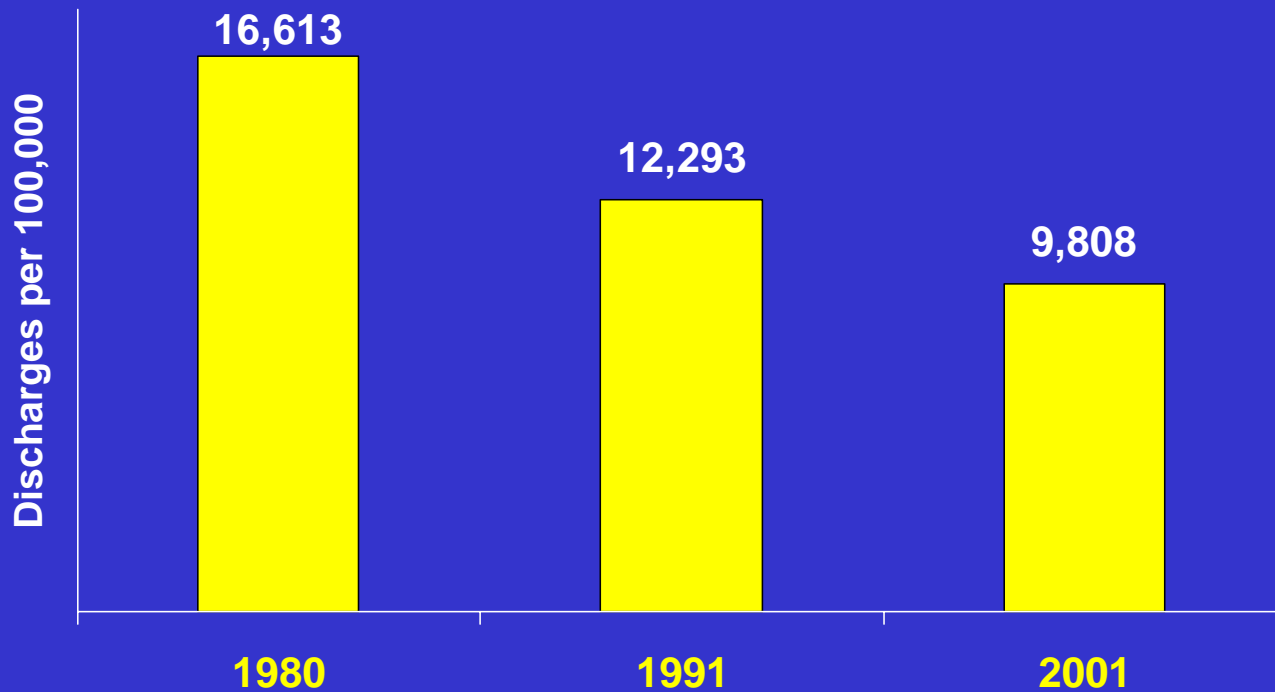


Importation & Issues in International Drug
Pricing & Drug Spending
March 2005

Chris Ward

Medical Innovation Contributes to Lowering Overall Healthcare Costs

Over the past two decades hospitalization rates in the US dropped more than 40%

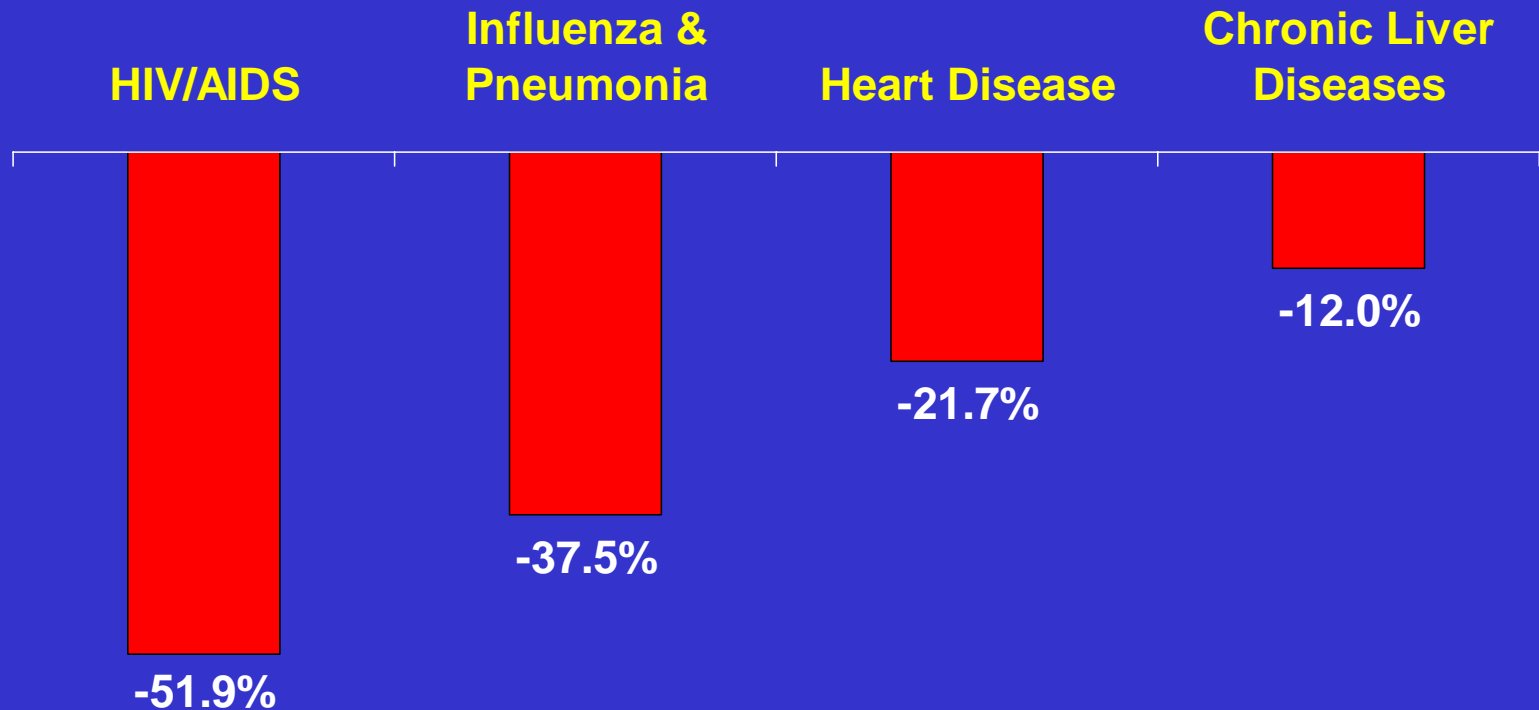


Source: OECD, *Health Data*, 2003.

Ward Health
Strategies Inc

Medical Innovation Saves Lives

Drop in death rates from selected causes (1991-2001)



