



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



Pharmaceutical Industry Association of Puerto Rico

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)

1. **Abbott**
2. **Amgen**
3. **AstraZeneca**
4. **Bristol Myers Squibb**
5. **Eli Lilly**
6. **GlaxoSmithKline**
7. **Johnson & Johnson**
8. **Merck**
9. **Novartis**
10. **Pfizer**
11. **Sanofi-Aventis**
12. **Warner Chilcott**



The Challenge of Emerging Markets...

An Industry under Pressure

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

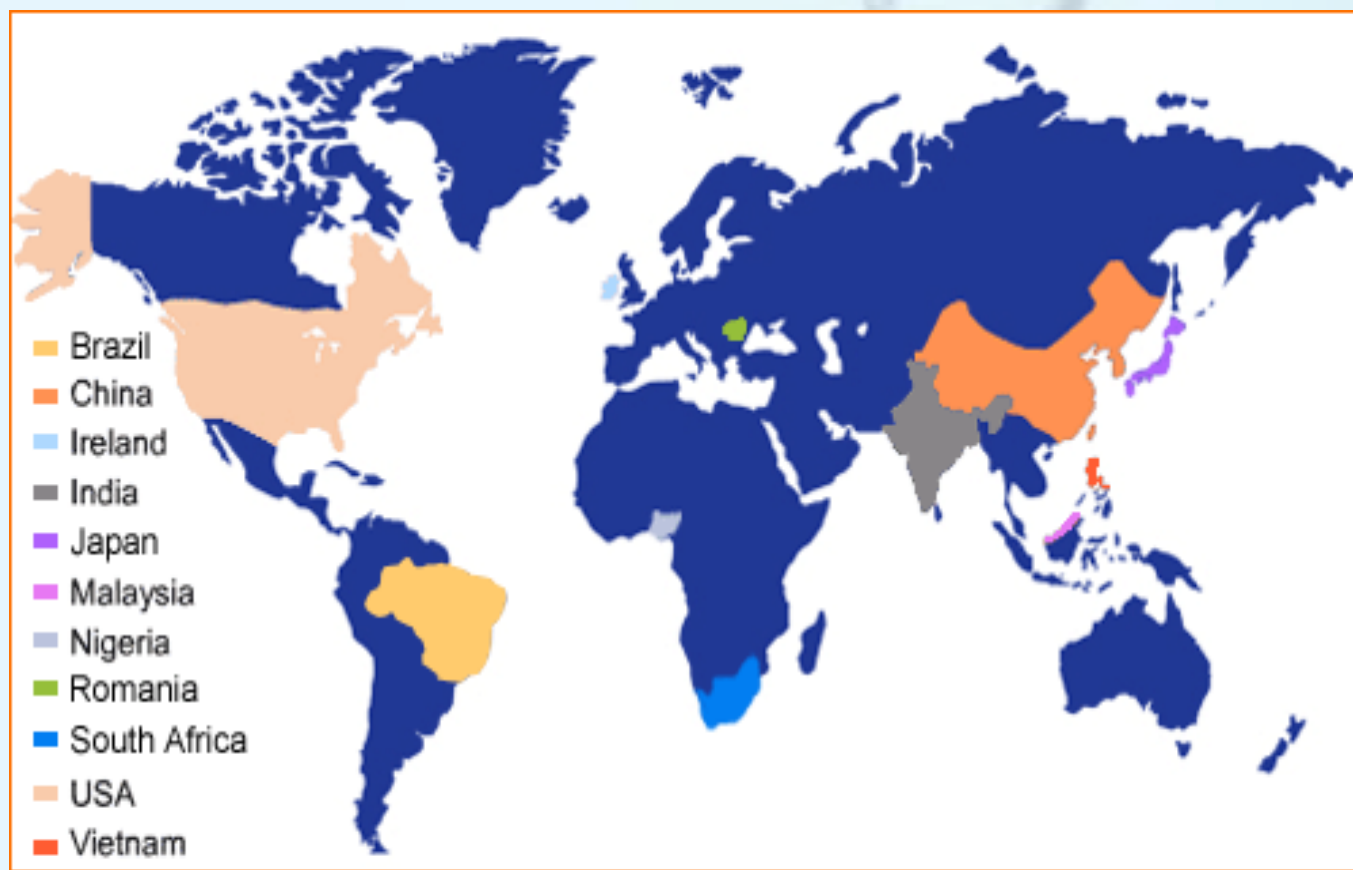




The Challenge of Emerging Markets...

