

Puerto Rico Chamber of Commerce's
Health Committee

OBAMACARE 2017



Drug Inflation, Biosimilars and Management Strategies

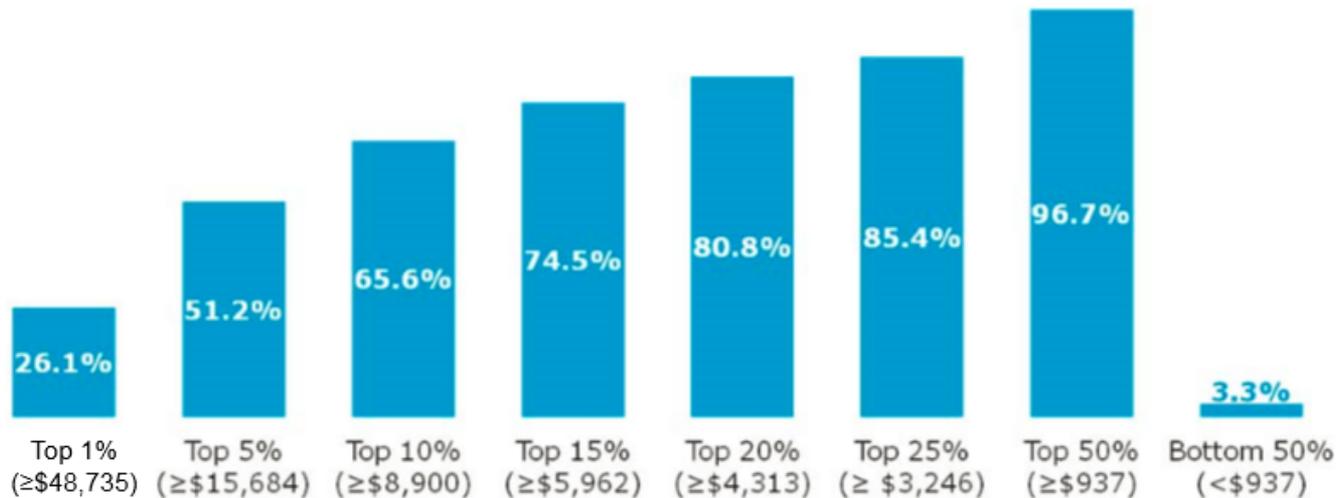
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October 3, 2016



Minority of Patients Account Majority Healthcare Costs

Percent of Health Plan Members Ranked by Annual Healthcare Spending (\$)