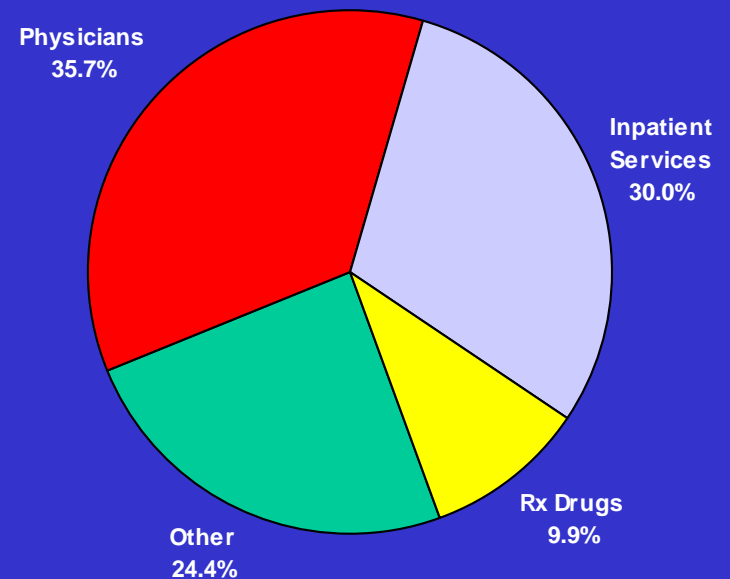
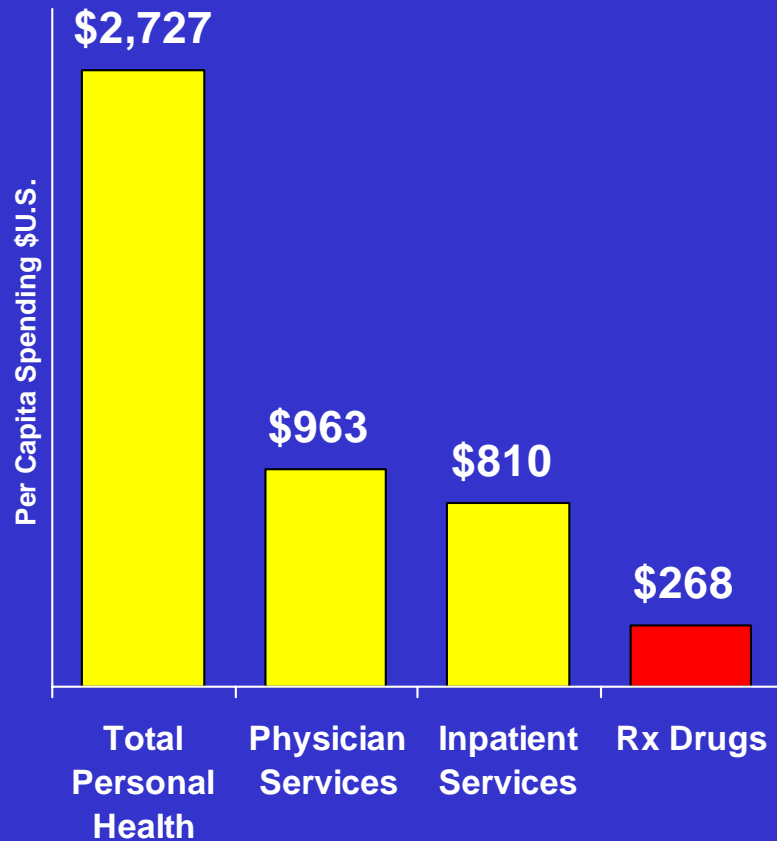
Source: U.S. National Center for Health Statistics, *National Vital Statistics*. From *Statistical Abstract of the United States: 2002*.

**Ward Health
Strategies Inc**

Importation

- **Puts consumers at risk by evading supply chain safeguards**
- **Requires Americans to waive their rights to protection of U.S. law**
- **Violates international trade laws and NAFTA**
- **Provides no certainty of supply**
- **Avoids dealing with the fundamental issue of providing adequate benefits to seniors & other vulnerable populations**
- **Destroys the incentive to search for new medicines that save lives and reduce the financial burden of illness and disease**

Canada U.S. Health Spending Gap 2002



Why Health Services & Supplies Cost More in the U.S. than in Canada

Macro Economic Differences

Differences in Liability Costs

Price Controls

Why Health Services & Supplies Cost More in the U.S. than in Canada: Price Controls

Selling drugs at lower prices in Canada is not a matter of choice for manufacturers.

