Minister of Health Musts

Be a pillar of integrity

1. Respect centuries of law-making, jurisprudence, and harsh lessons learned in medical practice that underwrite the authorities of individuals, and their choices and accountabilities in our healthcare system.

2. Defend with confidence, and without 'interim' legal maneuvers, scientific risk taking while leading the world in innovation.

3. Understand how to identify and avoid creating gaps in scientific integrity within the bureaucracy.

4. Overcome public and departmental trepidations with changes to science-based programs by focussing on the measurable, relevant, and real-world benefits of federal interventions in health.

Address Canada's addiction crisis

5. Take a position on 'Involuntary/Compassionate 'Treatment/Intervention' for mental health and addiction.

6. Achieve progress against Canada's crisis by understanding and modifying the contribution of 'prevention', 'treatment' and 'supply' to addiction metrics.

Restore a national trust in public health

7. Engage, and transparently harness, the national expertise of practicing health professionals when taking public health decisions.

8. Proactively design federal procedures and engagement, that limit federal oversight, leverage provinces, and exemplify delegation of power to Canada's healthcare system.

Regulate efficiency and effectively

9. Identify and end federal programs that are not a priority, based on their lack of real-world impact, or that are best performed by another entity (other governments, NGO, charity, academic, private).

10. Demand that all law making achieve measurable outputs against provincially/territorially validated health metrics and repeal those that do not.

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Diagnosing Health Canada

1. Cost of Living, Red-Tape, Commodity Consumption and Manufacturing

Baseline points:

- Health Canada spends the vast majority of its time making commodity regulations based on concerns with how commodities hurt Canadians.
- Health Canada spends little, to no amount of time, making regulations to enable new innovations in how commodities help us.
- A focus on harm impacts our ability as a country to make the things we use every day, the price of those things and how much we rely on manufacturers in other countries (that our government never inspects, and who often have less strict environmental/labour laws).
- Health Canada frequently excludes from risk management decisions, regarding commodities, retail environments, market share (denominator) data, cultural/social contexts, the US border and online sales, real-world public/patient risk tolerances, price, and considerations of identical substances that exist across commodities.
- The government of Canada is responsible <u>for criminal law powers</u> – not civil.

Health Canada's fixation on harm has culminated in policies, regulations, and actions born out of an abundance of caution. Too often, they identify risks using approaches that are heavily caveated, exclude data inappropriately, or that are otherwise compartmentalized. By doing so Health Canada creates analytical environments that prevent validation against the real world.

<u>First and foremost:</u> The federal government should never criminalize a failure to demonstrate 'an abundance of caution'. For example: imagine converting a civil litigation over a 'hot coffee' spill into criminal law. It could require mandating that every personal container/vessel capable of holding a 'hot liquid' carry a possible burn warning. It would be a crime for any cup/thermos/etc to not carry this warning. Alternatively, companies may choose on their own, based on the outcomes of a civil matter whether they wish to adopt cautionary labelling.

A recent example in Canada includes the criminalization of liver warnings on the spice turmeric. This warning was not associated with any known risk in Canada (in medicine or in food). Canada is one of the worlds largest importers/consumers of turmeric (importing over 2 million kilograms a year). All food consumption was excluded from the analysis, but the risk, which was poorly understood and identified outside of Canada, could appear at any level of exposure. This led Health Canada to put warnings on all medicines containing turmeric, including those proven to help with liver function, but not on any foods that contain the same amount or more turmeric. It is now a crime in Canada if you fail to put a liver warning on turmeric in a pill, but not the same amount of turmeric in food. In the past, idiosyncrasies such as these would have led to greater analysis. Now they are poorly articulated crimes applied in confusing and uneven ways to Canada's commodities.

Canada will never lead in innovation nor be capable of growing our own manufacturing sectors over those of competitive nations if our principal benchmark for criminal behaviour is a failure to demonstrate 'an abundance of caution'. Laws and so called 'risk-based' decisions that are based on 'an abundance of caution' have:

- Weak issue identification and little to no calibration against other risks to health.
- The potential to create infinite demands on enforcement resources.
- The potential to incubate irrational risk tolerances, and a victim-culture in the general population.
- The ability to confound manufacturer/retail relations and inflate liability concerns.
- No clear measurable benefits to society.
- Clear negative impacts on economic, social, and health priority setting.

CIVIL law – can be based on abundance of caution. This is not the role of the federal government.

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In addition, and for many years, Canada has produced commodity regulation who's benefits to health have never been validated. In recent years, law making integrity has deteriorated further and a proliferation of supposed benefits to health may now include unvalidated claims of improving retail returns or other extremely presumed impacts.

