



# BioNJ Manufacturing Summit

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March 10, 2011



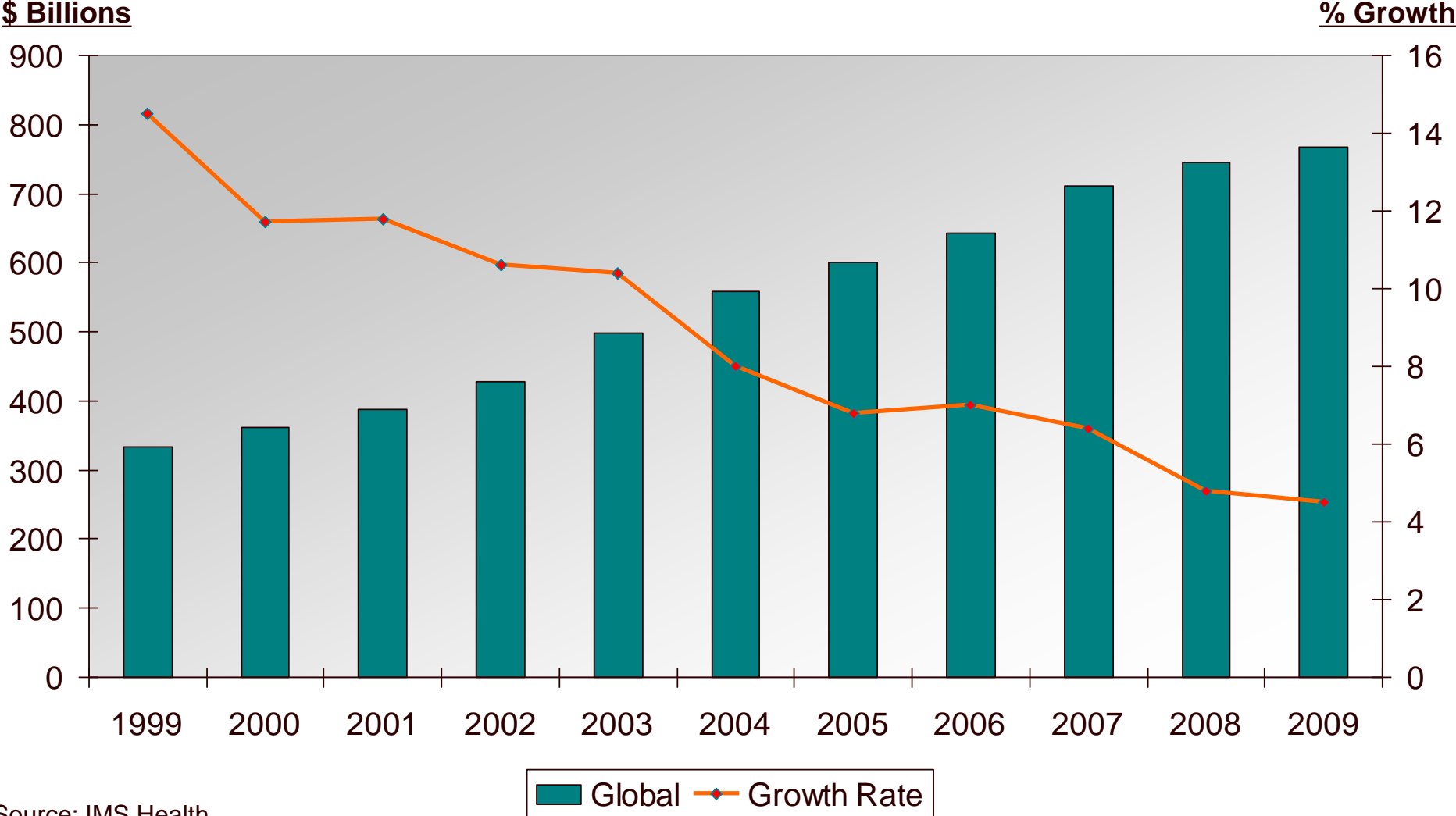
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## Agenda

- Our world is changing
- Global expansion
- Products are different
- Regulatory scrutiny
- Our supply chains need to change

