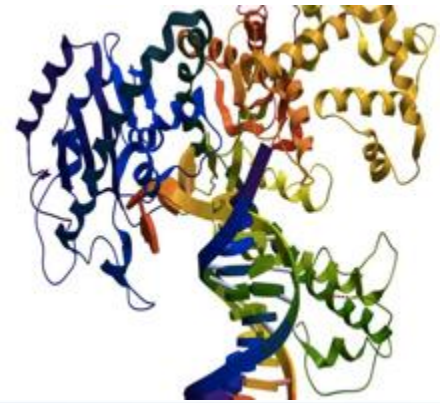

RIO NEGÓCIOS
The right city. The right way.

"The Global Biotech Industry: Challenges & Opportunities"

Michael S. Rosen

Rosen Bioscience Strategies

Greetings from Chicago!

Beaches Yes!

Pharma Beginnings!

Bogota – 1974
“Selling Drugs in Colombia”

Pfizer

Global Population Growth

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9 billion

2050

8 billion

2030

7 billion

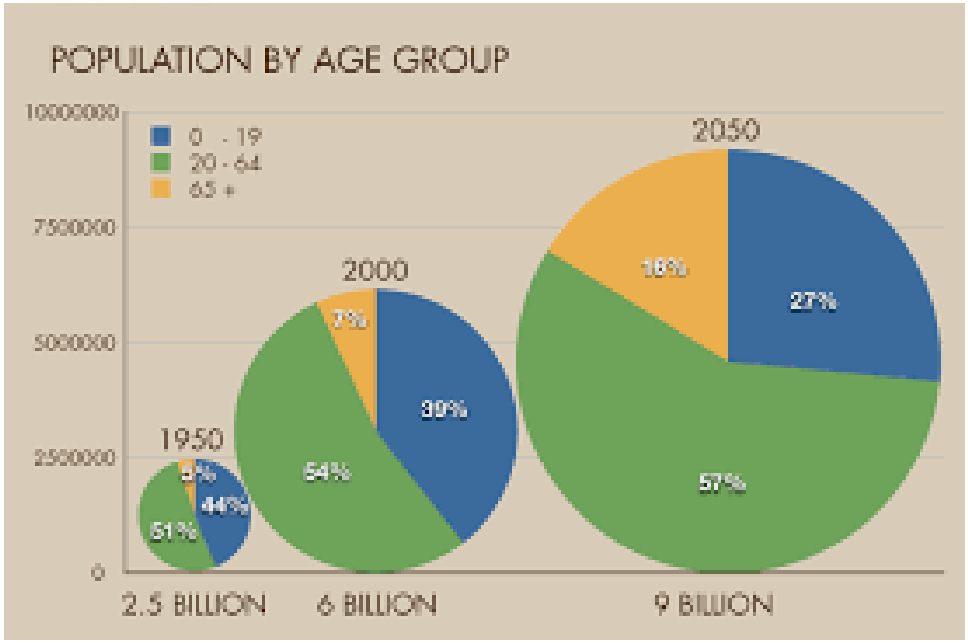
2010

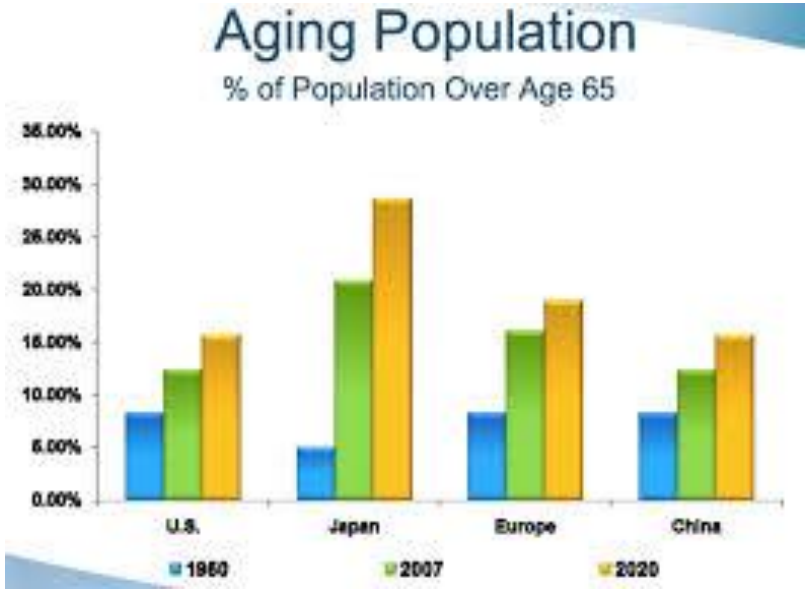
5 1990

Global Population Growth

Patients Around The World!

