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THE FUTURE OF US MEDTECH AT RISK
IS THERE AN EXIT FROM THE PERFECT STORM?
Disclosures

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- Board Member: NeoTract, Moximed, Vibrynt, Intrinsic Therapeutics, SuturePro, ExploraMed
- Consultant: several small and large medical device companies
Agenda

- Introduction
- The Perfect Storm
- Data From Recent FDA Focused Research
- Why Should We Care
- The Current State Of Play
- Call To Action
My Background...
A Perfect Storm?

- Global Financial Crisis
- Certain Aspects of Healthcare Reform
- Limitations on Physician-Industry Interactions
- Certain Aspects of Patent Reform
- Changes at the FDA
- A Broken Reimbursement System
The Financing Climate

- VC financing down nearly $1B*
  - $3.5B in 08
  - $2.5B in 09
  - $2.5B in 10
- Venture firms “feeding current children” not looking for more expensive mouths to feed
- VC syndicates are breaking
- More reliance on corporate financing
- Good start-ups failing to find capital
- First-funding of new medtech start-ups declining:
  - 2008: 118
  - 2009: 74
  - 2010: 60 ← best indicator of VC confidence & innovation impact

*PWC/NVCA
The Reimbursement Climate

- Lack of clarity for reimbursement decisions at the CMS level
- Organizations like WellPoint are becoming all powerful
- The CPT process is getting worse
  - More category III codes are being assigned
  - No industry representation on the panel (only BC/BS)
  - Political influence of specialty societies
  - Conflict of interest issues
Patent Reform

- Megatechs & entertainment vs. everyone else
- Key issues
  - Damages
  - Post Grant Opposition
  - Inequitable Conduct (IC)
- There is a recent resurgence on these topics and all are watching closely how the debate evolves
- Weakening the patent system in favor of Megatech would hurt lifescience companies substantially
Healthcare Reform

- Provisions Impacting the Device Industry:
  - Medical Device “Fee” (aka “Innovation Tax”)
    - $20B over 10 years
    - Likely begin in 2013 in the form of an excise tax
      - NOT A TAX ON PROFITS!!
    - Such a tax could hurt small as-yet-not profitable companies by diverting important investment capital meant for jobs and research to the federal government to pay the taxes
    - Bills introduced in the House and Senate to repeal the tax
  - Comparative Effectiveness Research (CER)
  - Physician Payment Sunshine Act
Conflict of Interest

- Physician Payment Sunshine Act
- MedTech must work closely with doctors
- Problem: Obsessively focused on monetary compensation to doctors
  - Does a dinner make a doctor forget what’s right?
- No acknowledgement of the more powerful conflicts of interest:
  - Political Power
  - Academic Prestige
  - Being ‘Right’
MedTech Innovation’s Greatest Challenge: FDA/CDRH

- Severe Risk Aversion/Fear Still Prevalent Internally
  - Agency has still not recovered from the “Letter of the concerned scientists” sent to Congress in 2008
  - Internal mandate to ensure “all IDEs lead to approval” has broken the IDE process
  - Potential overhaul of the 510k process continues despite mounting evidence the system was working well for patients and industry
Declining 510(k) clearances and PMAs over last 10 years

FDA PMA data: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm
FDA 510(k) data: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
Impact of FDA situation

- Increasing delays, expenses and frustration across the board for companies at FDA/CRDH
- Companies trying to advance their businesses overseas
- The most innovative therapies are developing a target on their heads with VCs
  - Less interest in funding PMAs or any projects with complicated long timelines or the possibility of panel
- Bright minds and innovators are considering leaving the industry to seek their fortunes elsewhere
FDA IMPACT ON US MEDICAL TECHNOLOGY INNOVATION
(A SURVEY OF OVER 200 MEDTECH COMPANIES)

December 2010

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Study Objectives

- To determine where problems (if any) are occurring for medtech companies with FDA processes and assess comparisons to the European pathway
- To provide quantitative data regarding the perception of the FDA and European regulatory pathways from medtech companies
- To assess the time and cost to medtech companies navigating the current FDA environment and assess any resultant impact
510(k) & CE timelines in US & Europe
Reported FDA transit times underestimate actual regulatory delay

- FDA (510k)
  - 2 months
    - is "average reported FDA review time"
  - 3 months
    - is "average reported total elapsed time from receipt to final decision"

- US Companies’ Experience With FDA (510k)
  - 10 months
    - from first filing to clearance
  - 31 months
    - from first communication to clearance (n=15) → low because most do not communicate w/ FDA prior to filing

- US Companies’ Experience In Europe (CE)
  - 7 months
    - from first communication to certificate

US/CE times reported by survey respondents
PMA & CE timelines in US & Europe
Reported FDA transit times underestimate actual regulatory delay

**FDA (PMA)**
- 9 months is “average reported total elapsed time from filing to approval for all original PMAs”

**US Companies Experience With FDA (PMA)**
- 54 months is time from first communication to approval (or till present)

**US Companies Experience In Europe (CE)**
- 11 months is time from first communication to certificate


US/CE times reported by survey respondents
European authorities are viewed as **more** predictable

![Bar chart showing the percentage of respondents viewing European authorities as predictable or unpredictable, with 'Highly predictable' at around 60%, 'Mostly predictable' at around 40%, 'Somewhat predictable' at around 20%, 'Mostly unpredictable' at around 10%, and 'Very unpredictable' at around 5%. The chart includes data from FDA (n=120) and CE (n=83).]
European authorities are viewed as **more** reasonable
European authorities are viewed as more transparent.
Cost to clear/approve a medical device

- $31,000,000* on average to bring a 510(k) product from concept through clearance
  - With $24,000,000 spent on FDA-dependent/related aspects

