

FDA Oversight of Laboratory Developed Tests

February 8, 2007

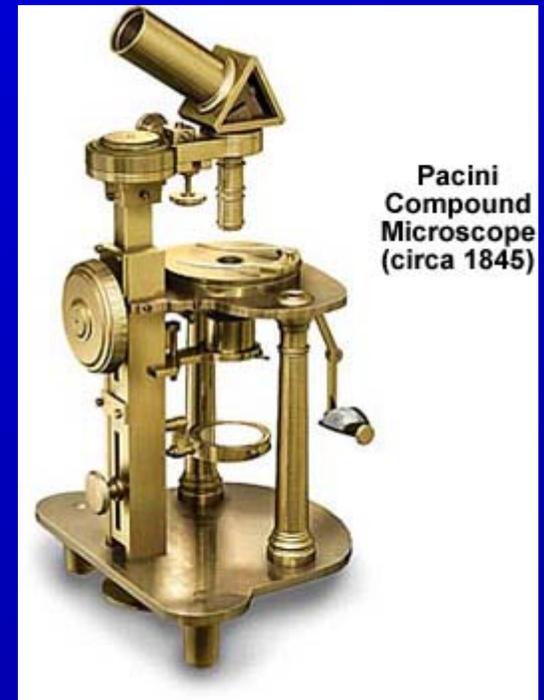
*By Jonathan Cohen
President & CEO
20/20 GeneSystems, Inc.*

Overview of Presentation

- **Diagnostics today**
- **Anticipated consequences of IVD MIA regulation**
- **What the FDA should do**
 - **Establish and maintain a public database registry**
 - **Act as a referee rather than a gatekeeper**
 - **Seek aggressive incentives for Dx development**
 - **Enhanced reimbursement for innovative improvements**
 - **DxARPA funding agency**
 - **Tax credits for Dx developers and investors**

Diagnosics Today

- Most tests are generic “me too” commodities
- Low margins; poor reimbursement
- Few incentives for substantial investment by companies or venture capitalists
- Often rooted in 19th century technologies and methodologies



Dx risk vs. reward

	Development Risks	Perceived Returns
Pharmaceuticals	<i>High</i>	<i>High</i>
Medical Devices	<i>Medium</i>	<i>Medium</i>
Diagnostics	<i>Medium</i>	<i>Low</i>

Likely consequences of IVDMIA rules

- Less investment = fewer products
- Static tests: *improvements discouraged*
- “Race to the bottom”: *only older, “proven” markers to be employed*
- Smaller markets (e.g. orphan indications) to be ignored
- Innovators will be punished

What should the FDA do?

1. Create and maintain a standardized database: *empower the healthcare marketplace to pick the winners*
2. Be a referee rather than a gatekeeper: *pre-market approval only for high volume kits*
3. Ask Congress for incentives to accelerate Dx development

Lab Test Database

- **Clearly disclose (i) clinical utility, (ii) key test characteristics (false +/-rates) and (iii) data in support thereof**
- **Maintained on-line by the FDA using standard templates to permit “apples to apples” comparison by healthcare marketplace**
- **Permit FDA to privately reprimand or publicly censure labs that offer exaggerated or misleading claims (w/ due process)**
- **Civil / criminal sanctions in extreme cases (willful falsification)**

