

The U.S. Model for Growing an Innovative Med Tech Sector

Enhanced ASEAN Workshop

July 29-31, 2007 Hanoi, Vietnam

Jeffrey Gren

Director, Office of Health and Consumer Goods

International Trade Administration, USDOC

Presentation Outline

U.S. Medical Technology Industry

U.S. Competitive Advantage

USFDA Reforms

Research and Development

Role of Venture Capital

Conclusion

U.S. Regions with Strong Medical Technology Presence

Orange County - San
Diego CA

Silicon Valley CA

Minneapolis MN

Boston MA

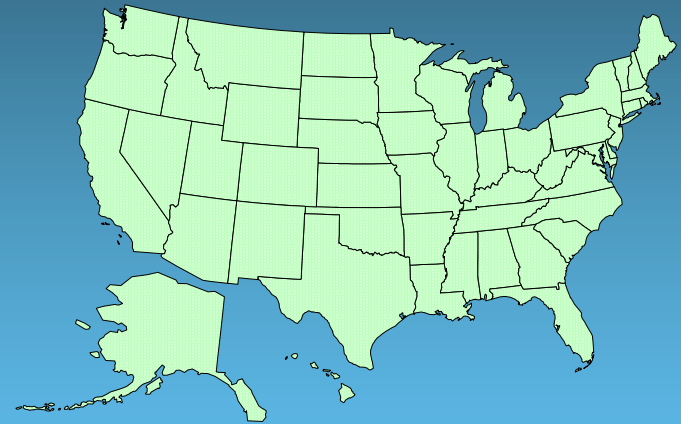
Atlanta GA

Chicago IL

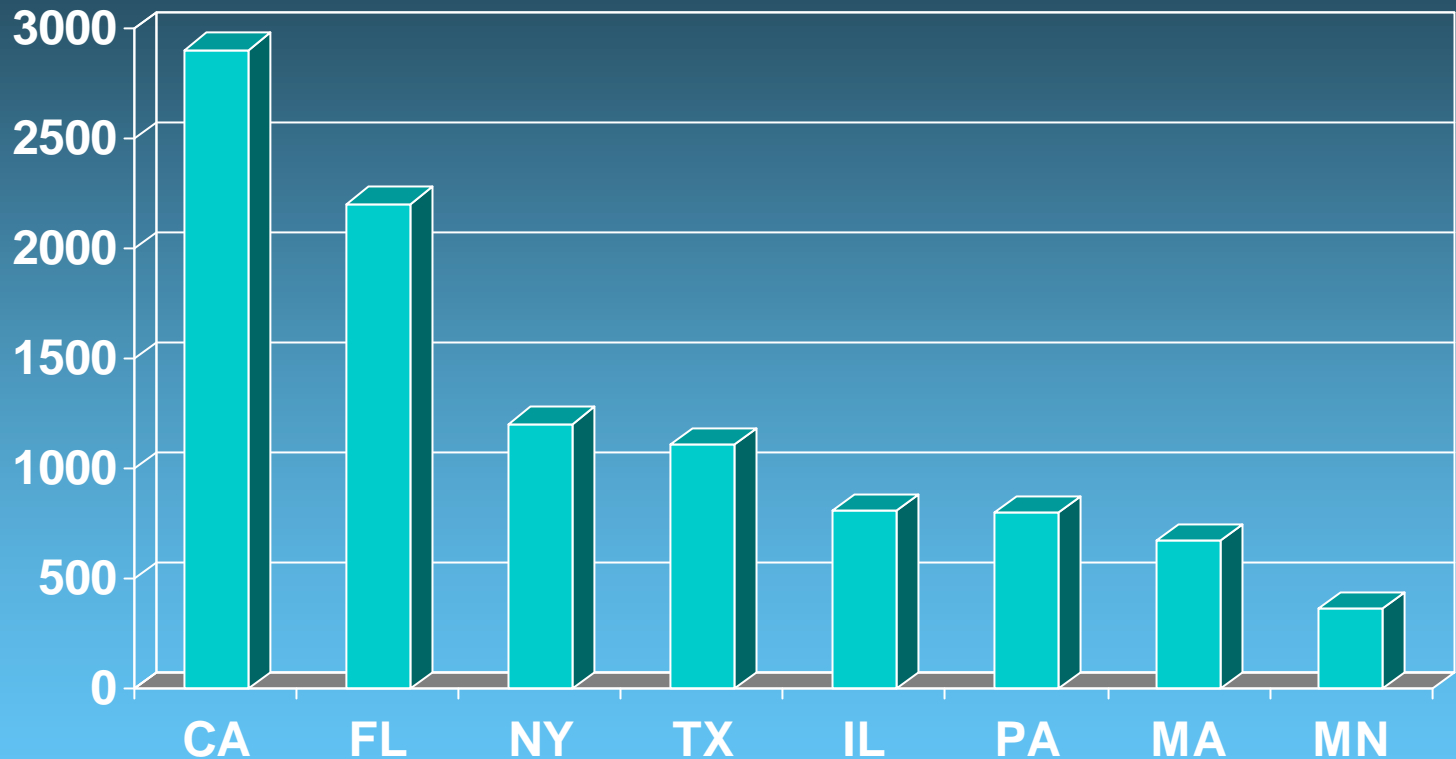
Fort Lauderdale,
Clearwater FL

Philadelphia PA

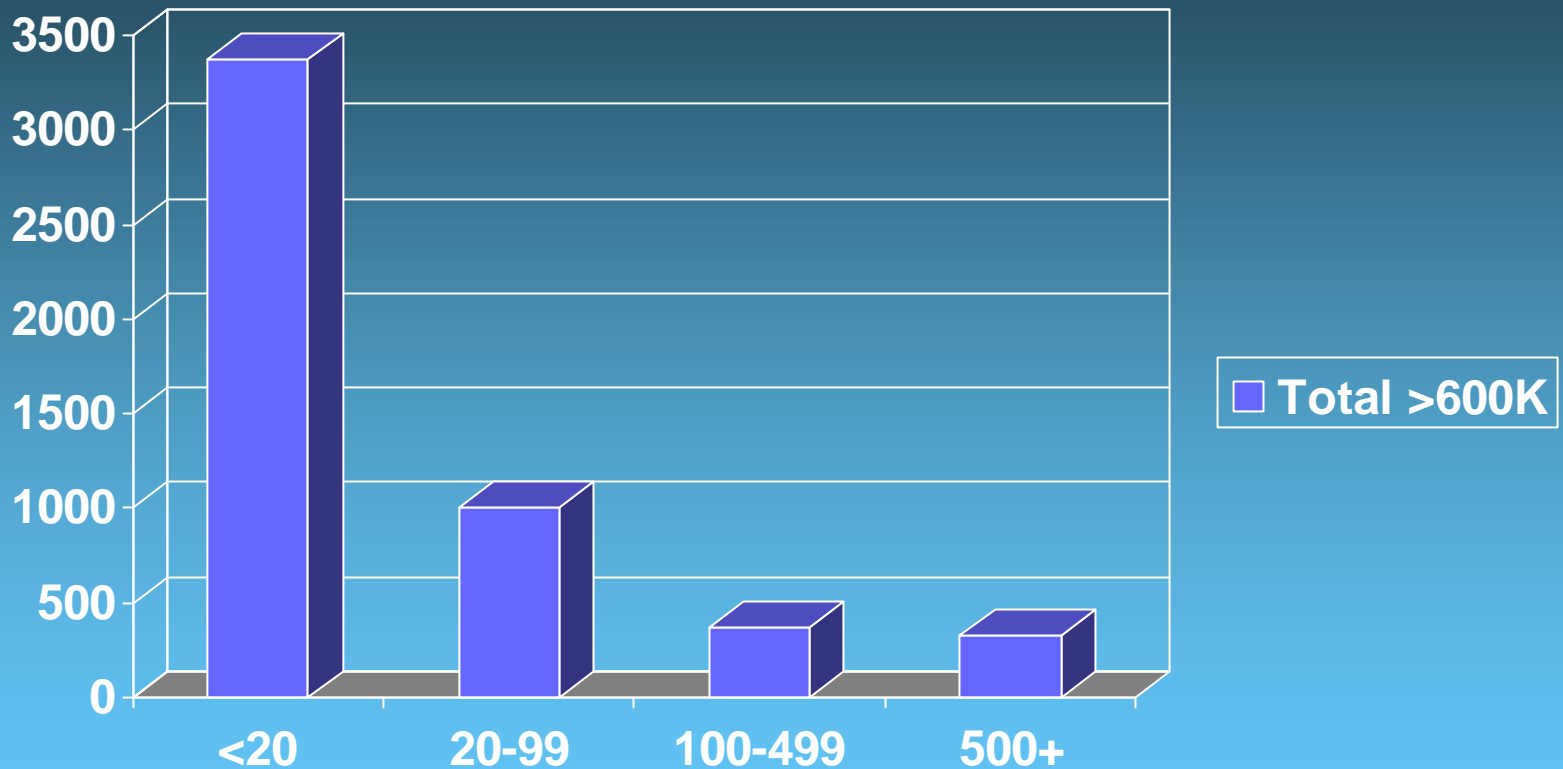
Houston, TX



Number of Medical Device Firms in Leading States



Distribution of U.S. Medical Technology Companies by Number of Employees



Origins of U.S. Competitive Advantage in Medical Technology

Largest Medical Device Market in the world
(48% of Global Consumption)

One Regulatory System and Common
Labeling Requirements

Creation of Regional “Critical Masses”

Collaboration with Academia

Coordination with National Institutes of
Health

CMS - High Reimbursement Values

USFDA Reforms

Medical Device User Fee and Modernization Act (MDUFMA) provides funds to expedite approvals

‘Critical Path Initiative’ explores ways to use advanced technologies to expedite approval

Guidance documents provide written assistance

Expanded use of Conformity Assessment Bodies (CABs) / Accredited Persons for product review and plant audits

R&D and Core Competencies

U.S. medical technology industry is highly invested in R&D

R&D allows firms to accelerate development of new products and improve existing products

Cooperative R&D encourages “cross-pollination” with related products

Creative Financing: Venture Capital

Addressing the funding challenge for
medical technology start-ups

Venture capital is an integral part of
growth in U.S. medical technology

Venture capital helps “multiplier effect”

Mergers and Acquisitions

Many start-ups are “groomed” by investors for purchase

Pattern: 1) small innovative firm, often associated with academia, develops a new med technology product; 2) company obtains U.S. FDA marketing approval; 3) company targeted for acquisition by large med device company

Advantages for both small and large firms – small firms benefit from added resources, large firm gain advanced technologies

Conclusion

During my presentation, I have outlined the U.S. medical technology model

U.S. medical technology has been very successful due to a variety of factors

Over the next 20 years the med tech the med tech industry will transform healthcare

Demand for medical technology will continue to grow due to aging population in developed countries and increased per capita income in developing economies

Thank you!

www.ita.doc.gov/health