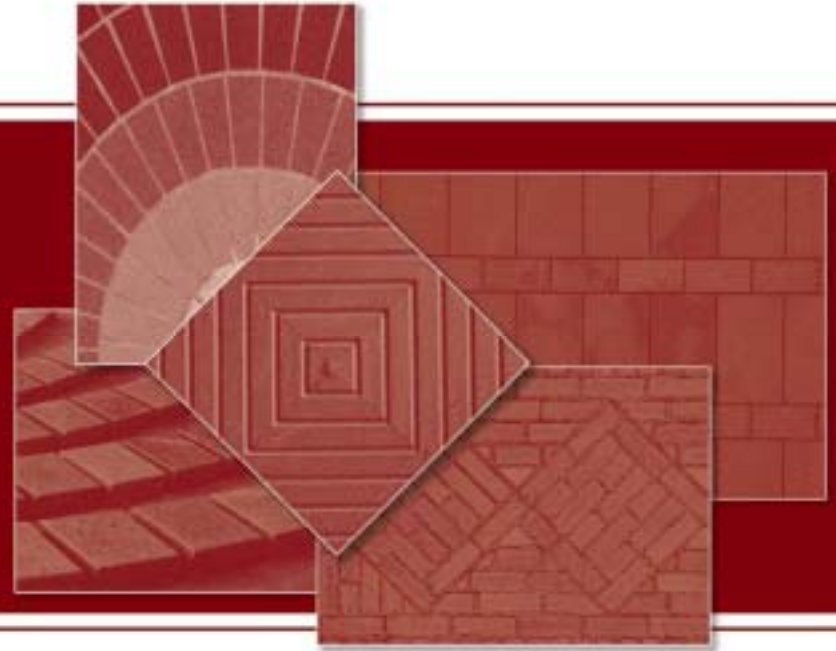




Canada-US Regulatory Co-Operation Charting a Path Forward



**A Presentation to
National Standards System (NSS) Conference**

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International Regulatory Cooperation Project

Background and Context

- North American Linkages projects:
 1. International Regulatory Cooperation
 2. Moving Toward a Customs Union
 3. Cross-Border Regions
 4. North American Labour Mobility

- Why focus on Canada- U.S.?
 - Full NAFTA benefits not fully realized
 - Productivity and income gaps between Canada and the U.S.
 - Proximity, economic integration, similar regulatory objectives
 - High degree of trust, familiarity, and close working relationships

- Over 20% of EACSR recommendations relate to regulatory cooperation



International Regulatory Cooperation

3-Step Research Plan

1. Review literature and lessons learned from around the world
2. Conduct independent empirical research
3. Examine specific sectors and possible initiatives
 - New product approvals (i.e., human and veterinary drugs, pest control products, medical devices, new chemical entities)



Regulations and Economic Performance: What do we know from empirical research?

- Significant relationship between regulations and productivity, investment, and R&D
- For example, empirical studies by the OECD indicate:
 - Regulatory convergence could increase exports by 10% and 30%, and FDI by 10% (OECD 2003);
 - Negative effects on domestic investment, FDI and speed of technological catch-up (OECD 2003); and
 - Eliminating the regulatory gap between Canada and the U.S. could increase productivity (TFP) growth by about 0.22% (OECD 2002).
- 1/3 of the gap in Canada-US R&D intensity is due to differences in regulations (Industry Canada 2002).



Regulations and Economic Performance: PRI's empirical research

- Using OECD data on investment rates, PRI estimates that:
 - Investment was 40% higher with regulatory reform
 - Investment could have been 30% higher with reforms equal to the U.S.
- PRI estimates that regulatory compatibility between Canada & U.S. could increase per capita income by up to 2%.



Regulatory Cooperation: A Toolbox of Approaches

Coordination

- Information and Work Sharing (bilateral)
- International Standardization (multilateral)
- Other coordination tools (unilateral, bilateral)

Mutual Recognition Agreements (MRAs)

- ✓ *Accept Foreign Approvals*
- ✓ *Accept Foreign Submission Formats*
- ✓ *Accept Test Results*
- ✓ *Accept Foreign Summary Data*
- ✓ *Alignment of Regulatory Standards*

Harmonization



Experience with Regulatory Cooperation



International Experience

- Regulatory cooperation takes time
- Regulatory cooperation works best where there is pressure for economic integration
- Political commitment is required

Canada-U.S. Experience

- Decades of experience, formal and informal linkages exist
- High degree of knowledge, understanding and mutual confidence exists between Canadian and U.S. authorities



Measuring Potential Gains in Selected Product Markets

Why Does this Matter?

- Canada - U.S regulatory differences a key concern
 - Limit trade and investment opportunities
 - Increase costs and limit access to market
 - Limit access to, and diversity of, products and services
- Economic evidence often anecdotal, lacking rigor
 - Are the concerns real, credible?
 - What are the implications for trade, investment, innovation and competitiveness?
- Inform policy makers by identifying potential gains based on independent analysis.