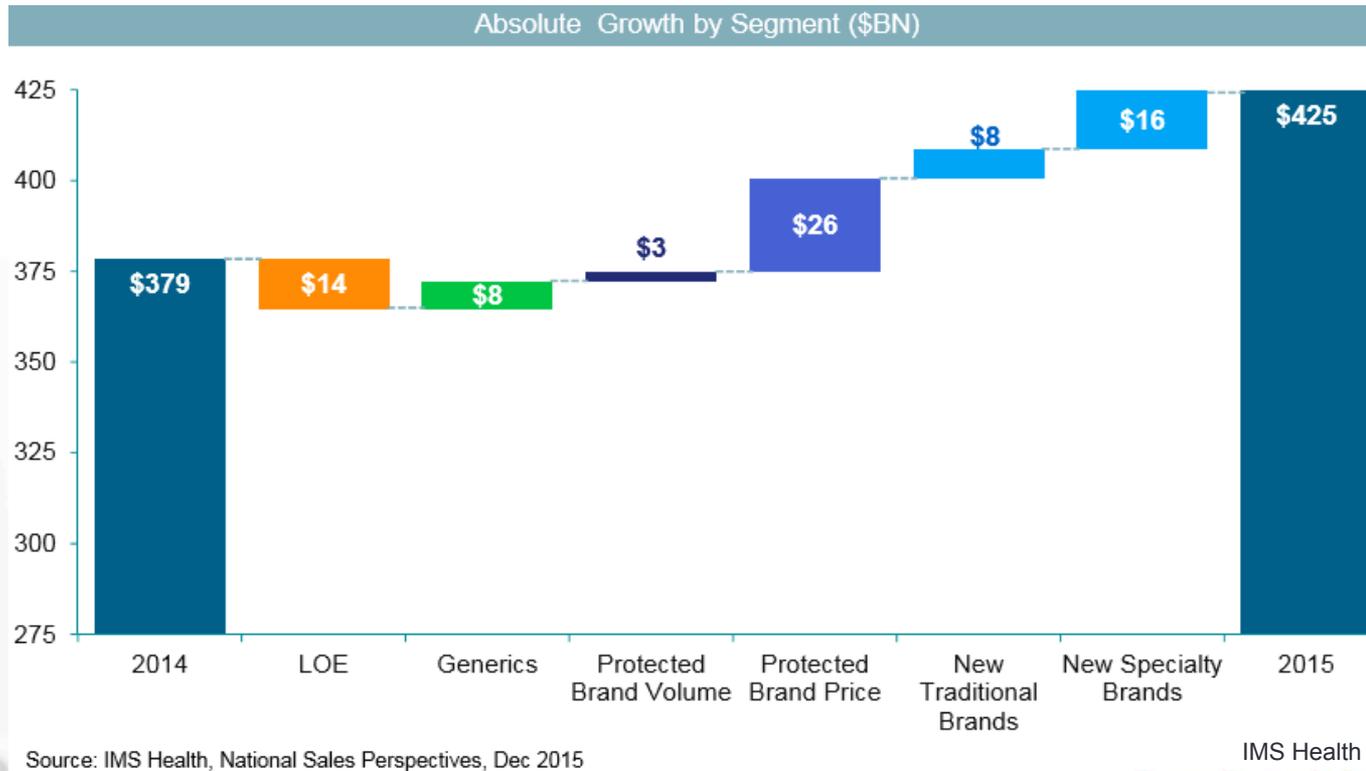
Source: IMS PharMetrics, Jun 2012

IMS Health



Relevant Drivers of Increases in Drug Spend

US Rx Market Grew by \$46Bn to \$425Bn Last 12 Mo: Higher Brand Spending & Fewer Patent Expires