- 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

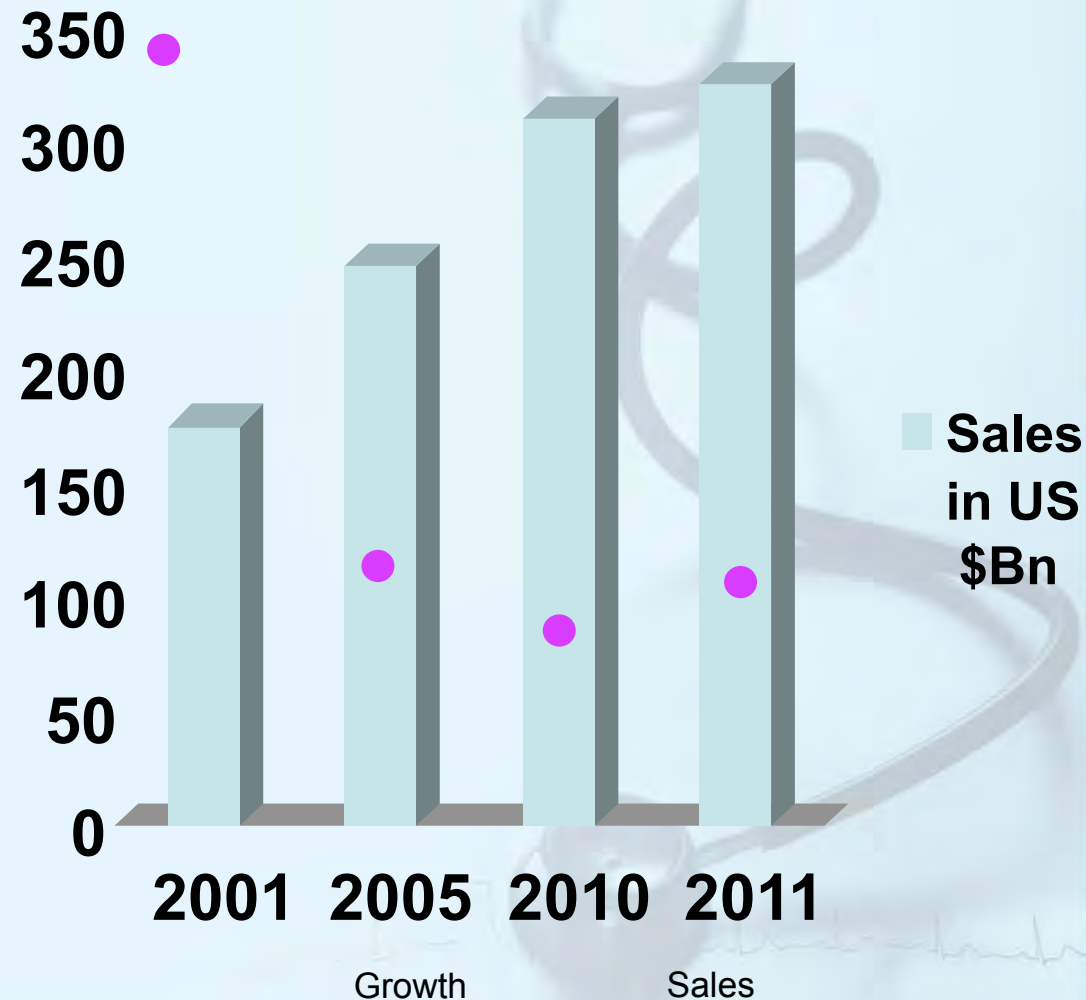
§ 40 primary pharma products patents to expire from 2008 to 2014.