Analysis supporting law and policy making have also become highly compartmentalized for example when making food law the following considerations are excluded: culture, taste, price, entertainment/events, supplements, restaurants/cafeterias, food made from scratch, and child-purchasing power when imagining the health impacts of food labelling/advertising laws.

Potentially the worst action ever taken by Health Canada occurred recently. Under the auspices of correcting its own marketplace errors surrounding nicotine-based therapies, Health Canada has introduced, without parliamentary debate, into the Food and Drugs Act, the capacity to act on Canadian commodity manufacturers without scientific justification:

> 30.01 (1) Subject to any regulations made under paragraph 30(1)(j.1) and if the Minister believes on reasonable grounds that the use of a therapeutic product, other than the intended use, may present a risk of injury to health, the Minister may, by order, establish rules in respect of the importation, sale, conditions of sale, advertising, manufacture, preparation, preservation, packaging, labelling, storage or testing of the therapeutic product for the purpose of preventing, managing or controlling the risk of injury to health.
> Uncertainty
> **(3) The Minister may make the order despite any uncertainty respecting the risk of injury to health that the use of the therapeutic product, other than the intended use, may present.**

We and our allies refer to our federal health departments as 'competent regulators'. No 'competent regulator' should ever award itself the ability act with impunity. **This is an extreme deterrent to investments in Canada's health product manufacturing sector.** This legislative change risks appearing as though **our federal health regulator no longer has confidence in its capacity to act in a competent and scientifically justifiable manner.** In other words, Canada has transcribed a widely known ineffective leadership behaviour of 'failing to explain decisions' directly into our health product laws.

- Canada can and must consider approaches to commodity regulation that end decades of unvalidated law making, and focus on greater engagement with the entire supply chain to re-discover purpose and solutions to the real-world issue management and innovation needs of Canada.

2. Risk Tolerances, Patients, and Criminal versus Civil Law: Who's Voice Matters When and Why

No voice is more important to the health product safety and efficacy decisions of the federal government than that of patients.

One of the best examples of the impact of patient input on the decisions of federal governments took place surrounding the authorization of the first AIDS/HIV therapies.

- Standard interpretation of clinical trial evidence led Health Canada (and regulators around the world) to conclude that the related antiviral therapies were ineffective. It was charitable patient groups and the surviving family members ('AIDS quilts' were part of the advocacy) that drove greater and appropriate risk tolerance into federal regulatory decision making.
- This is directly related to the cascade in evidence that has drastically reduced the mortality of AIDS/HIV. At the time it substantively changed the way governments looked at evidence in general. An important lesson now lost.

Today there are different ways the federal government may engage patients.

It can be direct, through Statistics Canada, or leveraging existing provincial/territorial and academic links. Or;

It can be representatives of patients of which there are two main distinct legal entities: Charities and Not-for-Profit Corporations. Presently, Health Canada almost never engages the charitable patient groups that matter most to its mandate and the dispensation of its authorities under the Food and Drugs Act. This is notwithstanding the fact that these same charities work with other departments under the Minister of Health to jointly fund health research relevant to Health Canada.

Health Canada, however, does greatly value, and has entangled its operations with not-for-profit patient safety corporations. **This has resulted in a mingling of federal criminal law powers with policies and tax payer funding models in support of individual civil liability**.

Knowing the differences between patient groups is a fundamental competency of any respected regulator that seeks to support their national healthcare system and the related domestic industries. This includes understanding the respective approaches of corporate versus charitable patient groups to what could be considered tenants of ethical and high integrity operations becoming that of a reputable public service partner.

	Patient **Charities**	Not-For-Profit Patient Safety **Corporations**
Examples	Heart and Stroke Foundation Diabetes Canada Liver Canada Cancer Society (many others)	Institute for Safe Medicine Practices Patients for Patient Safety
Legal entity	Registered Charities under the Income Tax Act and subject to related Canada Revenue Agency (CRA) guidance: Promotion of health and charitable registration (CG-021).	Not-for-Profit Organization under the Canada Not for Profit Corporations Act (same as industry/trade associations)
Relationship to the Food and Drugs Act	EXTENSIVE – Fund research that directly supports safety and efficacy decisions of the federal government. Represent the patients who participate in clinical trials and who take the products and experience the diseases and conditions that are the subject of Health Canada's work. Represent those patients directly accountable patient risk tolerances of pre-market product authorizations and post-market pharmacovigilance.	EXTEMELY LIMITED – Relevant only to post market product surveillance (such as Adverse Event Reporting) and only when those reports relate to errors/healthcare system harms for which a population-based decision (following pharmacovigilance/human factor analysis) results in a defensible regulatory intervention.
Budgets and financial transparency	Required to, and **do disclose** their financial reports. CRA limits on overhead. Funding is voluntary, mostly through fund raising events/exercises and subject to charitable tax law.	Not required to, and **do not, disclose** their financial reports. Eligible to receive funding from class action civil lawsuits (cy près doctrine) and maintain a purpose related to patient harms caused by the heath care system/product errors that is appropriate for class action lawsuit funding.

