, understandable work product worldwide, industry understands standards
Advanced Manufacturing

• I believe that continuous production will be revolutionary for solid oral dosage forms over the long run
• Firms will be able to use various platform technologies to easily and rapidly switch among strengths and APIs.
• Reduced costs, reduced or no off-line laboratory testing, reduced space and environmental footprint, better control of attributes, continuous 24 hr production when needed
Advanced Manufacturing

• Likely brand companies will adopt first, but ideal for manufacture of multiple different products that are similar
• It will be a number of years before the equipment, technology and know-how will be available commercially, but these will come
• This advance should decrease any regulatory problems significantly, due to ability to control attributes
Rise of Biosimilars

• Biologics are highest-priced medicines right now
• Biosimilars not generics—but greatly streamlined pathway
• Robust program taking place at FDA and industry—but still early times
• Any new scientific/technical program takes years to fully develop
• Cost pressure—rapid uptake once approved in US
New Science and Technology

• Some rapid uptake by generics—e.g., abuse deterrent opioid formulations

• Combination products
  – Advanced delivery systems
    • Inhalers
    • Auto-injectors
    • Future—into CNS, other spaces
  – Other drug-device combos
New Science and Technology

• Precision medicine/specialty pharma
  – Revolution coming in the treatment of many diseases
  – Large number or small/orphan subgroups
  – May be large number of related drugs using a “platform technology” i.e., small modifications needed to address different mutations within the same gene
  – Bottom line: increased number of different drugs needed
Digital Revolution: How Much Can We Automate?

• We are still in the pre-Henry Ford era of automation in drug development

• Ford’s lesson: standardization needed to get efficiency in a process

• We are getting electronic submissions, but the more we standardize, the fewer mistakes everyone will make and the more efficient the process will become

• Can’t make this too burdensome on your end, need to be congruent with business processes
Drug Costs

• Will be an ongoing theme
• Generic industry (most) seen as good guys, but issues with single source products
• Clearly will be a continued focus in US and elsewhere
• Various types of pressures on regulators
• We will continue to be asked ways to mitigate drug cost issues
GENERIC INDUSTRY AND ITS REGULATORS NEED TO BE AHEAD OF THESE TRENDS
GDUFA 2: Is it Forward-Looking?

• Not just about current efficiency/timeframes
• Prepares for the future, for example
  – Focused research to enable approval or more streamlined development of non-oral dosage forms
  – Complex drugs program: get advice upfront on development program
  – Interaction and guidance
CDER is Planning for the Future

• Lifecycle management
  – Awareness of lifecycle across center
  – Building in awareness at time of new drug approval

• Consistent, documented, automated procedures that are scalable: establishing QMS

• Continue to improve e-submission to streamline process and reduce cycling: hope to markedly reduce cycles so that CDER and industry can concentrate on getting work out and preparing for the future
Facility Assessment: An area of ongoing improvement efforts

- We understand the frustration about the timelines and relative lack of transparency of current process
- Area of high focus and intense effort
  - High priority for me personally
  - We will roll out new process with timelines and much more transparency
  - ORA reorganization in the spring, at that time our partners in facility assessment will be organized in a manner that will enable a much better process that reduces duplication
Summary

• Bold future for the affordable pharmaceuticals industry!
• Pace of change will be rapid
• Need to work with regulators to enable
• GDUFA 2 (and BSUFA 2) are next steps
• Industry undoubtedly will expand its role as major source of pharmaceutical care for the world’s population