§ 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





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 7 2010
- Amgen - world's largest mfg facility in Juncos





Impact in Puerto Rico in the past 5 years

- Mergers
- Closings
- Network Configuration
- Downsizing

2005

27 Pharmaceutical & Biotech
Companies (86 Sites)



2010

18 Pharmaceutical & Biotech
Companies (35 Sites)





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**

Employment in Pharmaceutical and Medicine Manufacturing (Rounded in Thousands of Persons)

	Fiscal Year	Absolute Change	Percent Change	Calendar Year	Absolute Change	Percent Change
1990				21.1		
1991	19.2			19.1	-2.0	-9.5
1992	21.5	2.3	12.0	22.1	3.0	15.7
1993	22.7	1.2	5.6	23.5	1.4	6.3
1994	24.2	1.5	6.6	24.5	1.0	4.3
1995	24.9	0.7	2.9	25.1	0.6	2.4
1996	24.9	0.0	0.0	24.5	-0.6	-2.4
1997	23.9	-1.0	-4.0	23.6	-0.9	-3.7
1998	23.5	-0.4	-1.7	23.4	-0.2	-0.8
1999	23.4	-0.1	-0.4	23.8	0.4	1.7
2000	24.3	0.9	3.8	24.6	0.8	3.4
2001	24.5	0.2	0.8	25.2	0.6	2.4
2002	27.2	2.7	11.0	27.9	2.7	10.7
2003	27.6	0.4	1.5	28.1	0.2	0.7
2004	28.2	0.6	2.2	28.4	0.3	1.1
2005	28.6	0.4	1.4	28.3	-0.1	-0.4
2006	28.0	-0.6	-2.1	27.4	-0.9	-3.2
2007	26.4	-1.6	-5.7	25.2	-2.2	-8.0
2008	24.0	-2.4	-9.1	22.8	-2.4	-9.5
2009	21.5	-2.5	-10.4	20.3	-2.5	-11.0
2010	19.8	-1.7	-7.9			





Tax Benefits: An Eroding Incentive



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

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





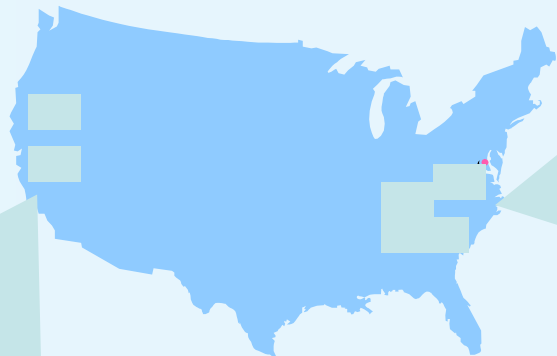
Act 154 Summary

- 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.

