The Economic Perspective of Pharmacy: Between Jobs & Costs
Panel: What does a Sound Economic Scenario and Cost-Effective Market mean to you?

Current Situation of the Pharmaceutical Industry in Puerto Rico

Daneris Fernández – President of the Board Pharmaceutical Industry Association of Puerto Rico
February 2, 2011
Established in 1978, PIA assembles and represents research-based pharmaceutical and biotechnology companies operating in Puerto Rico.

- **12 Bio-Pharmaceutical Corps** (Jan 2011)
- **15 Commercial Operations** (Jan 2011)
- **29 Manufacturing Operations** (Jan 2011)
- **19.6K FT Direct Employees** (Oct 2010)
- **21.9% of Mfg Employment** (Oct 2010)
- **@ 50K Indirect Employees** (Oct 2010)

Source: PR Planning Board – 20 Jan 11 Econ Indicators; PIA Jan 2011
The Challenge of Emerging Markets...

An Industry under Pressure

- R&D Productivity Challenges & Escalating Costs
- Generics Erosion Slope
- Increased Regulatory Requirements
- Fraud & Abuse
- Investor Expectations
- Global Differences / Price Differentials across Countries
- Patent Expirations

Competition from global markets is driving costs and permanence of industry in U.S. and P.R.
The Challenge of Emerging Markets...

• Tax rates in Singapore, Taiwan, Eastern Block countries close to 0%.
• Tax rates in Ireland and EU are 12%, often deferred; large government investment portfolios available for start-up facilities.
• Manufacturing costs in most BRIC (Brazil, Russia, India & China) and other low tax jurisdictions are substantially lower than in U.S. & P.R.

Our Global Competitors...
Challenges to Puerto Rico’s BioPharma Industry

Patent Expirations

§ 40 primary pharma products patents to expire from 2008 to 2014.

§ These generate over 50% of U.S. sales.

§ Patent expiries approximately $140 B in the next 5 years.

§ Aggregated drop in sales estimated at $32B or 30% of sales between 2008 & 2015.

US forecast 3-5% growth in 2011

Source: sincomillas.com 1 Feb 11 (Lockwood Financial Advisors); IMS Global Market Forecast 2010
Current Situation of BioPharma in Puerto Rico

- 18 companies - 35 sites
- 21% (19.6K) of the employment
- 69.0% of exports
- 33.4% of imports
- 79% of corporate tax
- 13 of top 20 highest sales patented products
- 5 of top 10 biotech worldwide products
- 3 of 18 biopharma companies establish biotech operations with a combined investment of $2B between 2005 and 2010
- Amgen - world’s largest mfg facility in Juncos

Source: PIA Annual Meeting Presentation
Impact in Puerto Rico in the past 5 years

- Mergers
- Closings
- Network Configuration
- Downsizing

Sources: INDUNIV Presentation 2005; PR Planning Board 2011
Current Situation of BioPharma in Puerto Rico

- 31 mfg operations closings - 2000 to 2009
- 30.7% mfg jobs loss - 28,300 in 2005 to 19,600 in 2010
Tax Benefits: An Eroding Incentive

Act 73 of 2008

General Scenario
- 4% income tax on industrial development income
- 12% withholding tax on royalties
- Total or partial exemption of other taxes

Alternative Scenario
- 8% income tax on industrial development income
- 2% withholding tax on royalties

Act 154 of 2010

Excise tax on sales of products manufactured in PR sold to a US affiliate:
- 4.0% during 2011
- 3.75% during 2012
- 2.75% during 2013
- 2.50% during 2014
- 2.24% during 2015
- 1.0% during 2016

Incentives take a down turn with elimination of 936 and now Act 154

Sources: Ernst&Young Tax Alert 25 Oct 2010; PIA Presentation 2010
Act 154 Summary

- 25 Oct 2010 - Governor signs Tax Reform Act 154
- Excise tax of 4% tax for CFCs for 4 yrs.
- Local & US trade associations publicly express opposition.
- Wide media coverage on the issue.
- Governor meets individual CEOs.
- Governor assures PIA affiliates IRS will grant a U.S. tax credit for excise tax.
- Regulations approved January 2011.
- Feb 2011 IRS has not approved the proposed tax credit.

Source: PIA Annual Meeting Presentation
If CFCs received IRS credit for PR excise tax on US bound products

Planning Bd Figures – 2010
- Total Exports - $53,397,617
  - Total Exports to US - $37,232,563 (69.7%)
  - Total Exports to Foreign Countries - $16,030,864 (30.0%)
  - Total Mfg Exports - $45,762.8 (85.7%)

Act 154 Excise Tax Targets
- $31,908.3 MM could be subject to excise tax
- Up to $13,738.5 MM subject to tax would not be offset by IRS credit

Sources: McConnell Valdés Carlos Serrano PIA Annual Meeting Presentation; PR Planning Board Statistics 20 Jan 11
Challenges to Puerto Rico’s BioPharma Industry

- The cost of energy (21.6 KwH) is higher than 50 States except Hawaii
- High payroll, taxes & benefits
- Infrastructure skyrocketed by construction costs
- Fuel dependent higher transportation costs
- No solid/hazardous waste facilities
- Tax incentives instability / Government unreliability

**Pharmaceutical Operations in Puerto Rico**

Average distribution of costs:

- **Energy**: 42%
- **Infrastructure**: 25%
- **Other**: 18%
- **Payroll**: 15%

Source: PIA 2011
Industry strategies to reduce healthcare costs

- Reduction of operating costs
- Outsourcing manufacturing of products and internal and supply-chain services
- Refocused smaller sales forces
- Discontinuing unpromising pipeline products in Phase II
- Regulatory harmonization to facilitate simultaneous multi-country launches
- Product mix to include biologics & generics

Source: PWC Press Releases 2009-11; MorganLewis Alert 2010;
What the future will bring...
Healthcare, a $5 trillion industry, continues to grow

Industry growth drivers

- Significant unmet need
- Increasing chronic disease levels
- Changing demographics
- Innovation
- Technology
- New partnerships

Source: Boston Consulting Group PIA 2010 Annual Meeting Presentation
R&D: Puerto Rico’s Next Frontier

• Incentives are in place:
  → 1% pioneer innovative novel activity (0% if product/process developed in PR)
  → 2-4% to certain businesses
  → Reduced income tax rates by location

• No government strategy
• Clinical trials have a limited scope
• Lack of critical mass and facilities in University-Hospitals
• Instability and interruption of research project in principal universities
• Insufficient post-graduates

![Clinical Studies by Therapeutic Area](image1)

<table>
<thead>
<tr>
<th>TA</th>
<th>Active Studies</th>
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<td>Oncology</td>
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<td>HIV</td>
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<td>Pain</td>
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<td>Others</td>
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<td>Total Ongoing Clinical Studies</td>
<td>208 (22%)</td>
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![On-going Clinical Studies In PR by Company](image2)

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<thead>
<tr>
<th>Company</th>
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<td>Eli Lilly</td>
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<td>BMS, BMS/ABX</td>
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<td>Pfizer</td>
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<td>Abbott, Abbott/ABX</td>
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<td>Aventis</td>
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<td>Bayer/CUI</td>
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<td>ALL Trials</td>
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<td>Total Industry-Sponsored</td>
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<td>NIH, NCI, VA, etc</td>
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<td>Total Active Studies</td>
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Source: PIA 2011; INDUNIV 2009
We are not the problem...

We are the solution...