Transformation/Innovation Opportunities for the NRC to Explore

Federal Perspective

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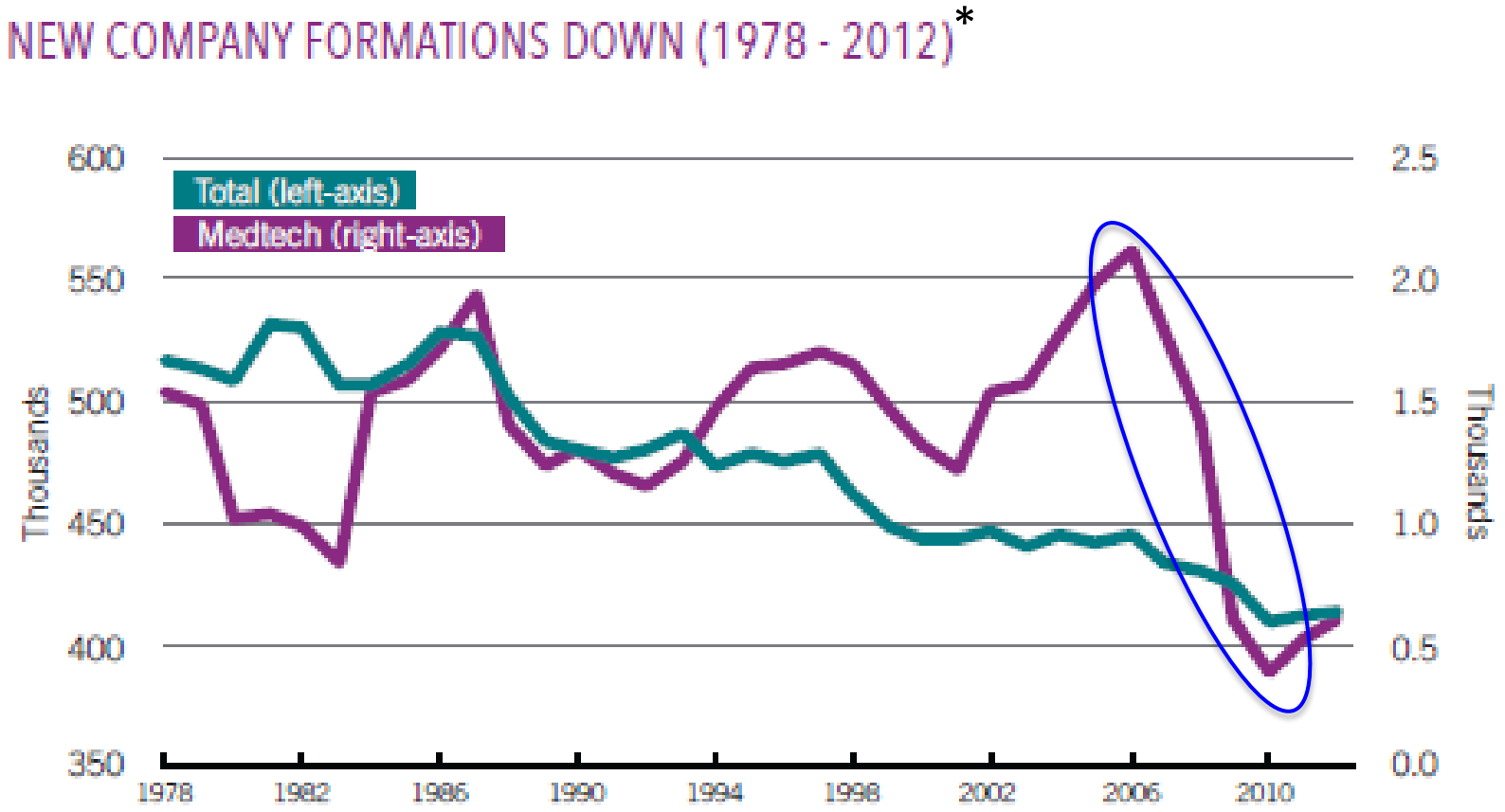
Nuclear Regulatory Commission
Discussion of Medical Uses of Radioactive Materials (public meeting)
Rockville, MD
January 28, 2020

CDRH Mission and Vision

<u>MISSION:</u> To Protect and Promote the Public Health. Assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices

<u>VISION:</u> Patients in the US have access to high quality, safe and effective medical devices of public health importance first in the world