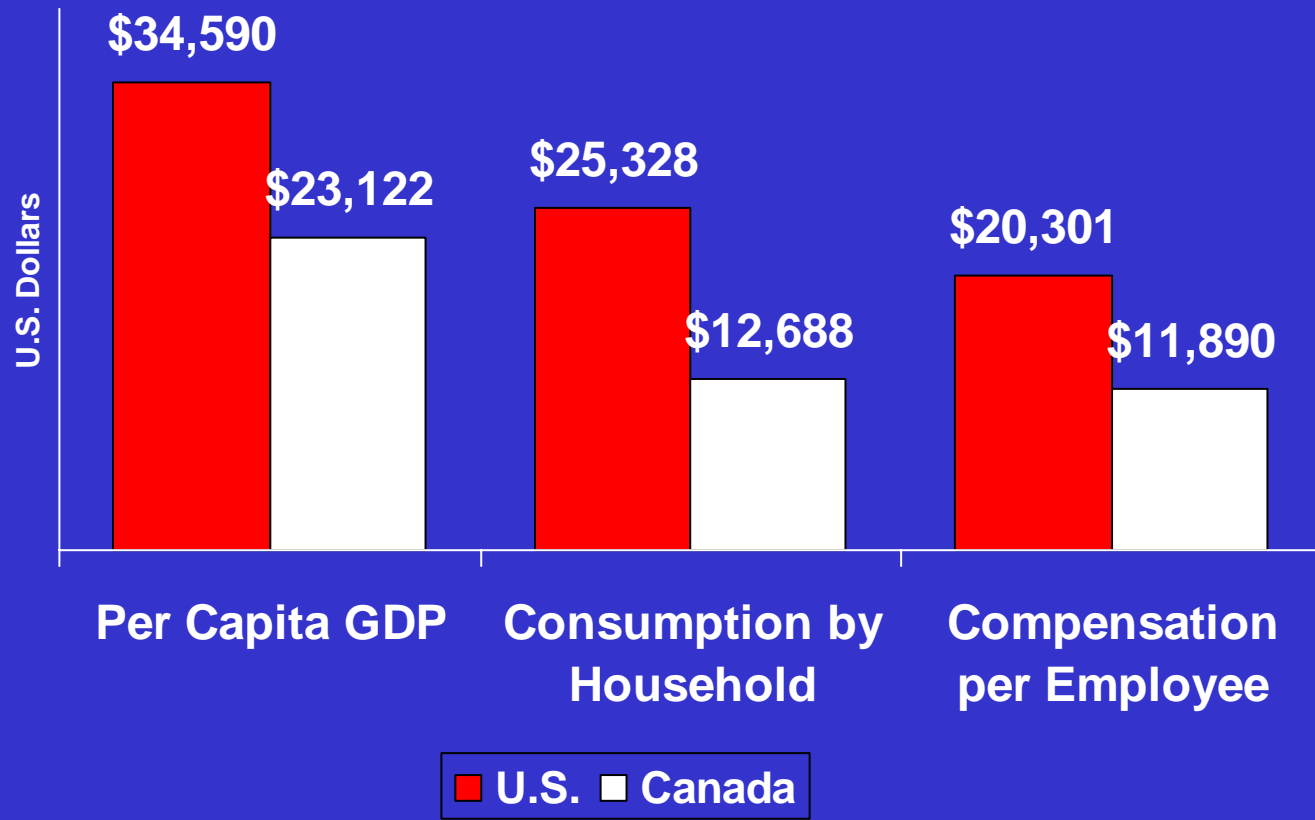
The government sets manufacturer's price for all patented drugs in Canada.

Canadian drug prices are not a matter of choice nor are they freely negotiated by pharmaceutical companies

A breakthrough drug in Canada can be sold for no more than existing drugs in the same therapeutic class or the median price of the same drug in 7 other countries (U.S., U.K., Switzerland, Sweden, France , Germany, and Italy).

