

---

Continuing Education 2016

# Advances in Specialty Pharmacy: Issues and Future Medical Miracles

Marsha Millionig, MBA, BPharm



McKesson

*ideaShare*2016

---

# Disclosure

Marsha Millonig reports no actual or potential conflicts of interest associated with this presentation

---

# Learning Objectives

*Upon successful completion of this activity, pharmacists should be able to:*

- Define biotechnology and nanotechnology;
- Describe the global and US biotechnology market size;
- Explain what fields are parts of the emerging business of life science and how the specialty drug market evolved
- List a number of new therapies resulting from bio and nanotechnology;
- Discuss the implications of these new therapies on pharmacy and its partners.

# Global Population Growth

---

- Earth's capacity is estimated at 12 billion people
- 100 million years before Earth had 1 billion people in 1830
- Only 170 years for the population to reach 6 billion plus
- 2005: 6,436,562,930
- 2015: 7,349,472,000
- October 2011 reached 7 billion—a mere 12 years after reaching 6 billion
- ½ the people who have ever lived are on the planet today
- Less than 100 years before we reach capacity

---

## Biotechnology is needed to...

- Create better fuels that don't harm environment
- Create tools to clean environment, feed a burgeoning global population, cure untold human suffering



---

# Biotechnology Definition

- Use of cellular and biomolecular processes to solve problems or make useful products. Life sciences...biology/chemistry technology affecting discovery and development of products for:
  - Healthcare (therapeutics, diagnostics, drug delivery, cell and gene therapy, devices, drug/device combinations)
  - Agriculture (food, feed, fibers, transgenics)
  - Industrial and Environment (reduce pollution, clean energy)
- All driven by a new set of enabling technology (genomics, combinatorial chemistry, SNPs, proteomics, sequencing...)

---

# Nanotechnology...

The creation of functional materials, devices and systems through control of matter at the scale of 1 to 100 nanometers, and the exploitation of novel properties and phenomena at the same scale.

Think STRONG + SMALL=EFFICIENCY

# Development is evolutionary...

---

4000-2000 BC: biotech used to leaven bread, ferment beer & wine, make cheese

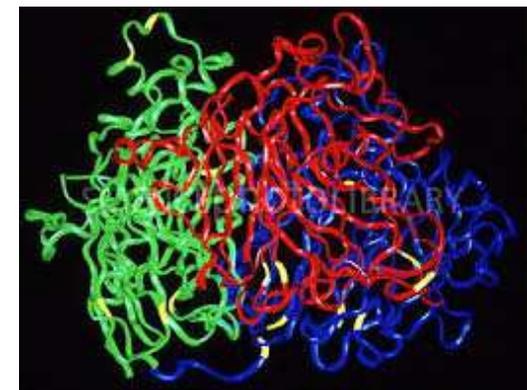
500 BC: Chinese use first antibiotic: moldy soybean curds for treating boils