Focus on individual (civil law) versus population based (criminal law) health decisions.	Focused on population/disease condition health -safety/efficacy (criminal law).	Focused on individual harm (civil law).
Expertise and Representatives	Consider it unethical to exploit patient experiences. Only ever represent the actual patient group with which they have direct experience/expertise.	Provide patient testimony in Parliamentary committees and government consultations on topics that can often be unrelated to the direct experiences or expertise of the representatives they provide.
Research	Directly fund alone, or in collaboration with, the federal government, academic/scientific research that is relevant to access to medicine decisions of the federal government.	Provide resources for patient safety harm reduction, unclear if any academic/scientific research is funded through their actions.
Ethics	Along with Canada's health professional associations, and health industry associations, health charities are members of the Canadian Consensus Framework for Ethical Collaboration.	Not a member of the Canadian Consensus Framework for Ethical Collaboration.

In order to respect the mandate and authorities of Health Canada, it could be said that tax payer dollars and public servant time should never inflate the budgets or, the influence of, organizations whose primary mandate is individual harm (civil). Health Canada's decision to weave patient corporations, often in lieu of patient charities, into their operations has resulted in a manifestation of overbearing attitudes that pervert federal risk/science-based decisions.

Health Canada has an entrenched a fear of perceived liability associated with allowing people to take care of themselves. That is, Health Canada acts as if they enable Canadians to care for themselves more then it will only inflate, in an unbalanced way, the number of people entering the healthcare system due to human errors over humans who avoid entering the healthcare system due to their health independence. This has placed purposeful limits on innovation and research investments into patient directed care that are ignorant of current product and diagnostic advances, online/virtual/remote care, and evolutions in healthcare practice. This very likely represents an unnecessary and overbearing federal burden on wait times and healthcare professional practice.

There is no liability for Health Canada take actions based on evidence that include human health risks but ultimately support and benefit our healthcare system on a population basis.

- Canada must adopt appropriate engagement of patients and health professionals who care about the benefits of medicine and the importance of understanding informed choice regarding risks.
- The federal government must extricate itself from the world of civil liability and begin again to functionally respect the importance, and incredible benefit of, having Canadians who know how to discover, make and distribute medicine.

There are more Health Canada diagnoses on the way. Coming soon and available for discussion…

3. **Addiction, alcohol, nicotine, cannabis, controlled drugs, and federal approaches to harm reduction.**
4. **Federal government, other governments, academic Institutions, health professionals, and the private sector: Who is Best Positioned to Do What and Why?**

The Future – Political Pitch and Resetting Policy

‘Canada Makes Medicine’

The Opportunity to Lead the World in Health: While Supporting our Economy, Security and Democracy.

- Establishing a vision for Canada as North American raw material producer of medicines, neutralizing reliance on other nations, and offsetting tariff-based pressures on agricultural outputs, demonstrating complete supply chain control over and expertise surrounding all aspects of medicine.

- Functional engagement with the provinces and territories on health indicators and their links to federal activities.

- Creating product innovation incentives where they do not already exist.

- Leveraging health priorities to support our resiliency, national security and that of our allies.

We have what it takes to restore Canada’s place on the mantle of health, and make the world take notice!

Canada’s strength in health is not currently based on interventions from the federal government.

Our strength is in the people currently practicing in healthcare, working in academia, growing and mining raw materials, rallying patients, and making, innovating and distributing products. Canadians are responsible for many life-saving contributions to the world of medicine: the discovery of insulin, the first cardiac pacemaker, an Ebola vaccine, the Montreal procedure for epilepsy, the invention of child-resistant medicine bottles, identification of the gene causing cystic-fibrosis, discovery of transplantable stem cells, and so much more.

Canada captures 4% of global clinical trials, ranking 3rd globally for the total number of new trials and 4th for active trials in 2023. Canada is the G7 leader in clinical trial productivity (defined as the number of trials relative to the population). However, we appear to act as an R&D execution hub but far less so as an R&D investment and discovery center.

By changing the federal focus from overbearing regulating, and health system harms towards product innovation, appropriate risk taking, and health system engagement, we can connect fields and explore growing our national raw material, and manufacturing expertise.

We have what it takes to lead the world in all thing’s health.

Contact True Moderation Inc. to discuss on-going development of federal health policy pitches, management, and operational change.

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