

A Consumer Perspective on
Ingenuity in Diabetes Research in 3 Parts
Colleen Fuller, PharmaWatch

February 24, 2009

The Power of Creative Imagination

Three parts

- Prevention
- Cure
- Treatment

Part 1: Prevention

- Research to prevent Type 2 Diabetes (T2D) is focused on individual risk factors (obesity, genes) and drug therapy
 - Obesity seen as a medical condition rooted in human biology, with link to T2D significant
 - Weight reducing drugs benefit only a few, with significant adverse events in many (eg., cancer, digestive and cardio problems) (R. Padwal 2003)
 - World market for anti-obesity drugs to reach estimated US\$6.9 billion by 2015

Creative Prevention Strategies

- Social determinants of health
 - Aboriginal status, early life, education, employment and working conditions, food security, health care services, housing, income and its distribution, social safety net, social exclusion, and unemployment and employment security (Raphael 2006)
 - Socioeconomic status is a more robust predictor of diabetes, especially among women (SC Maty 2008)
- Social determinants of health play a greater role in preventing disease than biomedical or lifestyle behaviour modification (Raphael 2003)
- Jay Wortman: pilot study begun Aug 2006 among members of Namgis First Nation, to prevent and reverse Type 2 diabetes among Aboriginal people using traditional high fat/protein, low carb diet (www.drjaywortman.com/)
 - Preliminary results are promising

Future Prevention Strategies

- Stronger focus on strategies to prevent diabetes by addressing *socio-economic* factors
- The emphasis on individual risk factors and drug treatment to the exclusion of all other considerations is a failed strategy
- Public policy and public research funding should be aligned with evidence and social goals

Part 2: Cure

- Most people with Type 1 diabetes doubt that drugs can cure their condition
- JDRF: “The biotechnology and pharmaceutical industries are an integral, vital, and growing part of the search for a cure for type 1 (juvenile) diabetes and its complications”
- If a cure for T1D is found, the biotech and pharma industries will lose a market worth billions

Cure: Beta Cell Regeneration

- In 2001 Denise Faustman (Harvard, MGH) discovered that pancreas is capable of spontaneous regeneration;
- Permanently reversed long-standing Type 1 diabetes in NOD mice using BCG (vaccine)
- Faustman attacked by JDRF, demands she apologise for raising false hopes among people with diabetes
- Despite promising study no Pharma funders came knocking
- Five years later JDRF replicates her protocols and achieves most of her results

Where's the Creativity?

- Faustman developed a relationship with people who have diabetes and their families
- She wasn't selling a new drug
- People who have or are affected by Type 1 diabetes raised \$20M; Ph 2 trials slated for 2010
- If results confirmed in human trials, cell transplants won't be necessary
- Protocols may be applicable to other autoimmune diseases, including RA, MS, lupus, Crohn's
- Research is creative, imaginative, not focused on profits

Part 3: Treatment

- The focus of pharmaceutical industry
- Pharma corporations have legal obligation to earn profits for shareholders, not address needs or goals of other stakeholders, including those they manufacture drugs for
- Diabetes drug costs increasing at 20% annually, 1996-2006 (Hauber, Gale 2006)
 - Major driver of global pharmaceutical market

Innovations in drug therapy

- 1921: Banting, Best & colleagues discover insulin
- 1951: Lente insulins (basal insulins)
- 1956: the first oral drugs became available to treat Type 2 diabetes (phenformin and metformin)
 - Approved in Canada and Europe in mid-80s
- 1974: chromatography purification techniques decreased impurities in animal insulins