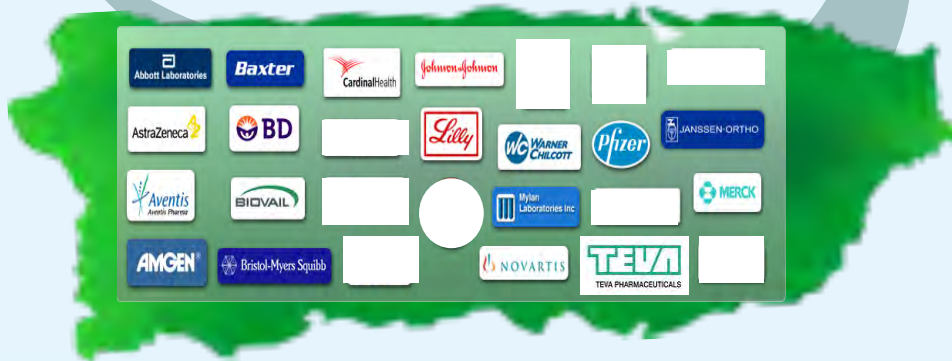




If CFCs received IRS credit for PR excise tax on US bound products



Excise Tax of CFC Manufactured Goods



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**

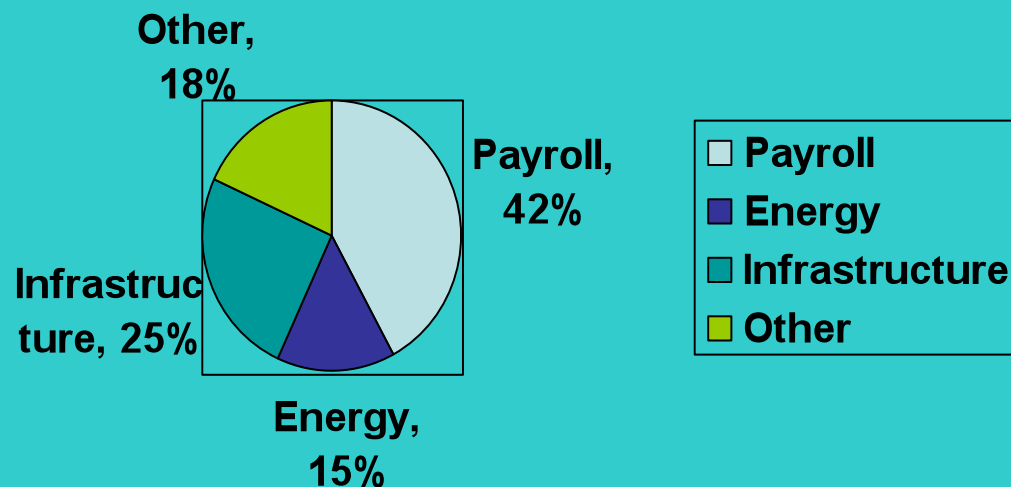
♣ **Up to \$13,738.5 MM subject to tax would not be offset by IRS credit**



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

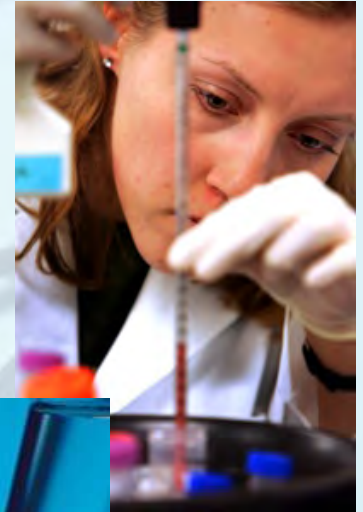
Pharmaceutical Operations in Puerto Rico Average distribution of costs