World Challenges





Biotechnology: A Science *or* A Culture?

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Science 45 year old industry

Biology vs. Chemistry

First 20 years → **Drugs**

Last 20 years → **Agriculture**, **Nanotechnology**

Last 15 years → **Biofuels**

Now and Future → **Cleantech**

Biotechnology :
The Science & the Culture

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Innovation

The Culture

Challenging Status Quo

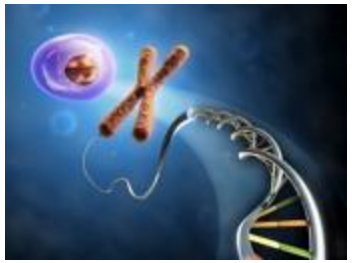
University/ Hospital/ Research Center

Teams

Patient/Disease

The Science

Biology



The First Biotech Companies

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Company	University	Year	Product
cetus	California - Berkley	1971	Interferon-B, IL-2, agro
Genentech	California - San Francisco	1976	TPA
genex SM	Princeton, NJ	1977	Aspartame
Biogen	MIT/Harvard/ Geneva/Zurich	1978	Interferon-A
AMGEN	Chicago	1980	EPO

Biotechnology Today:
A Global Industry

Number of Companies = ~6,000

U.S.
1,700

Europe
2,000

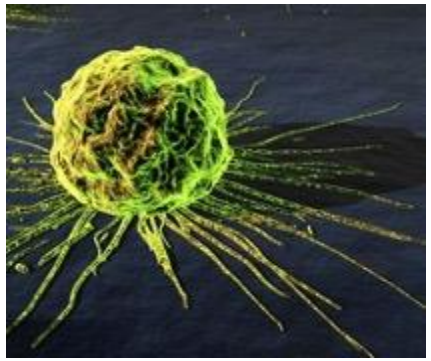
Canada
300

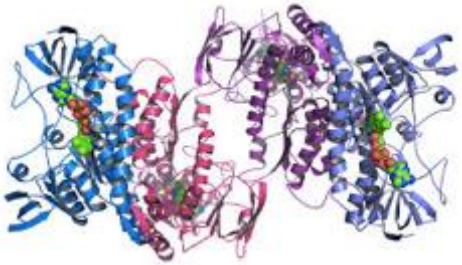
Latin
America
300

Asia
>1500

Biotechnology: the first 40 years

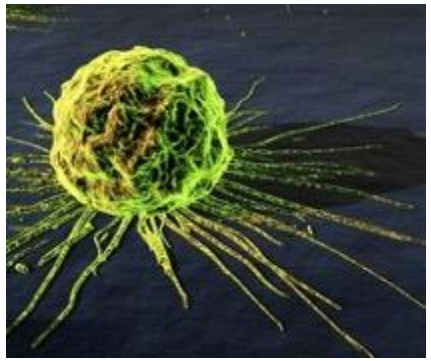
- More than 800 new drugs in clinical trials for 300 diseases:
  - **Alzheimer's**
  - **Heart disease**
  - **Multiple Sclerosis**
  - **Parkinson's**
  - **Cancer**
  - **Other Central Nervous System**
  - **Gastroenterology**
  - **Endocrinology**





Biotechnology: Industry Metrics - 2014

REVENUE	$123.1 B
R&D EXPENSE	$35.4 B
NET INCOME	$14.9 B
MARKET VALUE	$1,063.4 B
Number of Publicly - Traded Companies	714 B



Note: Above only includes pharma business in U.S., Canada, Europe & Australia

Global Drug Biotech Clusters

U.K.

U.S.