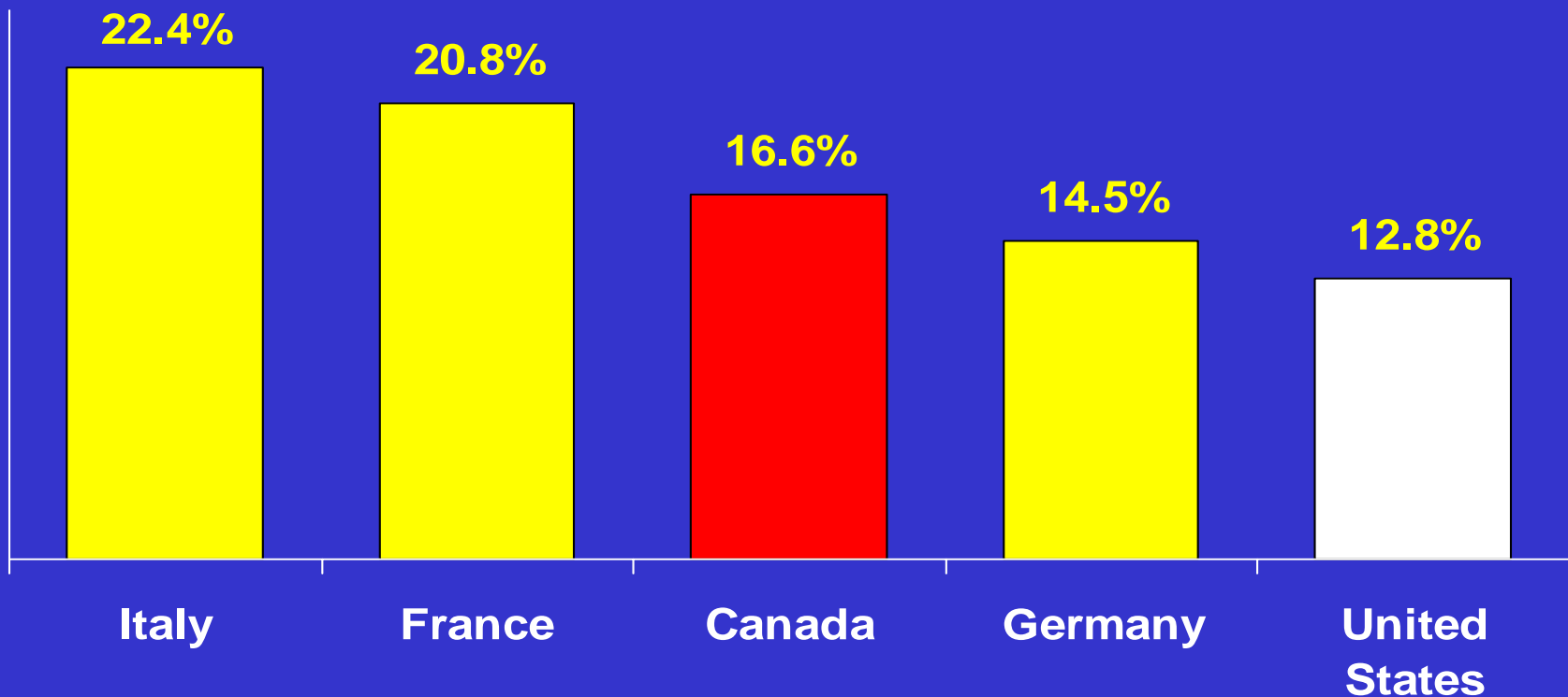
If a company refuses to market a drug in Canada the patent can be taken away through a compulsory license.