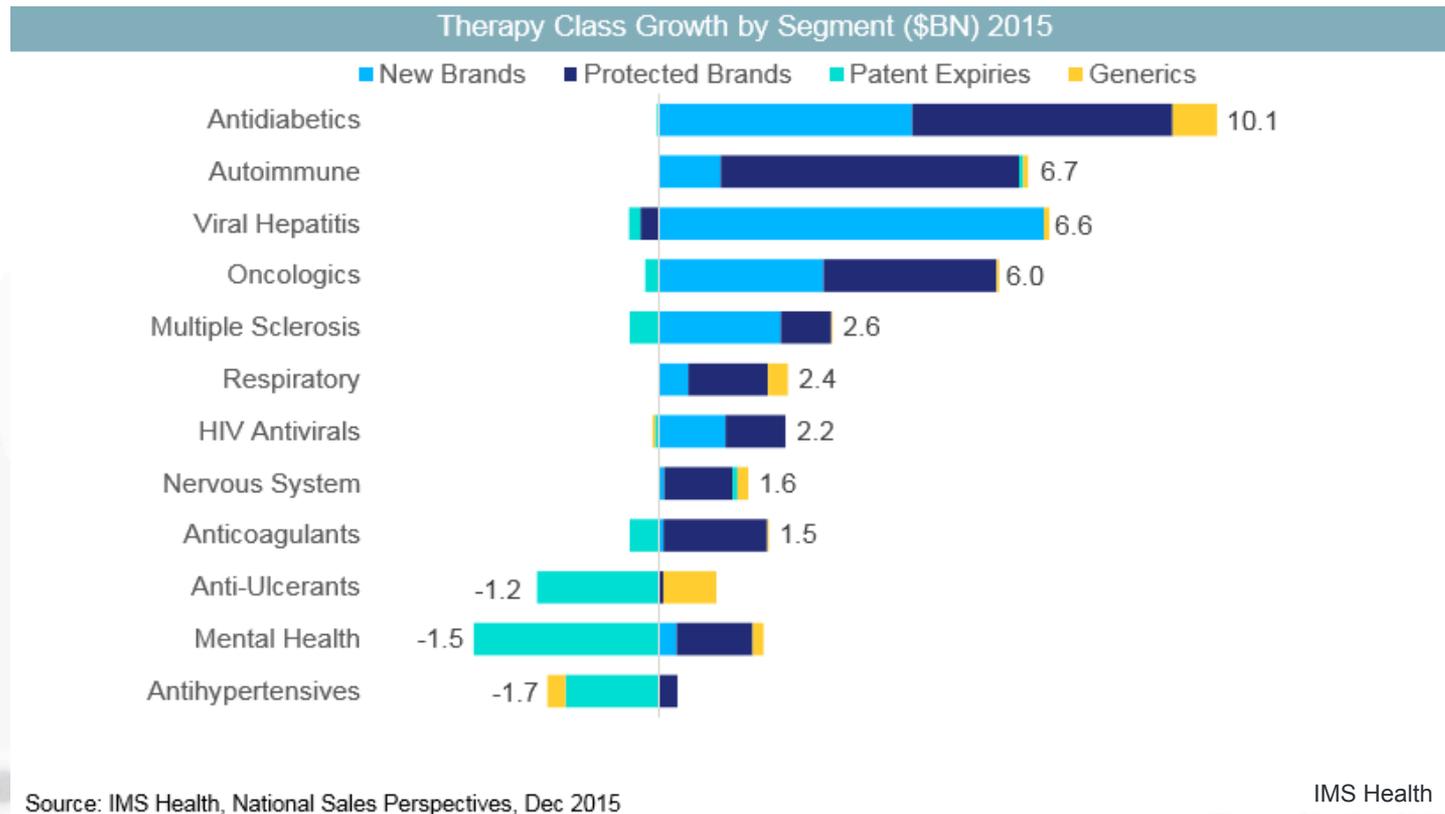


\$8Bn in new traditional brand growth, \$16Bn in new specialty brand growth



2015 Drug Spending Growth Drivers by Med Conditions

Diabetes, Autoimmune Diseases, Hepatitis & Oncology Lead the Spending Growth

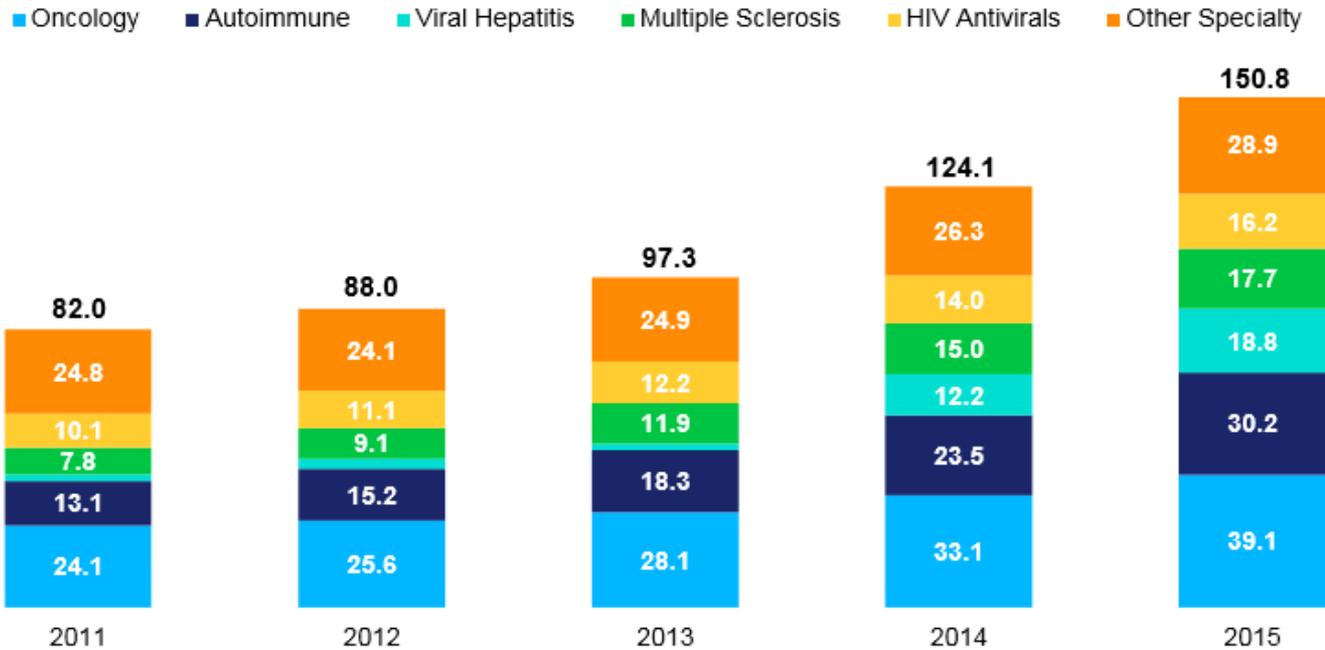


Spending on diabetes increased by \$10 Bn in 2015 (excluding Rebates or other discounts)



2015 U.S. Spending on Specialty Drugs

Increased 21.5% to \$151 Bn



Source: IMS Health, National Sales Perspectives, Jan 2016

IMS Health

Harvoni, Humira, Enbrel, Remicade were biggest growth drivers in 2015



Some Potential Solutions or Factors to Address Cost Concerns

- **More Biosimilars and Branded Drug Launches**
 - Specialty space may get more crowded with new entrants and more orals are coming