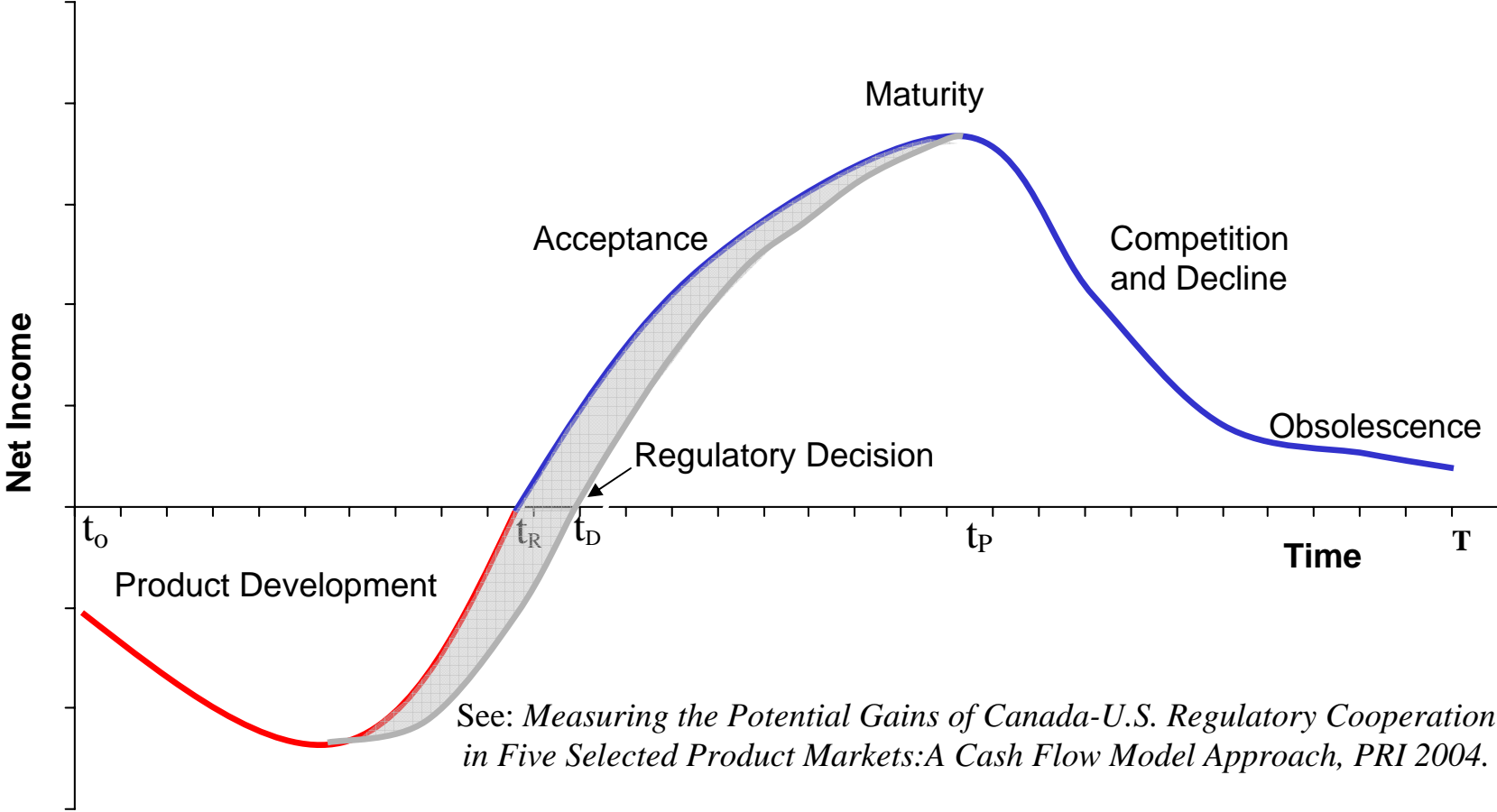
Cash Flow Analysis

Methodology

- Model based on academic literature
 - Refinements to reflect Canadian market realities
 - Applied to selected product markets
- Advantages of cash flow models
 - Dynamic nature of investment decisions, financial considerations
 - Measures of profitability --sales, net income, and rates of return
- Assumptions and limitations
 - Time-value of faster approvals and lower compliance cost
 - Health and environmental benefits discussed, not estimated empirically



Measuring Potential Gains: Product Level



See: *Measuring the Potential Gains of Canada-U.S. Regulatory Cooperation in Five Selected Product Markets: A Cash Flow Model Approach*, PRI 2004.



Measuring Potential Gains:

Overview of Results

- Faster regulatory decisions and lower compliance costs could lead to substantial benefits

Potential Annual Gains

	Human drugs	Veterinary Drugs	Pesticides	New Substances	Average
Net Income	6.6%	18.0%	9.9%	122%	8.2%
Sales	10.5%	11.3%	8.5%	39%	10.7%
Rate of Return	4.2%	12.2%	4.2%	54%	4.8%



Canada-U.S. Regulatory Cooperation

Overall Observations and Conclusions

Many regulatory differences with U.S. ***At what cost?***

- Costs appear substantial
- Benefits often unsubstantiated
- Concerns not supported by the literature

Policy challenges

- Sovereignty
- Values and identity
- Existing and new regulations
- Economic and social imperatives
- Process vs. outcomes
- Management, implementation challenges
- Risk and uncertainty



Canada-U.S. Regulatory Cooperation

Overall Observations and Conclusions

More could be done

- Canada-U.S. regulatory cooperation has not been maximized
- EACSR report and PRI research supports taking action
- Unilateral approaches may be in Canada's interests

Consider

- Immediate action in areas of low risk
- Pursuing cohesive strategy and specific goals to advance Canada's interests

How?

- What are the key hurdles for departments?
- What approaches have worked best to date?
- What tools, support do departments need to take action?