Economic Differences Canada U.S. 2000

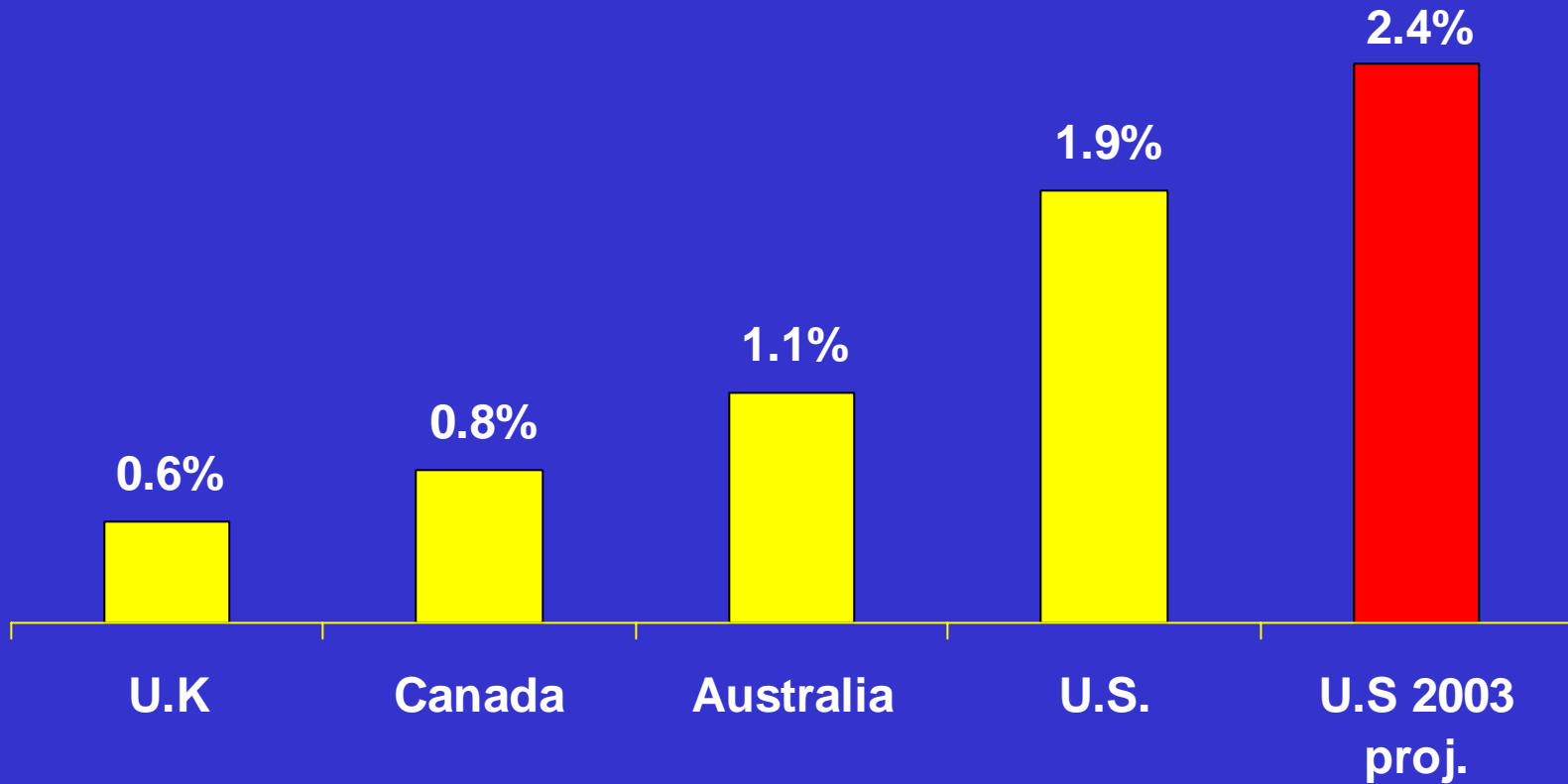


Comparing Drug Spending Among Developed Countries 2002

Drugs and other non-durables as a percent of total health spending

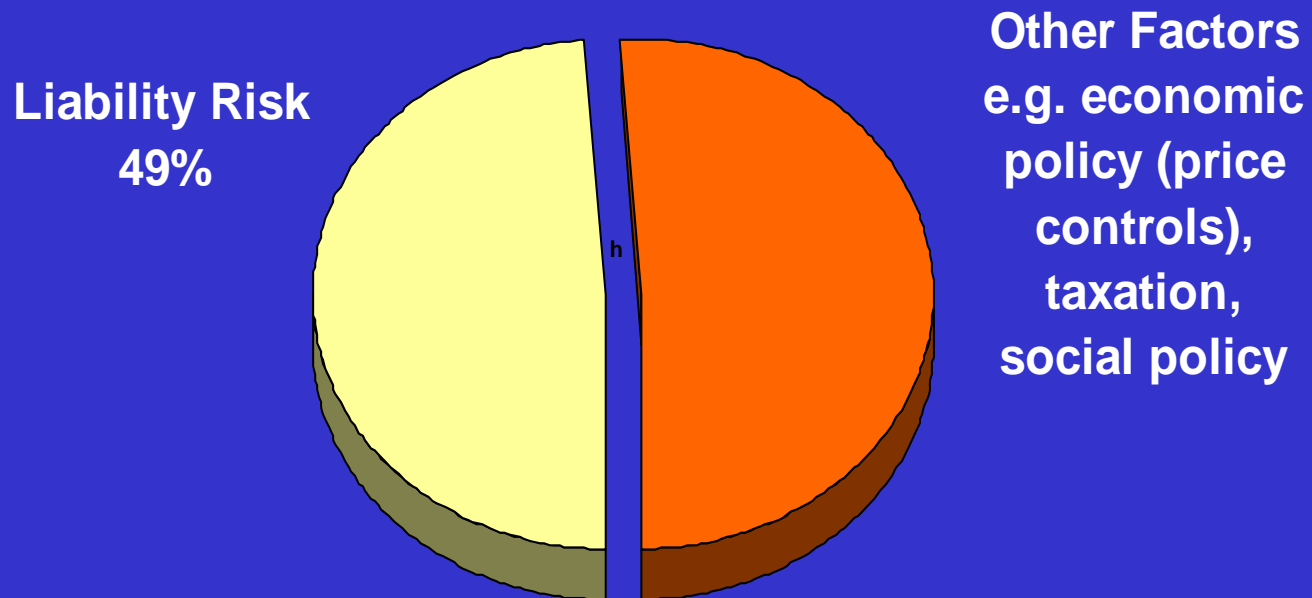


Tort Costs as a percent of GDP Selected Countries 1998



Liability Risk Accounts for Most of the Difference in U.S. Drug Prices

Drug Price Difference Between Canada and the U.S.
Attributable to Liability Risk



Safeguards that Ensure the Safety & Efficacy of the Drug Supply Chain

- The submission review process for individual products