 - Increased competitiveness and rebate concessions
- **Promote Value-Driven Health Care**
 - Clinical outcomes-based negotiations / contracting
 - Support appropriate use of medications
- **Engage and Empower Patients**
 - Make quality and cost information public to aid in decisions
- **Regulatory and Legislative Initiatives Imposing Price Inflation Controls**



Biosimilars Definitions

Biosimilar

1. The biological product is highly similar to the reference product except for minor differences in clinically inactive components
2. There are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product

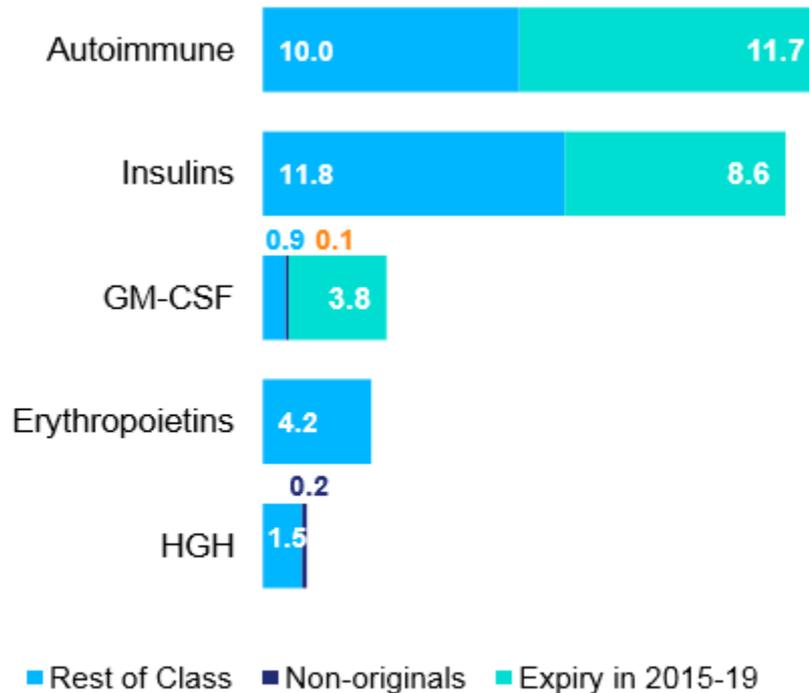
Reference

The single licensed biological product against which a biological product is evaluated in an application submitted under section 351(k) of the PHS Act.