# Global Pharmaceutical sales continue to grow, albeit at a slower pace.

## Global Pharmaceutical Sales

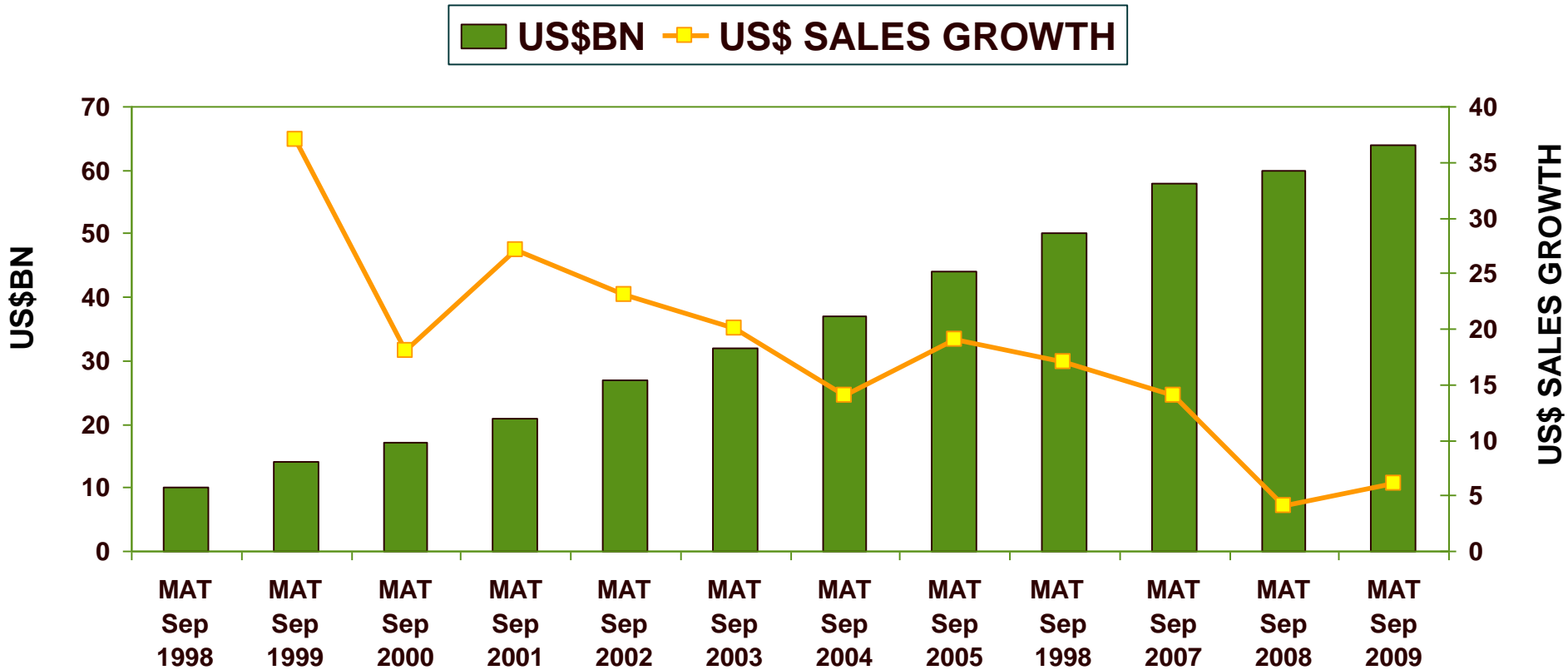


Source: IMS Health

Global Growth Rate

# U.S. biologic sales growth is slowing, as well.

## U.S. Biotech Sales



Source: IMS Health, MIDAS, MAT Sep 2009, US Biologic market at trade level

***The patent cliff effect is unlike any other we have known.***

Brand Pharmaceutical manufacturers being forced to reinvent themselves

- Replace Revenue – rapid M&A to fill pipeline with niche biologics
- Shrink to fit – operations, sales force
- Explore new markets
- All of the above

***Emerging markets are growing at three times the rate of established markets.***

Pharmaceutical Revenue Growth

<b><i>Total 2010</i></b>	<b>4 - 6%</b>
<i>US</i>	3 - 5%
<i>Japan</i>	(2 - 0%)
<i>EU</i>	1 - 3%
<i>Emerging</i>	12 - 14%
<b><i>2010 – 2013</i></b>	<b>4 - 7%</b>