- Establishment licenses for legal importers
- Record retention and recall mechanisms
- Mutual recognition agreements for pharmaceutical GMP requirements
- Packaging and labeling requirements.

Personally Imported Drugs are of Unknown Quality



Importation of Human Use Drugs for Personal Use Enforcement Directive

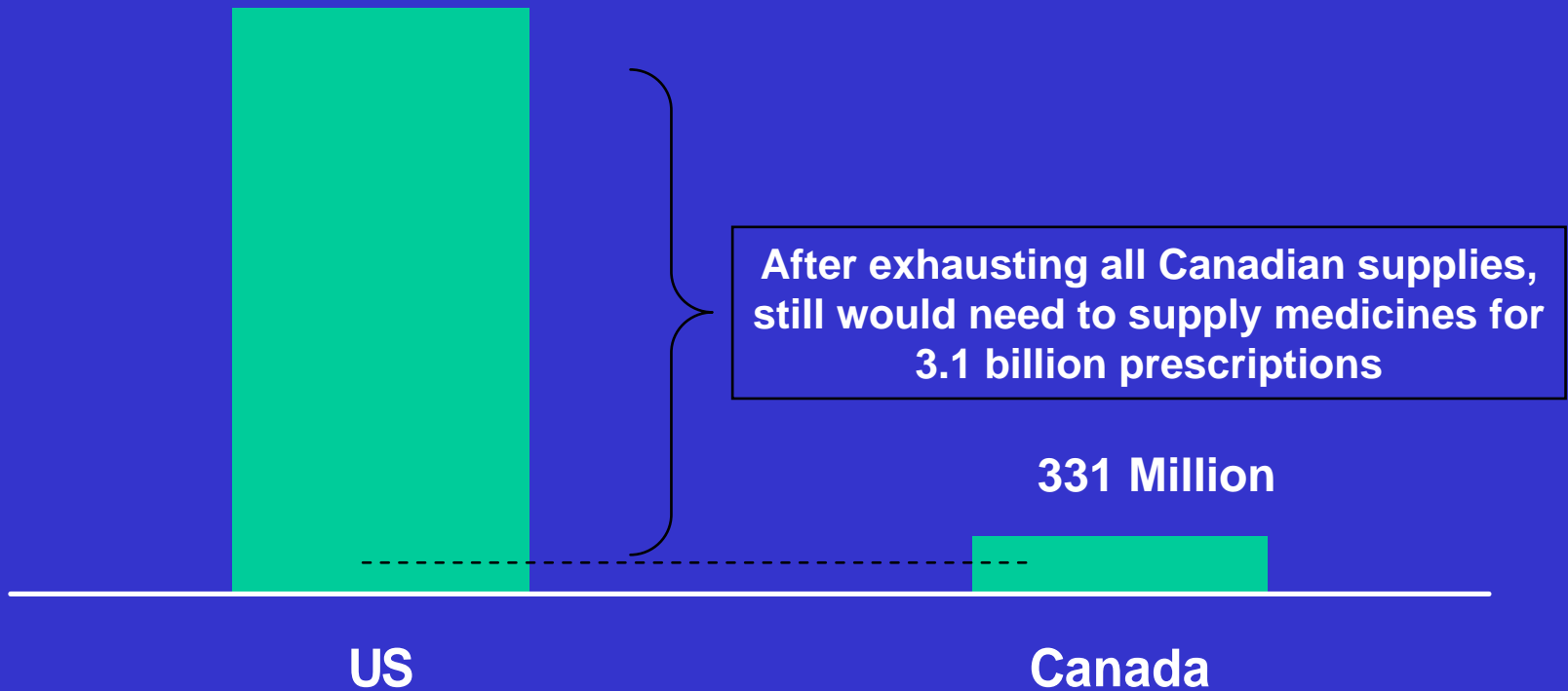
The personal use exemption unfortunately provides an opportunity for these suppliers to conduct commercial activities, and to evade the submission review process for individual products, and/or the Establishment Licence requirements for importers, by supplying their drug products primarily through the mail to individual Canadians. These activities at times may include violative marketing and advertising activities by means such as the Internet. This has ramifications related to safety because large quantities of products, which have not been reviewed for safety and/or efficacy, and which are of unknown quality, can enter the country and be distributed. The lack of an importer also means no person is responsible for meeting GMP requirements such as appropriate record retention or recall mechanisms.