Biosimilar Pipeline

2014 Biologics Spending in Classes with NonOriginal Biologics and Losses of Exclusivity (US\$Bn)



Related events	Expected US Launch
Adalimumab three Phase III trials completed	2015
Infliximab	2018
Insulin glargine tentatively approved pending litigation (2014)	2016
Tbo-filgrastim marketed Dec 2013	2013
Zarxio (filgrastim-sndz) approved in March and launched in Sept 2015	2015
Pegfilgrastim filing accepted	2015
Epogen alfa BLA filed	2015/16

Source: IMS Institute for Healthcare Informatics, Mar 2015; ClinicalTrials.gov; FDA.gov, Mar 2015

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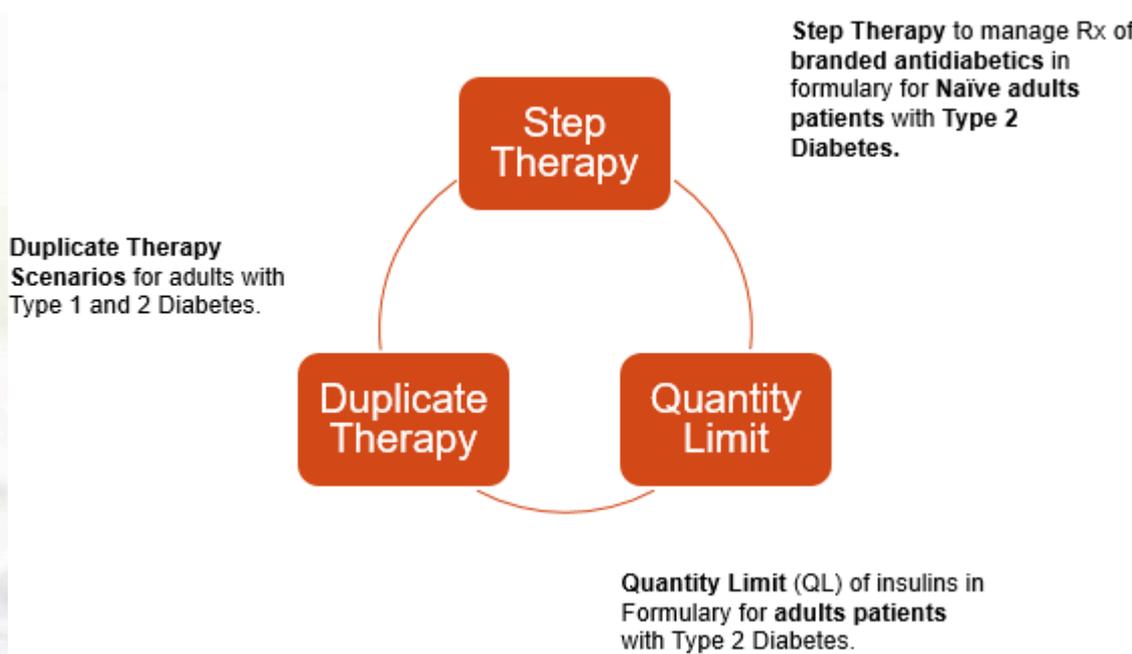
Based on the experience gained in the European market, biosimilars are expected to cost up-to 20% less than the reference product



Sample Drug Management Initiatives in Puerto Rico

2015 ASES Diabetes Utilization for Adults

- Members on any Anti-diabetic: 104 K
- Non-insulin Utilizers: 68 K
- Insulin Utilizers: 36 K
- Total Cost for Anti-diabetics: \$ 99.0 M





Drug Price Transparency Legislation in the US

- Drug price increases have triggered a drug transparency legislation movement in the continental United States
(DACO currently has drug price protection faculties)
- **Vermont (Act No. 165 of 2016)** – First State to approve a drug price transparency bill.
 - Main provision: State will identify up to 15 state purchased prescription drugs in which the State spent significant health care dollars and for which the WAC has increased by 50% or more over the past five years or by 15% or more over the past 12 months.
 - Pharmaceutical Company would need to provide a justification for the increase in the WAC of these drugs.
- Other States with pending drug price transparency legislation include: **Massachusetts** (MA S 1048), **New Jersey** (NJ A 762), **New York** (NY S 7686), **Rhode Island** (RI S 2560), and **Virginia** (HB 1113).
 - If approved, what would these bills do?
 - If price of drug is significantly high, the State may set the maximum allowable price that the manufacturer can charge for a drug in that State. (**Massachusetts, New Jersey**)
 - Manufacturers will need to file detailed reports with the State with information on R&D, production and marketing costs for each one of the manufacturer's high-cost drugs. (**New York, Rhode Island, Virginia**)



Questions?

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