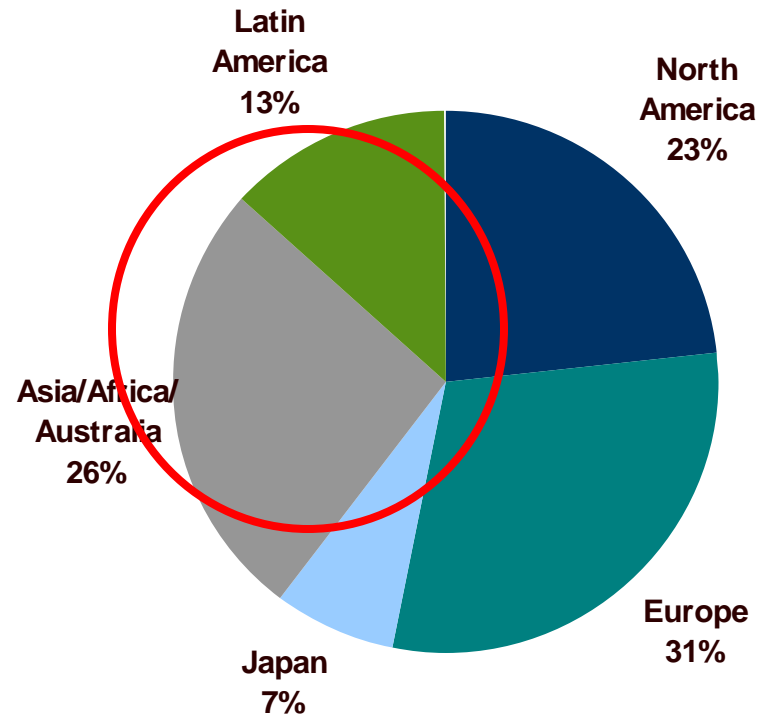
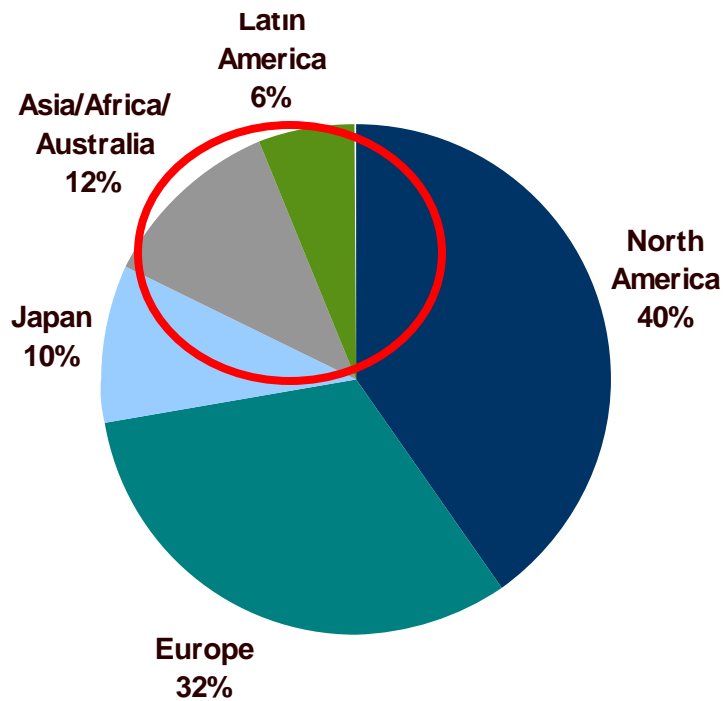
Source: IMS