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Canadian Drug Supply Too Small to Have a Real Impact in the US

Total Prescriptions Filled in US vs Canada, in Millions - 2002

>3.4 Billion



Ward Health
Strategies Inc

The Trans - Shipment of Pharmaceutical Imports

Imports of Pharmaceuticals & Medicine from Selected Countries
January to July 2004

COUNTRY	IMPORTS	
China	\$44.7 million	+ 8%
India	\$25.6 million	+16%
Mexico	\$24.6 million	+13%
Argentina	\$2.6 million	+208%
Indonesia	\$.37 million	+1307%
Thailand	\$1.6 million	+55%
Columbia	\$.48 million	+ 3036%

Drugs Exported to U.S. May Not be Subject to Health Canada Oversight

37. (1) This Act does not apply to any packaged food, drug, cosmetic or device, not manufactured for consumption in Canada and not sold for consumption in Canada, if the package is marked in distinct overprinting with the word "Export" or "Exportation" and a certificate that the package and its contents do not contravene any known requirement of the law of the country to which it is or is about to be consigned has been issued in respect of the package and its contents in prescribed form and manner.

Canada's Food & Drug Act

“In documents filed in Federal Court late last month, CanadaRX Corp. has asked a judge to prevent Health Canada inspectors from visiting its facility, calling the proposed inspection "invalid and unlawful" and a violation of the company's charter rights.”

Michelle MacAffee, Canadian Press, March 3, 2004

Importation & Liability

Mail order importers require patients to waive their rights of protection under US law before filling a prescription.

Before a prescription can be filled in Canada it must be signed by a Canadian doctor. Canadian doctors have been told by the agency that insures them that they have no liability coverage for prescriptions they write for US patients receiving imported drugs.

Pharmaceutical companies have no way of tracking drugs illegally exported to the United States, therefore they have no means to issue warnings or recalls should post-marketing safety issues arise.

Importation: Waiving Consumers' Rights of Protection Under U.S. Law

- “I hereby release and save GP and its employees and contractors... harmless from any and all acts, liabilities, damages (etc.) of any kind or nature... from any side effects... their manner of prescribing generic drugs and non-child-protective packaging.”
- “This agreement along with any disputes that may arise.....will be governed and construed in accordance with the laws of Canada.”
- “The State of Minnesota makes no warranty express or implied... and accepts no legal liability with respect to any product offered or pharmaceutical care provided .”

The Political Environment in Canada

Protecting Canadian Consumers

January 31, 2005:

"I want to make sure that we protect ordinary Canadians, that we protect the supply, that we protect the pricing regime." **Hon. U. Dosanjh, Minister of Health, Canada**

- Prohibit Canadian doctors from co-signing prescriptions for U.S. patients they haven't seen.
- Prohibit prescriptions for foreigners who are not present in Canada.
- Create a list of widely used drugs that could not be exported from Canada

Key Findings of HHS Study

- There are significant risks with the way people are currently importing drugs. “extraordinarily difficult and costly” for personal importation to be implemented in a way that ensures the safety and effectiveness of imported drugs
- Legalized importation will likely adversely affect the future development of new drugs for consumers.
- Legalized importation raises liability concerns for consumers, manufacturers, distributors, pharmacies and other entities. Consumers harmed by imported drugs may not have legal recourse against foreign pharmacies, distributors or other suppliers.