1797: Jenner inoculates a child with vial vaccine to protect him from small pox

1830: Proteins discovered

1833: First enzyme discovered & isolated



McKesson

ideaShare2016

# Development is evolutionary...

1859: Darwin's Theory of Evolution

1865: Genetic science begins-Mendel discovers laws of heredity

1868: Existence of DNA discovered

1879: Chromosomes discovered

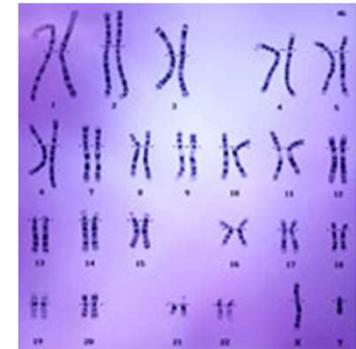
1906: The term genetics introduced

1919: The word biotechnology is first used in print

1927: Muller discovers radiation cause mutations

1938: The term molecular biology coined

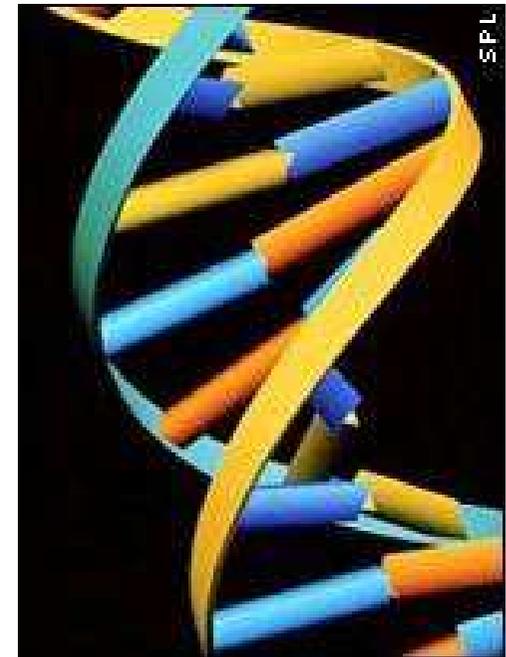
1941: The term genetic engineering is first used



# Development is evolutionary...

---

- 1944: DNA proven to carry genetic information by Avery, MacLeod and McCarty
- 1953: Watson and Crick DNA Structure
- 1955: Sanger determines insulin amino acids-first protein to be sequenced
- 1958: DNA made in test tube  
Sickle cell caused by AA change
- 1960: Messenger RNA discovered
- 1966: DNA genetic code cracked
- 1967: First automatic protein sequencer is perfected
- 1969: Enzyme synthesized in vitro the first time
- 1970: First enzyme discovered to cut DNA molecules at a specific site



---

## Development is evolutionary...

1971: First complete synthesis of a gene

1973: First time DNA fragments linked

1975: First monoclonal antibodies made

1976: First NIH research guidelines

Boyer co-founds Genentech, 1<sup>st</sup> bio co.

1978: Recombinant insulin first produced

1980: Oil-eating microbes patented by Exxon

---

## Development is evolutionary...

1982: First biotech drug: insulin from genetically modified bacteria

1983: First artificial chromosome synthesized

First whole plant grown from biotechnology

First genetic markers for inherited disease found



---

## Development is evolutionary...

1984: DNA fingerprinting developed

1985: Genetic fingerprinting entered  
as evidence in courtroom

1986: Interferon first anti-cancer drug  
from biotech

First genetically engineered  
vaccine for humans: Hepatitis B

Microbes used to clean oil spill



---

## ...but speeding up...

1988: First US patent for genetically altered animal—a transgenic mouse

1989: First DNA exoneration now 398 (2015)

1990: First food product from biotech approved: modified yeast

1994: First FDA approval for first whole food product: FLAVRSAVR™ tomato

1997: First weed & insect resistant crops developed

First cloned animal: Hello Dolly!



---

## ...but speeding up...

1998: Human embryonic stem cells lines established

Herceptin approved-considered first pharmacogenomic (personalized) medicine

First complete animal genome: roundworm

2000: First complete map of a plant genome

2002: First draft human genome published

---

## ...but speeding up...

2003: 99.99% accurate version human genome

2004: First genetically modified pet: the GloFish

FDA clears genotyping test to aid in medication selection

First cloned pet, a kitten called CopyCat

2005: Skin cells converted to embryonic stem cells

1 billionth acre biotech seed planted

First complete dog genome: boxer

2006: FDA approves Gardasil-first vaccine for cancer-causing virus

Wake Forest creates first laboratory-grown organs by successfully transplanting bladders



---

## ...but speeding up...



2007: Successful reprogramming human skin cells to create cells indistinguishable from embryonic stem cells  
Biotech cattle that cannot develop prions=no mad cow disease

2008: Draft corn genome

10 disease bearing stem cell lines created

Mature human embryos created from adult skin cells:  
personalized stem cells for disease treatment

First synthetic genome: the road to creating life

First complete map of cancer patient genome

First US FDA application for gene-therapy/cancer

---

...but speeding up...