- $94,000,000* on average to bring a PMA product from concept through approval
  - With $75,000,000 spent on FDA-dependent/related aspects

*Does not include reimbursement approval and sales/marketing costs.
This study clearly documents the costs to patients as well

- Patients in the US wait an average of 2 yrs longer (3 – 70 months) than Europeans to gain access to new US created medical technologies

- Due to these substantial delays, it costs millions more to bring products to the US than Europe

- Based on the prevalence of the diseases addressed by the companies in the study, millions of Americans are currently being impacted by these delays
Summary

- From the perspective of medtech companies innovating new medical technologies in the US:
  - FDA substantially lags behind Europe in several performance indices
  - Many US medical technologies are available outside the US long before they are available to US citizens
  - Reported FDA review times drastically underestimate the actual time required to navigate the FDA process to obtain clearance/approval
  - Due to delays and inefficiency in the process, companies navigating the US regulatory environment incur substantial incremental cost.
  - A majority of medtech companies feel they have been negatively impacted by the current FDA environment
Are additional pre-clinical and pre-market hurdles for 510k device likely to improve safety?

- Based on Class I (safety) recalls, FDA already has an excellent safety record on 510k devices*
  - ~99.55% of product submissions did not experience a Class I recall in a 5 year period
  - Majority (55%) of recalls are due to post-market issues
  - Issues exist with certain product types (AEDs and infusion pumps)
- Majority of all recalls related to QSR issues
  - Additional human testing not likely to be highly impactful
- No clearly identifiable sub group of Class IIb products

*Using Data to Drive Regulatory Decision Making – An Analysis of all Class I recalls over the past 5 years, Hall R, University of Minnesota
Is the delay and extra expense affording a safety benefit?

- Using class I recalls as a metric, there is no evidence of a safety advantage between the US and EU systems*
- The number of recalls were equivalent US/EU
- Therapeutic Mix and Type of Recall equivalent US/EU

FDA’s Mission

- REASONABLE assurance of safety & efficacy AND
- Promoting Innovation

- But in this era of increasing healthcare expense does this mission still make sense?
- Many think the FDA can be a useful tool to slow the pace of innovation and slow healthcare costs. Maybe we should drop the promote part?
- Why should we care about MedTech?
US Economic Impact

- **MedTech Is A Strong Economic Force:**
  - 422,000+ jobs
  - $21.5B salaries (average salary = $60K)
  - $123B product sales
  - Every 1 MTI job generates 4.5 jobs nationwide
    - This multiplier impact created by disposable income connects the MTI to 2M jobs in the US

- **But Fragile...**
  - 80% MedTech companies employ <50 people**
  - Venture Capital is a key source of funding

* 2010 “State Impacts of The Medical Technology Industry” The Lewin Group**
World Economic Impact

- MedTech Produces 2.7% of the US GDP
- US is the only net exporter medical devices across the world
  - $5.4B Trade Surplus*
- The impact of patients worldwide returning to work sooner, more productivity

* 2007 World Trade Atlas
MedTech Is Not To Blame For Rising Healthcare Costs

- Easy target, but...
- MedTech revenue comprises approximately 5% of all healthcare spending ($2.5 Trillion)
- Other expenditures have outpaced MedTech spending
  - Percentage of all healthcare spending attributable to MedTech spending has decreased

“Medical Technology and Venture Capital: A Fruitful but Fragile Ecosystem” MDMA/NVCA
What Has MedTech Accomplished?

- We have created innovative technologies and procedures to improve the quality of lives and save lives
  - Angioplasty, cardiac pacemakers/defibrillators, pulse oximetry, minimally invasive surgery, tissue sparing cancer therapies, arrhythmia ablation, etc.

- Since 1980,
  - Death rates have declined 16%*
  - Life expectancy has increased 4%*
  - Americans spend 56% less days in the hospital*

- And all this was done with the HELP of FDA!
  *The Value of Investment in Health Care, MEDTAP
How Do We Turn This Around?

- **FDA and Industry Need to Work Together**
  - Patients are best served when industry and FDA collaborate

- **Appropriate balancing of benefits and risks**
  - Outliers should not drive FDA into a defensive mode where they stop approving products
  - Headlines and politics should not sway what is best for patients, doctors/patients need to play a bigger role

- **Innovation Will Bring The Solutions And Is Not The Problem**
  - Faster patient access to safe and effective therapies is better for patients and innovation and will ultimately lower healthcare costs
State of Play

- Uncertain Whether Recent Proposals From FDA Will Address The Fundamental Issues Within The Agency And Their Impact on Innovation
  - “Innovation Initiative” Feb 8
  - FDA’s 510k announcement sending issues to IOM
- IOM is currently reviewing the premarket review process and will make recommendations this summer
- User fee reauthorization next year should be watched
- Improvements will not occur until FDA restores a reasonable risk-benefit profile
What Must Happen?

- Strengthen not weaken our patent system
- Advance pathways for reimbursement of new innovative technologies until they can be compared fairly
- Recognize conflicts throughout the system and manage them better – not exclude them
- FDA process must be reasonable and predictable
- Reinforce how important medical innovation is to people’s lives and our economy
- If we repair these issues, we will revive investors, improve the quality of lives and retain talent in our industry to help drive our economy forward
A Call For Action:

- Become a member of the society that represents your interests (MDMA, NCVA, AdvaMed, MedIC)
  - A special plug for MDMA: Mark Leahey at mleahey@medicaldevices.org OR (202) 354-7171

- Tell your story to your representatives in Congress DIRECTLY

- Participate in FDA, CMS, etc. hearings

- Recruit others in our industry and the community

- STAY ACTIVELY INVOLVED

- YOUR VOICE MATTERS
Is There An Exit From The Perfect Storm?

- Yes, but we all have a lot more work to do.