Germany

Canada

Scandinavia

India

Israel

China

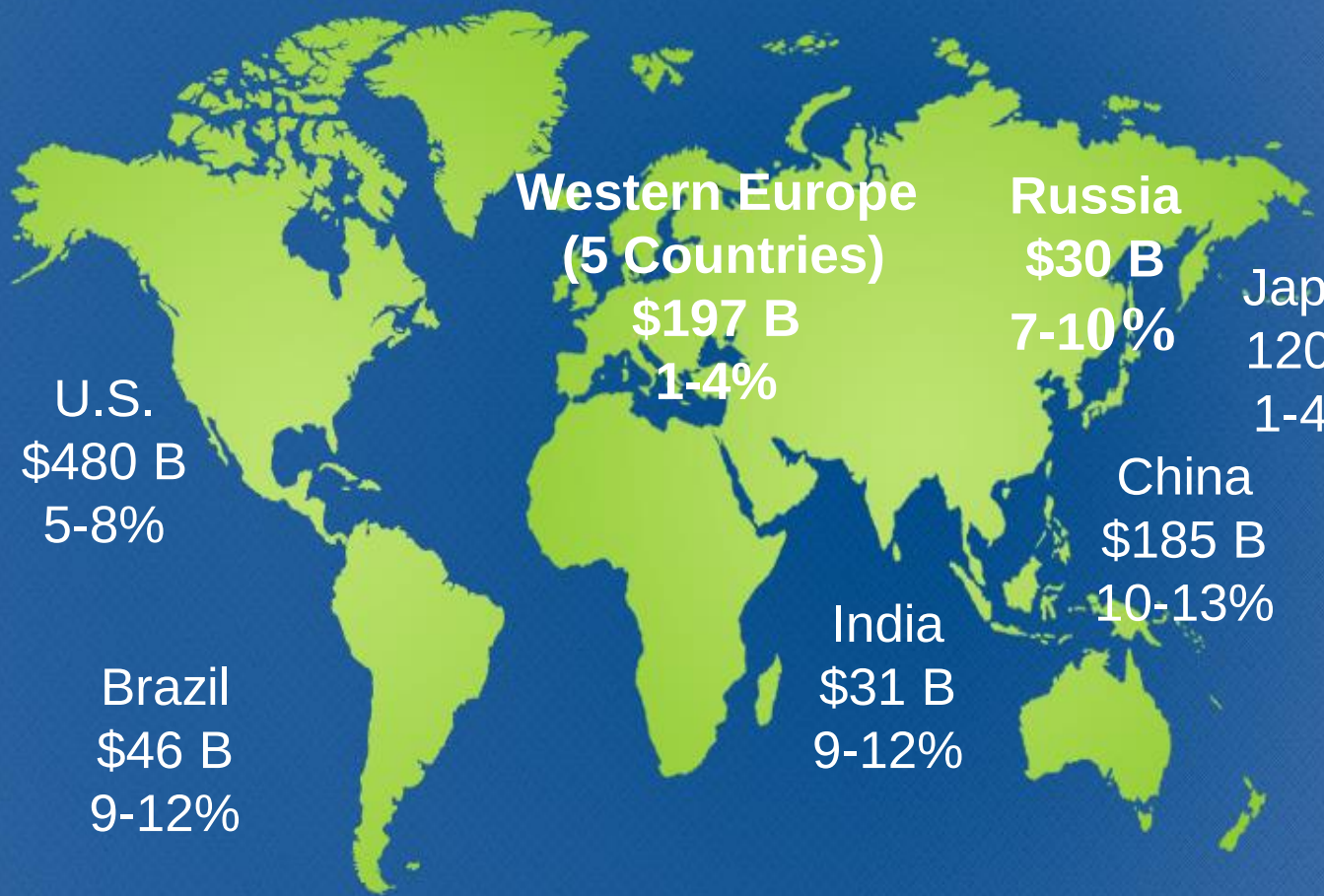
Japan

Australia

Top Cities for Biotech in the U.S.

Global Pharma Market

$ 1.28 - $1.310 trillion in 2018 (CAGR 4-7%)



Global Pharma Market

Rank	Company	2014 Sales - B	% Growth
1	Novartis	$47.1	<1%>
2	Pfizer	$45.7	<5%>
3	**Roche**	**$39.1**	**0**
4	Sanofi	$36.4	<2%>
5	Merck	$36.0	<4%>
6	Johnson & Johnson	$32.3	+15%
7	GlaxoSmithKline	$29.6	<11%>
8	AstraZeneca	$26.1	+1%
9	**Gilead Sciences**	**$25.5**	**127%**
10	Takeda	$20.4	+7%
11	**Abbvie**	**$20.2**	**+8%**
12	**Amgen**	**$19.3**	**+6%**
13	TEVA	$18.4	0
14	Lilly	$17.3	<18%>
15	Bristol-Myers Squibb	$15.9	<3%>