*A global consumption shift is underway.*

Pharmaceutical Markets by Revenue

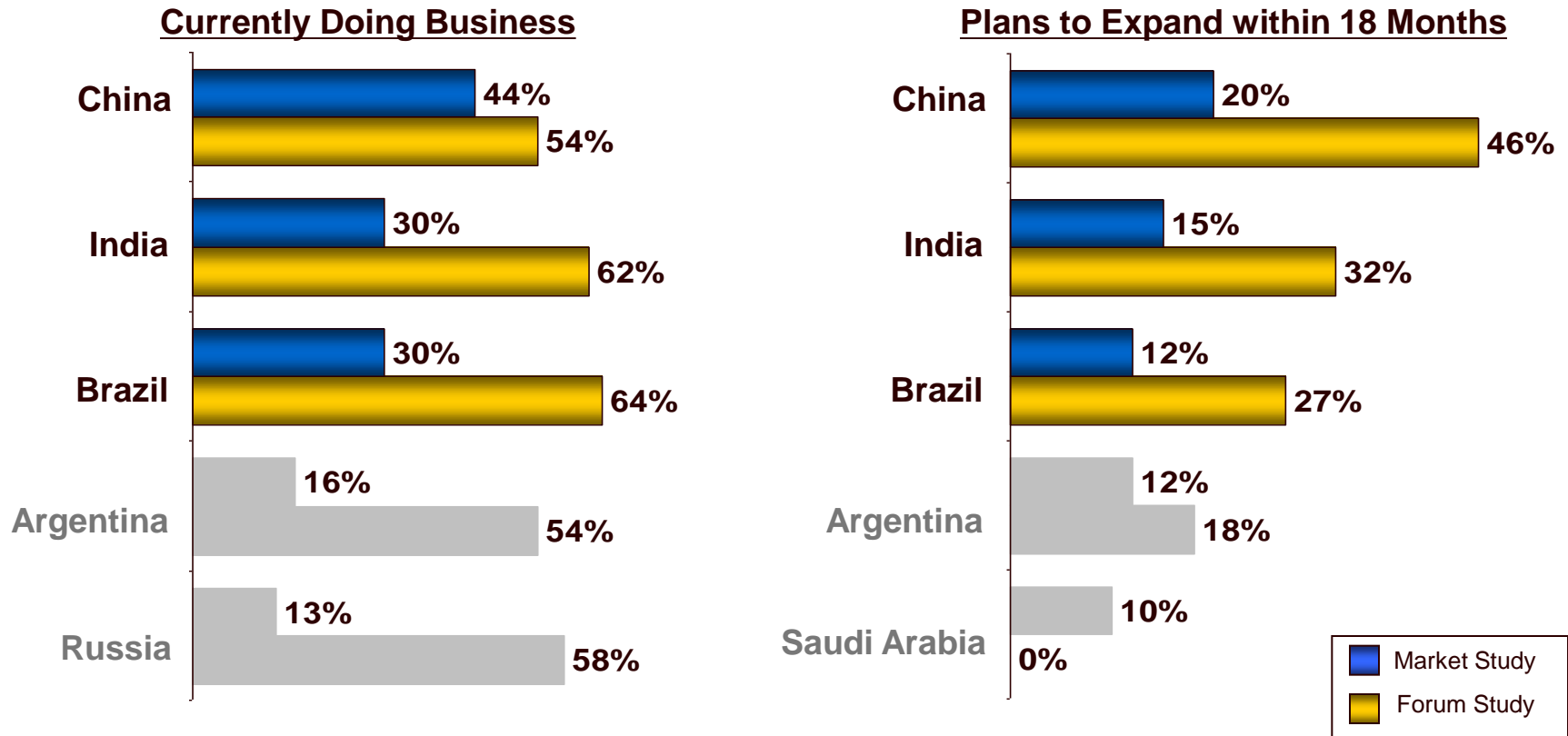
**2008**

**2020**

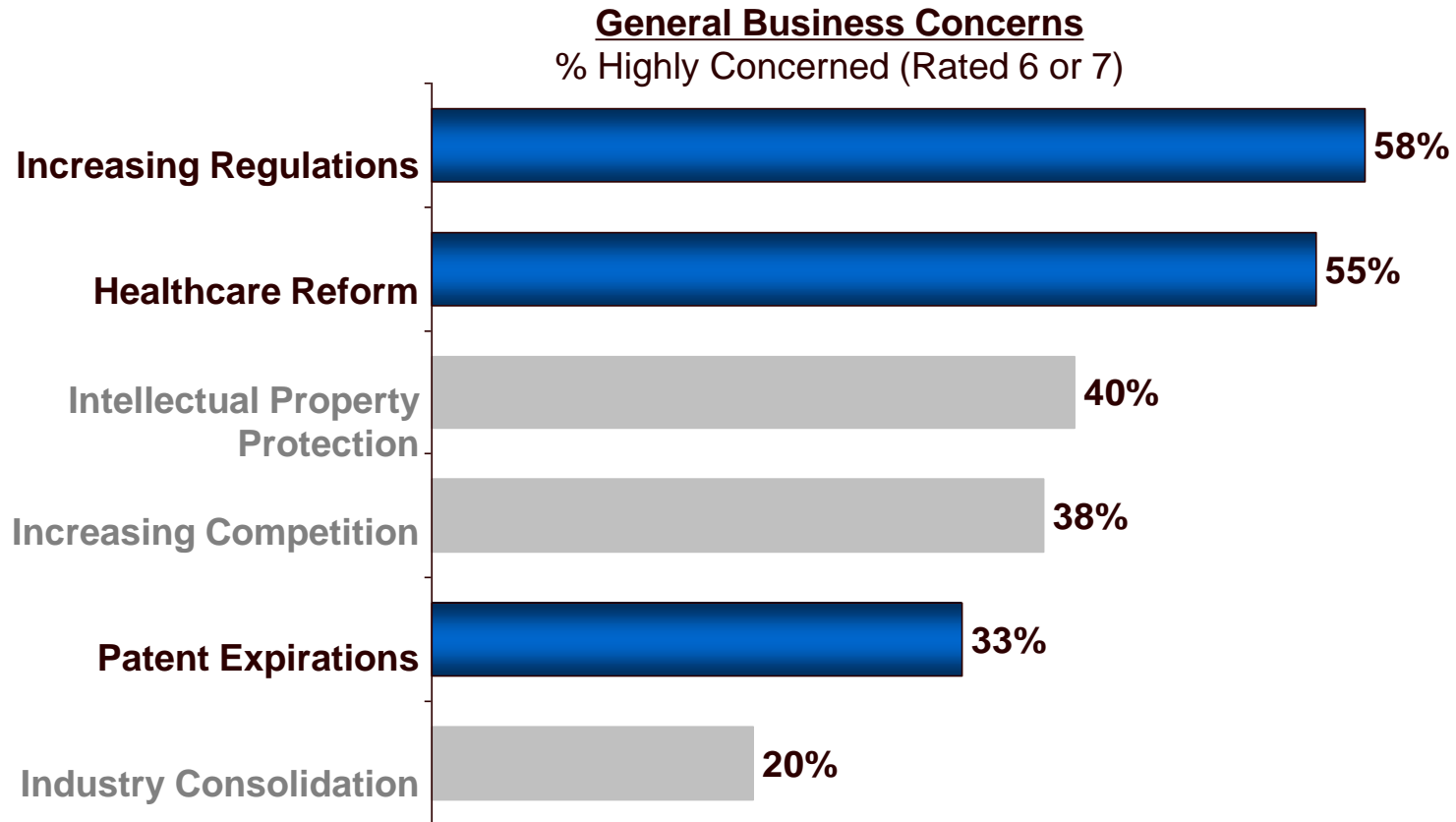


**China, India and Brazil** are the focus of Emerging Markets.

Which Emerging Markets?



***Increasing Regulations*** and ***Healthcare Reform*** are major General Business Concerns.



## ***FDA has stepped up its efforts.***

- FDA inspections are up 70% year over year
- FDA hired 700 additional inspectors last year
- FDA told manufacturers that they bear responsibility for the entire supply chain
- FDA estimates there are 330,000 global suppliers that have input to the manufacturing process - but the FDA regulates the manufacturer
- FDA sees poor supplier control causing recalls - they see two gaps:
  - Multi-national companies not managing international divisions with the same level of scrutiny in all geos
  - Manufacturers not managing external vendor relationships closely enough
- Manufacturers must develop a quality management system that manages quality throughout the entire product lifecycle
- FDA - controlling suppliers now more important than ever as we go global

Companies with no material quality failures in the last two years grew on average 8.8%

