Defend YOUR Health

*Say **NO** to "Agile Licensing" Amendments to Our Food & Drug Act*

KEY POINTS — **Watch this VIDEO at 5:43:00 for Industry Expert Analysis**

- **Canada historically held to the highest regulatory standards by ensuring all medical products were PROVEN SAFE and effective PRIOR to market authorization.** This required Randomized Controlled Trials (RCTs) to ensure that the benefits outweigh the risks.
- In 2018, th**e federal government adopted** Big Business **recommendations that compromise**, and even bypass, **established safety requirements** in Canada's drug regulatory system, **enabling Big Pharma to push** under-tested, potentially high-risk **products that have NOT BEEN PROVEN SAFE** on unsuspecting Canadians.
- **This industry-devised backdoor** -- the 2019 "Advanced Therapeutic Products (**ATP**) Pathway" -- **permits the use of lower standards like** after-market **Observational Data:** which can never prove harm as correlation does not infer causation; or **Risk Management Plans:** which means intentionally risking harm to individuals in order to assess safety. If RCTs are not completed this would **even prevent injured Canadians from getting compensation** as it would be difficult to prove harm.
- Positioned as "advancing innovation" and "promoting life-saving therapies" or "agile licensing" this subjective, arbitrary, and more centralized process places an **inappropriate level of control** in the hands of a single person: the Health Minister.
- Further changes to our Food and Drugs Act are now being proposed that would **formalize and expand the types of products granted backdoor access** potentially resulting in more novel, under-tested, high-risk drugs and medical devices being given to healthy Canadians. These changes would also apply to the regulation of **veterinary products**, bypassing the in-depth studies needed to assess food safety.
- It is **ALARMING** that th**is backdoor policy would be promoted knowing** full well that **this could harm Canadians. Inviting Big Pharma to rewrite the very regulations that were supposed to protect Canadians from Big Pharma abuse, is like asking criminals to design your alarm system.**

URGENT ACTION REQUIRED BY APRIL 26 !

- **Say NO to any and all food and drug regulatory amendments that would permit the authorization of any product or device that have not first been PROVEN safe and effective through rigorously conducted randomized controlled trials**.
- **Insist on** an immediate **re-examination of the ATP and all proposed regulatory changes** to the Food and Drugs Act by qualified, independent health professionals and public representatives who are free from conflicts of interest, such as benefiting from direct or indirect Big Pharma funding.
- **Demand** that **Canadian safety be re-prioritized** by setting prudent, transparent, objective safety criteria for all products and devices that cannot be manipulated for political or economic gain.
- **Send a clear message** that the **"speed of science" should never outpace public safety.**

1. **Take 5 minutes to express the concerns above to Health Canada.**
   - **Submit a 'General Comment'** about "Agile Licensing" at the top of this Canada Gazette webpage by **April 26, 2023** - AND –
   - **Send that same comment to:**
     Bruno Rodrigue, Executive Director, Office of Legislative and Regulatory Modernization, Health Products and Food Branch, Department of Health, 3000A, 11 Holland Avenue, Suite P2108, Ottawa, Ontario K1A 0K9 (email: lrm.consultations-mlr@hc-sc.gc.ca)

2. **Contact your MP to express your concern about "Agile Licensing"!** Demand an immediate re-examination of all Agile Licensing regulations and proposed amendments and demand an investigation into the individuals involved in creating this industry-favoring backdoor that places Canadians at risk of product harm by rushing novel products to the market without first proving their safety and efficacy.
   - Find your Member of Parliament here: https://www.ourcommons.ca/members/en/search