Industry strategies to reduce healthcare costs

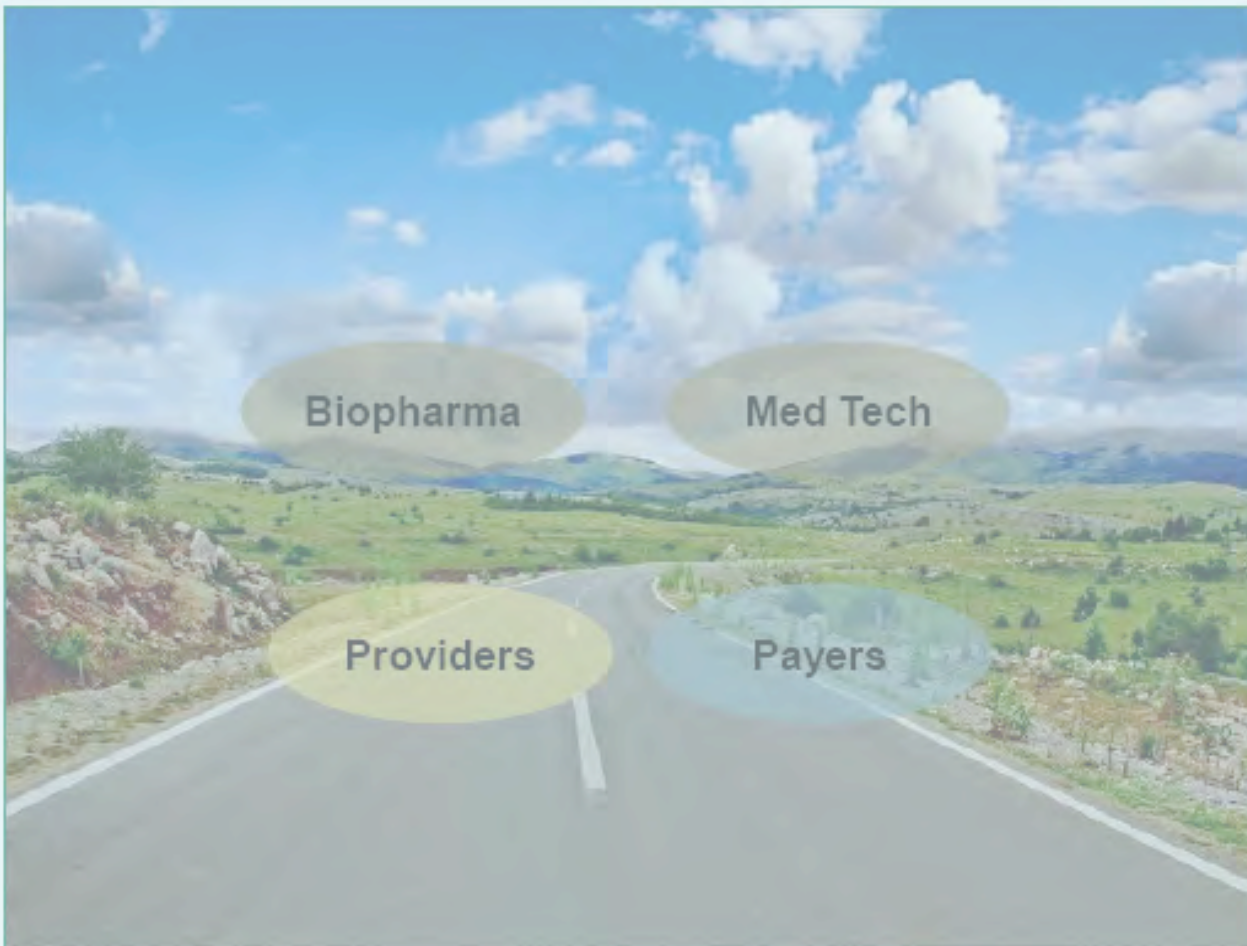
- Reduction of operating costs
- Outsourcing manufacturing of products and internal and supply-chain services
- Refocused smaller sales forces
- Discontinuing unpromising pipeline products in Phase II
- Regulatory harmonization to facilitate simultaneous multi-country launches
- Product mix to include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





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



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

TA	Active Studies
Oncology	73
HIV	34
CV	23
Diabetes	20
Immunology	10
CNS	8
Pain	6
Others	34
Total Ongoing Clinical Studies	208 (22%)

Phase I:	6%
Phase II	24%
Phase III	63%
Phase IV	8%

On-going Clinical Studies In PR by Company

Company	Active Studies
El Lilly	22
BMS, BMSAZ	13
Pfizer	12
Hoffman La Roche	8
Sanofi-Aventis	8
Gilead Wellcome	6
Merck	5
Gilead	4
Milkenion	4
Novartis	4
Abbott, AbbottAZ	4
Amgen	2
Bayer/ALJ	2
Wyeth	2
Schering-Plough	2
ALJ Tibotec	2
ALJ Pricara	1
Other Companies	36
Total Industry Sponsorship	137
NIH, NCI, VA, etc	71
Total Active Studies	208

2009

"A New Economy in Health Care"



We are not the problem...



We are the solution...



"A New Economy in Health Care"