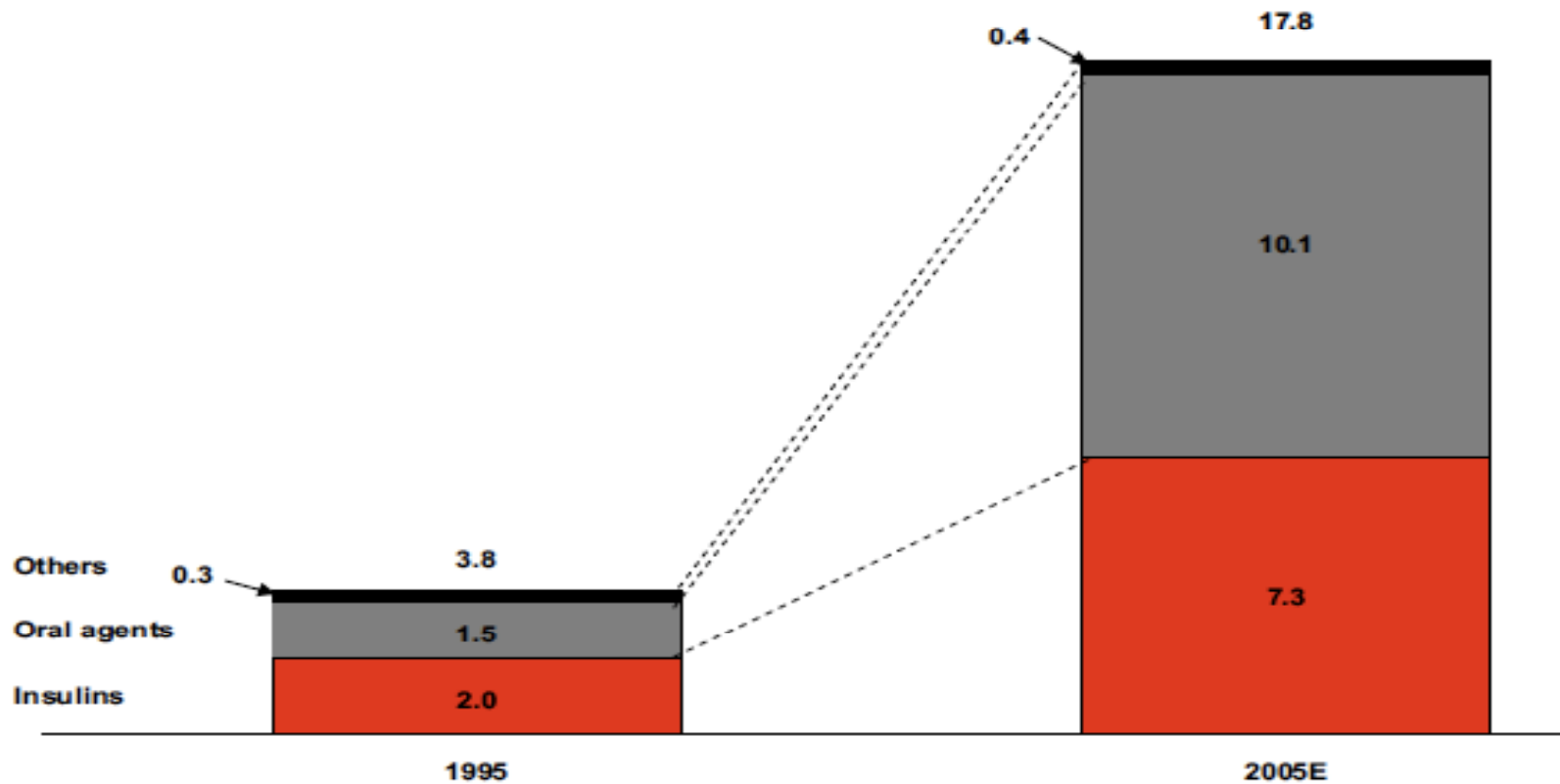
Insulin

- In 1979 Novo Nordisk & Eli Lilly reinvent insulin
 - No safer, not more effective, fewer options
 - Price 300% higher when it hits market
- 1983-2008:
 - Lowest price increased from \$6 to \$23
 - Highest price increased from \$10 to \$120
- Global cost of insulin therapy: \$2B in 1995; \$7.3B in 2005; \$14.5B (projected) in 2010
- Cheaper animal insulins withdrawn *en masse* in 1990s
- Devices (syringes, pens, pumps, test strips) skyrocketing

Oral Diabetes Drugs

- Cost of diabetes drug treatment escalating
 - ① More oral drugs used per patient
 - ② More expensive brand name drugs used
 - ③ Increased incidence of diabetes
- Global cost of oral medications \$1.5 Billion in 1996; \$15.1B estimated worth in 2010 (Hauber, Gale 2006)
- Increased use of brand name drugs matched by declining use of generics
- 80% of patients use 2 or more diabetes drugs every day;
- One in every five dollars spent on diabetes medications worldwide goes to pioglitazone (Actos) and rosiglitazone (Avandia)

Global diabetes drug market 1995-2005



- Hauber, Gale 2006

Summary

- Pharmaceutical industry cannot be relied upon to provide creative prevention strategies or cures for diabetes; these strategies need public funding
- There are too many drugs; treatment strategies with financial support of manufacturers benefit pharmaceutical investors
- Inherent conflicts of interest in research must be addressed through regulation

Creative Conclusion

- Moratorium on new diabetes drugs that do not demonstrate improvements in safety, effectiveness, affordability
- Insulin therapy should not be driven by patents
- Public research funds should not be contingent on industry partners
 - And should not support private patents