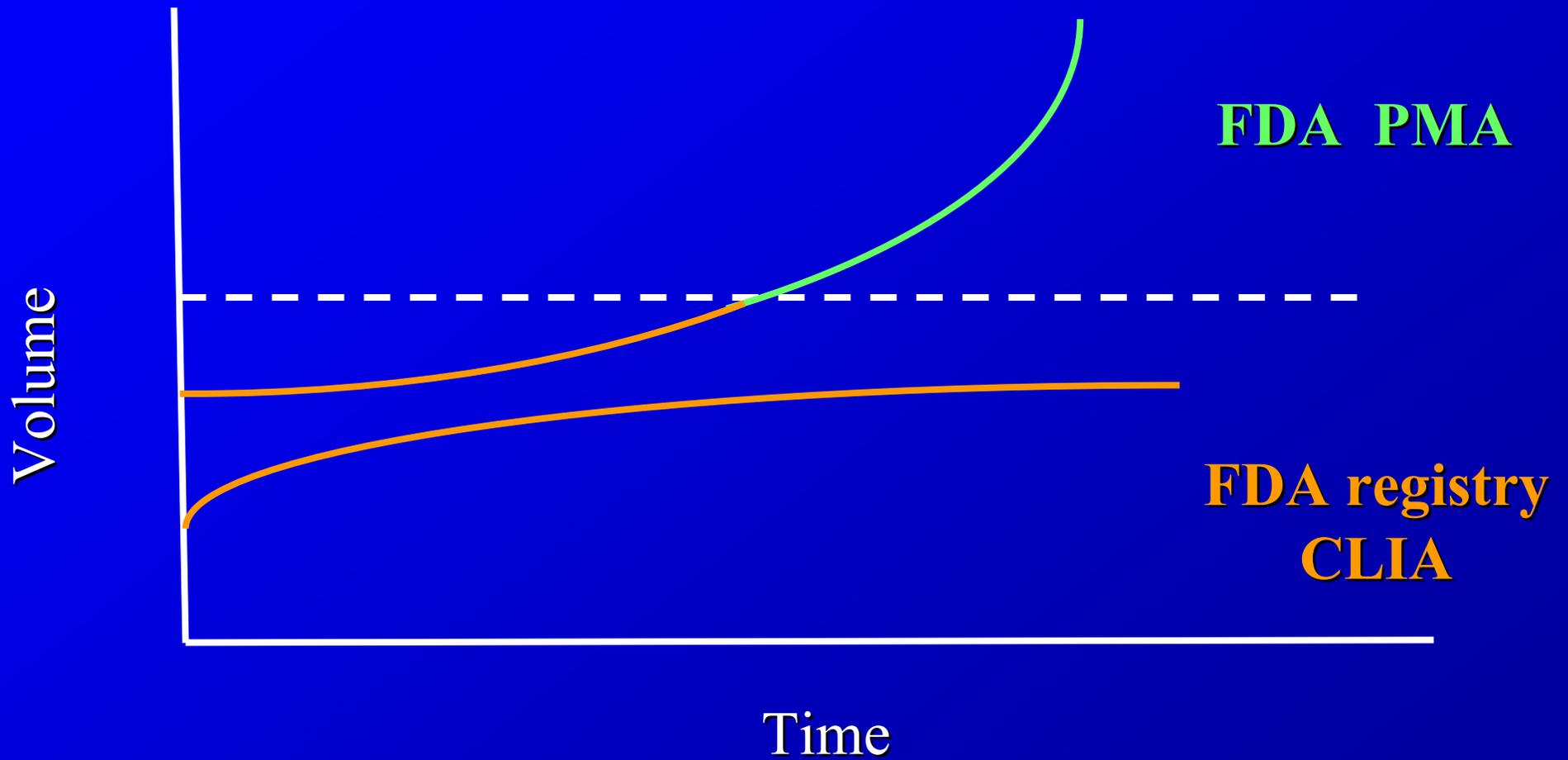
Database Template

Test name:	Lab:
Indication:	
Dx	Sensitivity (false- rate):
Accuracy:	Specificity (false+ rate):
Validation history: (sample sets, results, etc.)	
FDA comments:	

FDA: referee not gatekeeper

- **Only high volume IVD kits tests would require FDA approval before marketing**
- **Other test regulated by CLIA + FDA database registry**

Limited FDA Approval



Dx Accelerators

- **Expanded reimbursement for innovative products that substantially improve the state-of-the art**
- ***Diagnostics Advanced Research to Products Agency (DxARPA) under HHS***
- **Income tax credits to Dx product developers and investors (e.g. Orphan drug program)**