Today's chances of getting your biologic...
A Little Context

In North America:
- 1,000s die every year from drug errors
- 1,000s more are hospitalized

- Drug Budgets in the $Billions
- Seniors – growing segment of population
- Growing #s with Chronic Disease
- Specialty drugs and Biologics – disproportionate cost < 1% claims and +15% costs

Lest we forget

- Medication “Drugs”:
  - save millions of lives
  - give a quality of life for millions
  - reduce hospital stays
  - reduce Doctor visits

- Medication is a cornerstone of most treatment plans

- Drug Innovation is probably the most significant advancement in Health Care

- Thanks to the Innovative Pharmaceutical Industry

- Thanks to our Research Community
Challenge for Patients

- How do we get the average person (taxpayer), the employer, the regular patient, the informed patient, the Insurance company, the patient organization, the health professional, the health organization to actually take the time to understand the system and issues and then understand what it takes to make the system work in the interests of all.

The System for Canadian Patients:

- The whole environment in Canada of the Government and the Pharmaceutical industry in its dealing with new and old drugs is nothing but a “bramble patch of interlocking, often overlapping, often competing committees, boards, services, departments, ministries, and jurisdictions.

- Drug arrives in Canada but before the patient gets it...
The system...

- HC: Health Canada
- TPD: Therapeutics Products Directorate
- BGTD: Biologics & Genetics Therapies Directorate
- NOC: Notice of Compliance
- NOC/Cs: Notice of Compliance with Conditions
- MHPD: Marketed Health Products Directorate
- PMPRB: Patent Medicines Prices Review Board
- CADTH: Canadian Agency Drugs Technologies Health
- CDR: Common Drug Review
- CEDEC: Canadian Expert Drug Advisory Committee
- COMPUS: Canadian Optimal Med. Utilization Serv.
- NPDUIS: Nat. Prescription Drug Utilization Inf. Serv.
- DSEN: Drug Safety Effectiveness Relevant
- PAAB: Pharmaceutical Advertising Advisory Board
- QDSPR: Quarterly Drug Submission Performance Rept.

More of the system...

- 19 Formularies
- RBP: Reference Based Pricing
- MAC: Maximal Allowable Costs
- NPS: National Prescribing Service
- Bill C-91: Patent Protection Legislation
- DQUC: Drug Quality Utilization Committees
- BPCP: Best Practices Contribution Program
- KT, KE: Knowledge Translation/Exchange
- Ne-TN: National e Therapeutics Network
- CBIP: Cross Border Internet Pharmacy
- NPS: National Pharmaceutical System
- HTA: Health Technology Assessment
- ISMP: Institute for Safe Medication Practices
- PSUR: Periodic Safety Update Reports
And more of the system

- CADRMP: Can Adverse Drug Reaction Mon. Program
- HDAP: Human Drug Advisory Panel
- DPD: Drug Product Data Base
- TAS: Therapeutic Access Strategy
- EDRD: Expensive Drugs for Rare Disorders
- RRP: Rapid Review Process
- CED: Coverage with Evidence Development
- HTA: Health Technology Assessment
- ACIET: Advisory Council on Info & Emerging Tech
- EAP: Exceptional Access Program
- EDR: Emergency Drug Release
- NHPD: National Health Products Directorate
- PSI: Patient Safety Institute
- IWG: Premier’s Innovation Working Group
- PANCPA: Pan-Canadian Purchasing Alliance
- CED: Committee to Evaluate Drugs
- PLA: Product Listing Agreement

Explain Biologic Access to the average person - well anyone
Then there are the **Private Payers**

- **PMS** - Plan Members
- **PSs** - Plan Sponsors (Employers)
- **PAs** - Plan Advisors
- **PBM** - Pharmacy Benefit Managers
- **PHs** - Pharmacies
- **MOPs** - Mail Order Pharmacies
- **DPhs** - Designated Pharmacies
- **PA** - Prior Authorization
- **SA** - Special Authorization
- **CMs** - Case Managers
- **NCMs** - Nurse Case Managers
- **ICCs** - Insurer Call Centres
- **P** - Pooling
- **EP3** - Extended Healthcare Policy Protection
- **VBP** - Value Based Pricing
…and more