Companies that had a material failure grew 2.3%

## ***U.S. dispensing channels are shifting.***

### 2009 U.S. Pharmaceutical Revenue / Channels

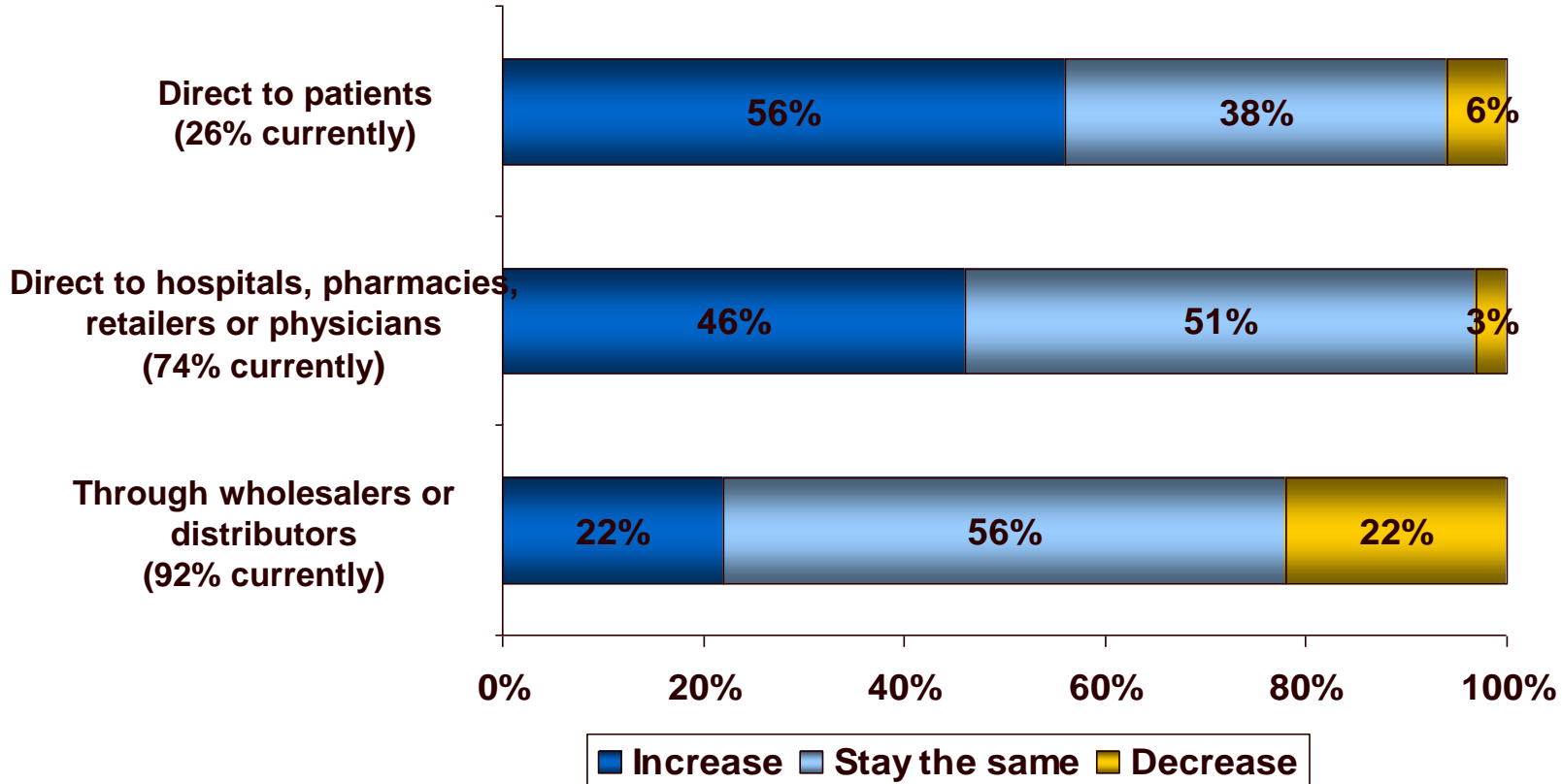
	<u><b>Growth</b></u>	<u><b>Share</b></u>
<b><i>Chains / Mass</i></b>	<b>5.8%</b>	<b>35.1%</b>
<b><i>Mail</i></b>	<b>10.7%</b>	<b>17.1%</b>
<b><i>Independents</i></b>	<b>1.0%</b>	<b>12.4%</b>
<b><i>Food Stores</i></b>	<b>3.9%</b>	<b>7.0%</b>
<b><i>Clinics</i></b>	<b>4.8%</b>	<b>11.5%</b>
<b><i>Hospitals</i></b>	<b>4.0%</b>	<b>10.6%</b>

Source: IMS

**Channel Shifts** are expected over the coming months.

**Percent Currently Using and  
Expected Change in Distribution Channels**  
Next 18 Months

Forum  
Attendees



***Embracing the new realities with a different business model is essential.***

**New Commercial Models**

**Adjust the cost base**

**Reinforce Value of Medicines**

**More patient-centric approach**

**Grow emerging markets**

***Having the right supply chain solution in place is needed so that you are expansion-ready.***

- Longer supply chains lead to more opportunities for things to go awry
- Get access to multiple assets (storage facilities, including temperature-controlled, distribution centers, various modes of transportation)
- Embrace outsourcing of supply chain functions on a greater scale
- Work collaboratively with fewer suppliers globally - managing growth and overcoming complexity
- Need for more visibility across the supply chain and a greater focus on risk management
- Require a high level of flexibility to be able to quickly scale up and down

*Easy access to critical drugs and devices; the assurance of safe healthcare products; and fast and reliable customer service*

# Thank You