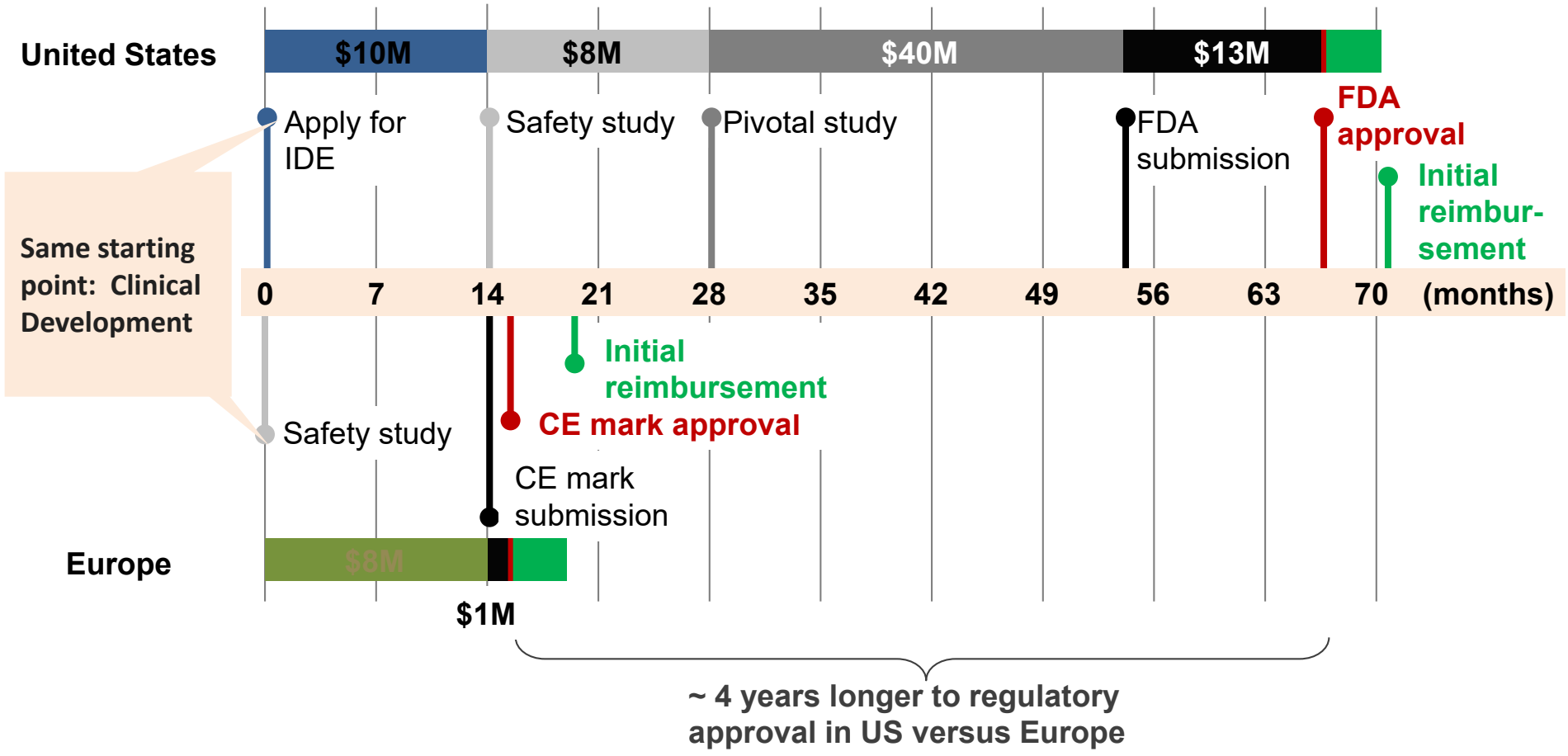
Long-term Decline in Start-up Density Since 1988



Stark decline in Medtech since 2006 to ~600 in 2012

*from: A Future At Risk: Economic Performance, Entrepreneurship, and Venture Capital in the U.S. Medical Technology Sector. Written by Innovation Counsellors LLC with support from AdvaMed Accell October, 2016
https://www.advamed.org/sites/default/files/resource/a_future_at_risk_advamed_october_2016.pdf

Makower Report (2010):
FDA Impact on US Medical Technology Innovation



Adapted from: Josh Makower white paper, "FDA Impact on US Medical Technology Innovation", November 2010

Entrepreneurs-in-Residence
Program One (Oct 2011 – May 2012)

Overview: The Entrepreneurs-in-Residence (EIR) program at CDRH is a time-limited recruitment of world-class entrepreneurs and innovators to join highly-qualified internal government employees in the development of solutions in areas that impact innovation

Goal: The EIR goal is to deliver transformational change by combining the best internal and external talent applying the principles of lean engineering in rapidly testing, validating and scaling new approaches

Focus: To better understand the drivers for the CDRH vision and to develop a new expedited pathway to improve patient access to innovative medical devices

- ESRD Innovation Challenge (2013 – 2016)
- Breakthrough Devices Program (2018)

Source: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHInnovation/InnovationPathway/ucm286138.htm

US Medical Device Industry: Innovation Challenges

Factors cited as having the highest impact on decisions to move medical device investment outside of U.S.*

Regulatory Challenges - 38%

Reimbursement Concerns - 18%

Clinical Trial Time and Costs - 14%

* from National Venture Capital Association/Medical Innovation & Competitiveness Coalition survey of 259 NVCA member firms investing in the healthcare sectors; 60% (156 firms responding) October, 2011

Entrepreneurs-in-Residence
Program Two (Oct 2012 – May 2013)

Focus: The EIR teams confronted the three challenging areas identified by NVCA that have the potential to better support a more robust environment for medical device innovation:

- Streamlining clinical trials
- Streamlining FDA approval to reimbursement
- Striking the right balance between pre- and post-market requirements

Source: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHInnovation/InnovationPathway/ucm286138.htm

FDA Responds to the Challenge

- Clinical Trials Program in ODE based on recommendations from the EiR Program
  - Early feasibility program: 17 approvals in FY 2013; 51 in FY 2019
  - Adaptive and Bayesian design
  - Patient-Centric Benefit/Risk; Patient perspectives
- Payor Communication Task Force to Streamline the path from FDA Approval to Payer Coverage (from EiR)
- Balancing Pre and Post-market Evidentiary Requirements
  - NEST – the use of Real-World Evidence
  - Coordinated Registry Networks (CRNs)

Continuous Innovation

Internal Innovation

- Training visits to innovative incubators/accelerators
- Training visits to payors

Public Private Partnerships

- KHI – American Society of Nephrology and FDA (2012)
- KidneyX – American Society of Nephrology and HHS (2018): Uses prize competitions to accelerate the development of innovative solution that can prevent, diagnose and/or treat kidney diseases

Thank You