- URP  Utilization Review Policy
- NCSM  New cost sharing mechanism
- MTP  Multi tiered Plans
- PIC  Private Infusion Clinics
- PNVP  Pharmacy Network Value Plan
- COB  Coordination of Benefits
- RS  Reimbursement Specialists
- ST  Step Therapy
- SEBs  Subsequent Entry Biologics
- I  Interchangeability
- GS  Generic Substitution
- MGS  Mandatory Generic Substitution
- TS  Therapeutic Substitution
- CER  Comparative Effectiveness Research

So the patient is confronted with complex cost containment programmes while wholesalers do their markup, pharmacy does a markup + dispensing fees, plan advisors get commission, Insurance Co. get their admin fees, hire Case Mang. Generic/Pharma $millions on lawyers, Pharma CEOs $millions in bonuses, etc

- Insult to injury e.g. Pregabalin in 45 countries before Canada and company only goes for the pain indication
Patient example: Pain

- Insurance companies seem to deem it necessary to push pain patients to their limits of endurance
- Forty-five year old female, single mother of two
- Injury designation: catastrophic
- After two years on LTD she was cut off automatic payment for medications
- In constant excruciating neuropathic pain and unable to drive or work and is nearing the breaking point
- She is unable to take more traditional neuropathic medications - medications prescribed by her PHYSICIAN, are not covered

Patient example: Kidney

- Her kidneys ravaged by chronic disease
- For five years, the medicine had kept the Cambridge woman’s cancer under control
- Her husband’s work insurance was changed to another provider, with a cap
- They could not afford the monthly cost of the medication on his modest income
- Fear of losing his job if he went HR Dept.
- She had no choice but to stop taking the drug
- She suffered a drastic decline, then died. (59yrs)
- Her only choice would have been to sell the home and bankrupting her family, which she refused to do.
Patient example: Arthritis

- A young boy with severe systemic juvenile idiopathic arthritis, characterized by fevers, rash and arthritis and features of Macrophage Activation Syndrome (MAS).
- This boy has significant steroid toxicity (marked weight gain, severe striae and sleep disturbance) and there is no prospect of lowering his steroids without additional treatment.
- We would like to start anakinra (Kineret) in this situation as soon as possible.
- We really have no other therapeutic options that are effective and safe in this situation. (Internationally respected Paediatric Rheumatologist)
- Denied

Arthritis

- It is not a disease of the elderly
- Leading cause of disability in Canada
- 60% that stopped working: 18 – 54yrs
- 25% unable to access prescription meds.
- With proper access they can keep working
Major Studies

Multi-millions of dollars have been spent on Canadian medication issues:

National Forum on Health, Romanow Royal Commission, Drummond Report, Canadian Health Policy Institute, Professional Associations CMA, CPhA, etc.

- Their points to ponder...

From Major Studies

- Medications have fundamentally changed the face of health care in Canada.

- Prescription drugs are just as medically necessary as hospital or physician services.
...from major studies

- Prescription drugs are increasingly used as a substitution for other treatments and medical interventions, including surgery.

- Even small payments can prevent individuals from following prescribed treatment regimens, leading to worsened health and costly events elsewhere in the health care system.

Biologics

- Who wants to inject or infuse a biologic

- Decision: Specialist and Patient

- Patient carefully monitored

- Biologics Best Practice Research Initiative

- Adherence not an issue or concern
...from major studies

- Governments are spending huge sums of money on expensive bureaucratic infrastructure to control patented drug costs
- The importance of biologics to public health cannot be overstated
- People/Patients want to be productive

Personal comment:
Now it seems it’s all about:

Cost Containment & Sustainability

M3 System:

Money vs Morbidity and Mortality

- *Time: Medication under Canada Health Act???
...from major studies

- By working together - Government and Industry can:

  Ensure that all Canadians have equitable access to medically necessary prescription drugs regardless of where they live or their personal circumstances and ensure the quality and safety of new and existing drugs and contain cost
Patient Involvement

- Patient involvement in our health care system has never been more important

- The health care environment is changing, physician power and influence has been curtailed

- There is no one more affected by drug development and drug policies than the patient that takes the drug.

- Patients are gaining power and demanding unfiltered and reliable information.

- International Federation of Patient Organizations says it best:

  "NOTHING ABOUT US WITHOUT US"