Global Pharma Market

Rank	Company	2014 Sales - B	% Growth
16	Bayer	$15.5	+4%
17	**Novo Nordisk**	**$15.3**	**+3%**
18	Astellas	$14.1	+4%
19	Boehringer Ingelheim	$13.8	<12%>
20	Actavis	$13.1	+51%
21	Otsuka	$11.3	+1%
22	Daiichi Sankyo	$10.4	<14%>
23	**Biogen Idec**	**$9.4**	**+41%**
24	**Baxter**	**$8.8**	**+6%**
25	Merck KGaA	$7.7	<9%>

U.S. Pharma Market - 2014

- Sales of $373.9 Billion: + 13.1%
  - Spending on **New Innovative Treatment** Options at Higher Prices
  - **New drugs:** contributed $20.3 billion (new hepatitis C treatments)
  - **Obamacare**: added almost 16 million new patients into healthcare system

Key U.S. PharmaTrends in 2014/15

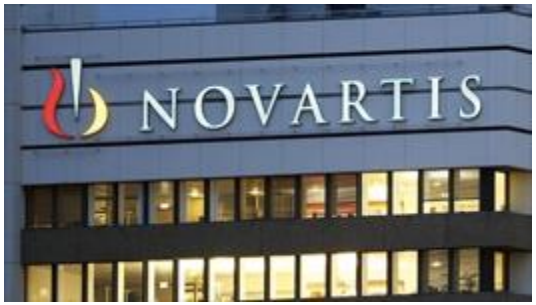
- **Solvaldi for Hep. C** – reaches $10 B in 1 year (Gilead -top 10 pharma companies)
- **FDA:** approves 51 new drugs vs. 42 in 2014: 6 biotech drugs.
  - First new biosimilar approved: Novartis' filgrastim (Amgen's Neupogen)
- **IPO market:** 61 (2015) vs. 72 in 2014
- **M&A Increase**: $18.2 B in biotech
  - Big Pharma continues to struggle with patent expirations
  - Lack of R&D Productivity

Biotechnology/Pharma Dilemma

Global Sales & Distribution

Innovation

New Products



Small Molecules
Chemistry

Research
University

Large Molecules
Biology

Rigid Management
R&D Failures

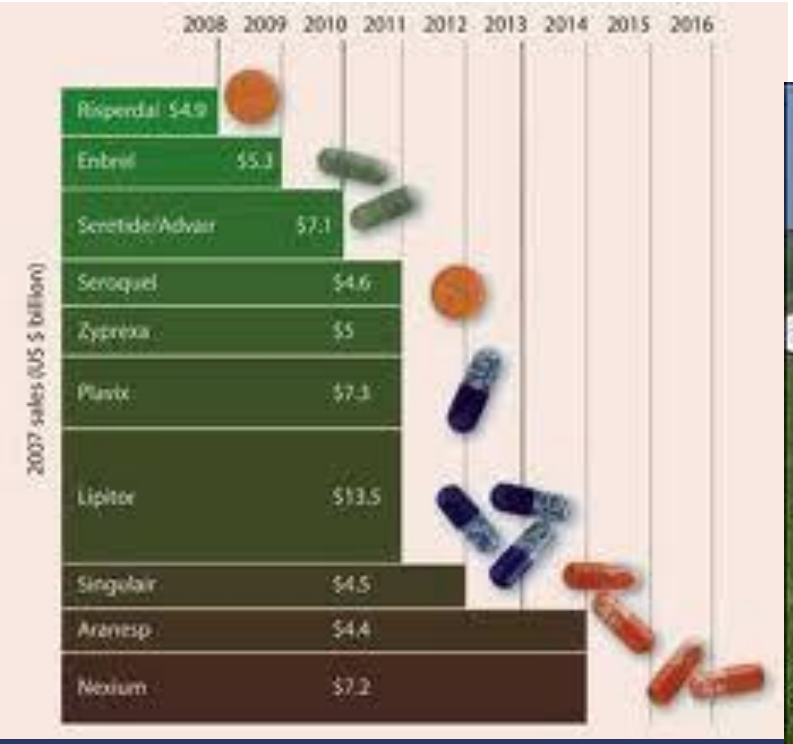
Lack of
Global Scale

The FDA:
The Global Regulatory Office?