2009: US Congress frees up federal funding for broader embryonic stem cell research

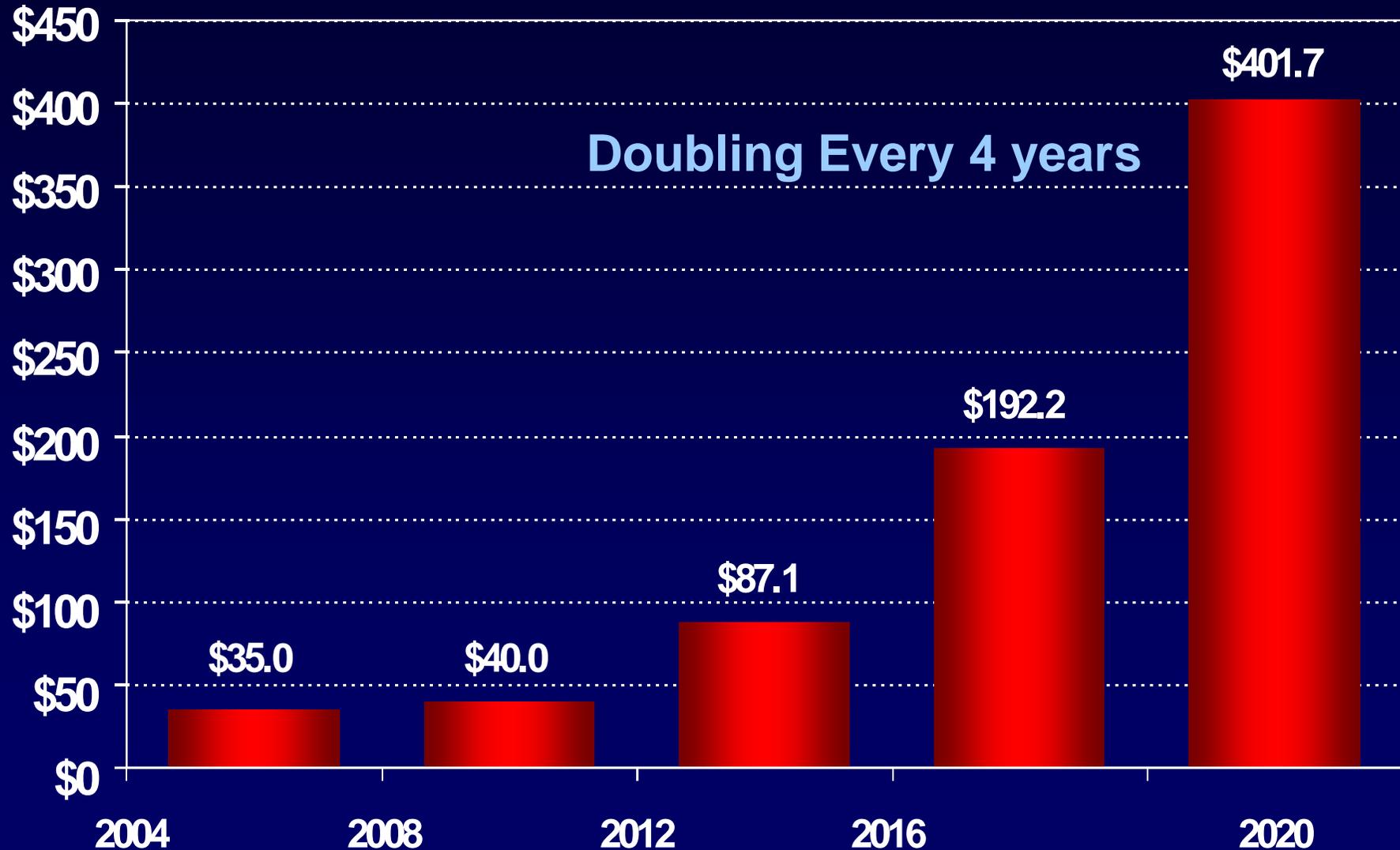
Canadian company produces first plant-based influenza vaccine in tobacco leaves



# Specialty Drug Spend: 2004-2020\*

\$ (billions)

(est. 2016-2020)



Source: EMD Serono Specialty Digest, 10<sup>th</sup> edition, p.13; IMS Health & Express Scripts