



CML
HORIZONS 2016

CML ADVOCACY - LEARN, SHARE, GROW
14TH INTERNATIONAL CONFERENCE FOR
ORGANIZATIONS REPRESENTING PEOPLE
WITH CML



LJUBLJANA
SLOVENIA
6-8 MAY 2016

Access issues worsen as generic imatinib arrives in USA

Presentation by

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The presentation will feature case studies and focus on cost & availability issues, past advocacy efforts and next steps.



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CML Busters and NCMLS Daily Advocacy Focus

- ✓ Personal Access & Support (CML Specific)
 - ❖ Family Support Groups
 - ❖ Social Media Groups
 - ❖ One-on-one phone access for newly diagnosed
- ✓ We also provide links to complimentary organizations
 - ❖ Financial assistance organizations
 - ❖ CML specific medical & trials information
 - ❖ Other relevant support organizations



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CML Busters and NCMLS SPECIAL Advocacy Efforts

- ✓ Producing, speaking, and attending CML relevant conferences
- ✓ Voice to Pharmaceutical companies for CML patients
 - ❖ As reference group members act as patient consultants
- ✓ Active feedback voice to Medical community (NIH, NCCN, NCI)
 - ❖ Medical issues of living with CML, side-effect solutions, trials participation
- ✓ Political advocacy voice for CML patients
 - ❖ Visits to Washington D.C., State, and local government officials
 - ❖ Advocacy for: Lower cost, better availability, research \$s



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Generic imatinib concerns in the USA

- ✓ Generic imatinib Sun Pharma (i.e. Ranbaxy) entered the USA market in February 1, 2016.
- ✓ Major areas of concern voiced by USA CML patients
 - ❖ Will generic imatinib bring much needed cost reduction?
 - ❖ Will the new generic formulation cause changes or additions to side effects?
 - ❖ Will the transition change the remission status on the patients?
 - ❖ What are the transition protocols to generic?
 - ❖ Can the CML patient go back to branded imatinib if generic is intolerable or ineffective?



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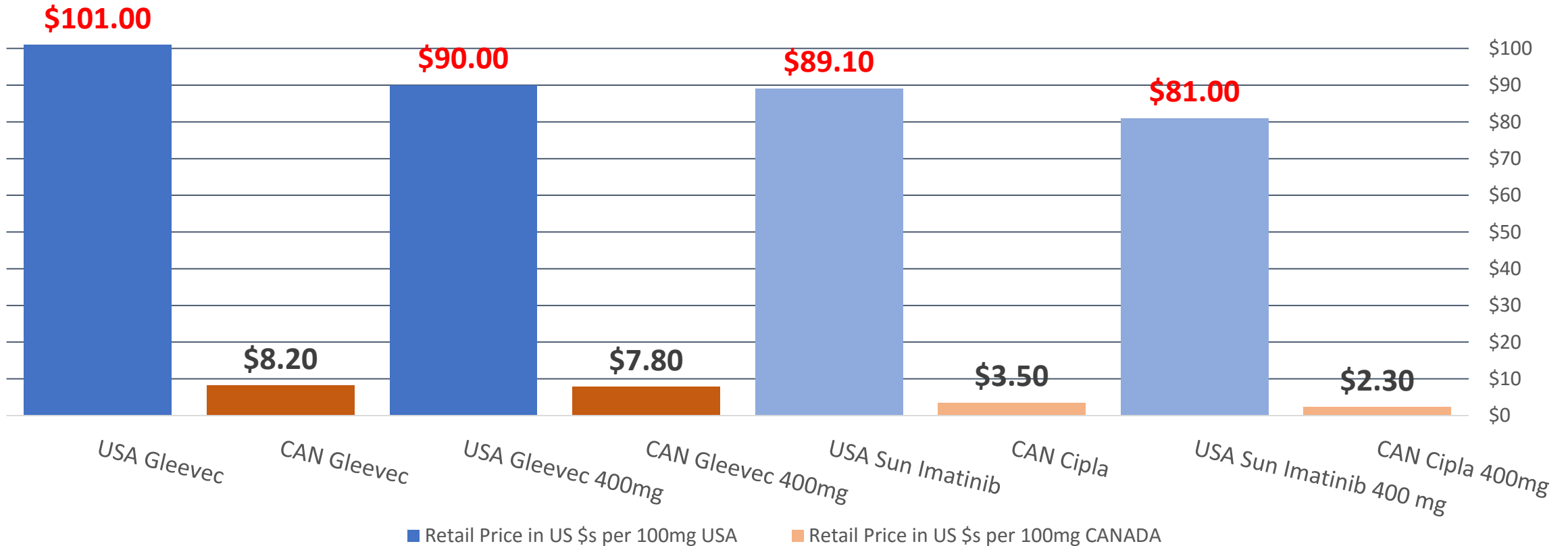
Drug price issues affecting USA patients

- ✓ Price of all CML drugs in the USA is unaffordable and unsustainable Why?
 - ❖ USA pays 10-40 times the price for TKIs than elsewhere in the world
 - ❖ It is estimated that over 250,000 patients will be on oral cancer drugs in the USA by 2017
 - ❖ Since 2000, there have been 32 new oral cancer medications introduced
 - ❖ Financial assistance programs are limited and some patients do not meet program requirements
 - ❖ It is devastating our USA families financially



A Case for National Drug Price Negotiations

Sample retail price of Gleevec and generics USA vs Canada markets
(i.e. Non-negotiated vs Negotiated price per 100mg)





Other issues affecting patients

- ✓ USA Insurance companies and pharmacies can switch patients to generics without the doctor's or patient's approval
 - ❖ National Comprehensive Cancer Network (NCCN) has no established protocols monitoring patients who are switching to generics, as there are for alternative TKIs
 - ❖ Additives and/or excipients in each generic may differ from the branded drugs

- ✓ Some patients have reported different side effects with generic imatinib
 - ❖ Absorption and decay testing, on only 10-40 subjects, is required by the FDA for any new generic drug
 - ❖ No trials for “generic” side effects or “generic” drug interactions are required by FDA
 - ❖ There are no follow on FDA requirements for side effects for any drug



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Summary

- ✓ Fact: Development of new and expensive treatments are saving lives
- ✓ Fact: The population for TKI's use is growing
- ✓ Fact: Access to CML drug protocols in the USA are cost prohibitive for the average patient
- ✓ Fact: High prices for these cancer treatments are effecting the medical support system