- Offices in:
  - China :
    Shanghai and Beijing
  - Mexico, Chile, Costa Rica
  - India
    > >200 FDA-approved manufacturing facilities
  - UK
  - Belgium

Key Issues for Big Pharma Companies

- Need for New Products due to Patent Expiration in U.S. and Europe:
  - **Loss of $160 billion in sales by 2015**
  - **Driving M&A: 31 deals for $18.2 billion**



Key Trends in the U.S. Healthcare Market

- Accelerated Aging of Population (over age 65):
  - **U.S. (*"Baby Boomers"*), Europe, Japan & China**
  - **Increased spending on medical care**
    - **80% of Person's Healthcare costs after Age 65**
- Many diseases still unconquered:
  - **Cancer, Alzheimer's, Diabetes**
    - **Diabetes in Emerging Markets: India, Brazil, Middle East**
    - **New Diseases: ZIKA Virus**
- Growth of **Personalized Medicine**
  - **Herceptin for Breast Cancer (Her2Neu gene)**
- Role/Growth of **Diagnostics**

Accelerating
U.S. & Europe Entry Capabilities

Outsourcing

- **Contract Research Organizations (CRO's)**
  - Clinical
  - Preclinical (Efficacy/Toxicology)
  - Regulatory

- **Contract Manufacturing Organizations (CMO's)**
  - API
  - Finished Formulations

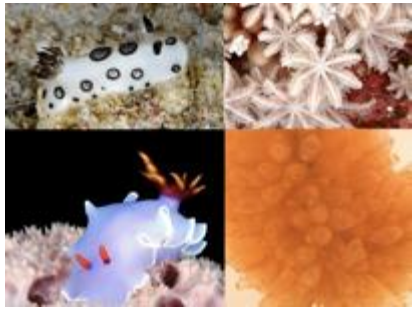
- **Contract Sales Organizations (CSO's)**
  - Sales Force
  - Marketing
  - Physical Distribution

Case Study :
A Spanish Biotech Company

- **Started:** 1980's - spinout of Harbor Branch Oceanographic Institute (J&J family)
- Licensed drugs from universities
- **Expertise:** Marine Biology and Natural Products Chemistry
- **Unknown outside Spain!!!!**
- **Focus on New Drugs from Marine Organisms**:
  - **Cancer**
  - **HIV (Pasteur Institute)**
  - **Malaria (Univ. of Geneva)**
  - **Immunosupressives (Harvard)**
- **Boston office**: early 1990's
- **U.S. CEO in 1995**: IPO and partnering
- **Refocus on Cancer** in mid- 1990's

Pharma Mar

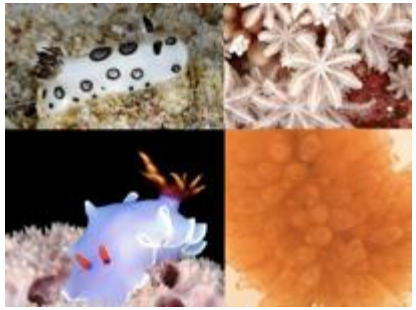
Grupo Zeltia



Case Study :
A Spanish Biotech Company

- **Creation:** International Oncology Advisory Board
- **Participation:** International Cancer Medical Meetings/publication of papers
- **First Partnering Deal:** Bristol-Myers Squibb

Pharma Mar
Grupo Zeltia



- **Decision to Outlicense**: U.S., Latin America, and Asia, **but to market directly in Europe**
- **Deals with:** Johnson & Johnson
- TAIHO ONCOLOGY
- **Approved in Europe**: 2007
- **Approved by FDA** for Ovarian cancer and sarcomas: 2015
- >500 employees
- 10 more cancer drugs in development

Conclusions

- Biotech Pharma will continue to be a “growth business” for next 35 + years in U.S., Europe, Japan and now China due to:
  - **Aging populations**
  - **“Old” Diseases needing improved therapy & New Diseases (ZIKA)**
  - **Globalization of industry**
- Increased Role of BRIC Countries:
  - **R&D site for infectious & other diseases**
  - **Clinical trials (naïve patients)**
  - **Manufacturing**