IMMUNIZATION GOVERNANCE CHALLENGES EXPOSED BY COVID-19: MISSING STANDARDS IN VACCINE SURVEILLANCE AND ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFIS)

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TABLE OF CONTENTS

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I. INTRODUCTION

Prior to the health calamity that is the COVID-19 pandemic, many countries, including Canada and the United States, were experiencing lower-than-optimal uptake of immunization.[1] This is despite the fact that immunization is recognized as one of the most effective means of controlling certain diseases and conditions, and as contributing to a range of other concomitant social, health, and economic benefits.[2] Immunization rates can be undermined by a variety of personal circumstances (e.g., ignorance and lack of access to good information, poverty, geography, employments conditions, etc.), external influences (e.g., misinformation, disinformation, vaccine-negative social networks), and structural barriers (e.g., dispersal of healthcare facilities, vaccine stock-outs, ineffective public health infrastructure, technical capacity, or practices and logistics). Immunization rates can be further eroded by unanticipated or unprepared-for disruptive events such as the outbreak of an infectious disease for which there is no vaccine (e.g., COVID-19).[3] Indeed, such events can disrupt immunization strategies and activities in a variety of ways that linger well after the emergency itself has been managed. This makes anticipating, planning for, assessing, and then learning from such events critically important.

As of February 1, 2021, COVID-19 has resulted in some 102,399,513 recorded or confirmed cases of COVID-19 worldwide, with 2,217,005 deaths,[4] to

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[1] Ranee Seither et al., *Vaccination Coverage Among Children in Kindergarten: United States, 2015-16 School Year*, 65 MORBIDITY & MORTALITY WKLY REP. 1057–64 (2016); Sarah Reagan-Steiner et al., *National, Regional, State, and Selected Local Area Vaccination Coverage Among Adolescents Aged 13-17 Years: United States, 2015*, 65 MORBIDITY & MORTALITY WKLY REP. 850-58 (2016); *Flu Vaccination Coverage, United States, 2014-15 Influenza Season*, CTRS. FOR DISEASE CONTROL & PREVENTION (2016), http://www.cdc.gov/flu/fluvaxview/coverage-1415estimates.htm; Joan Robinson, *Potential Strategies to Improve Childhood Immunization Rates in Canada*, 23 PAEDIATRICS & CHILD HEALTH 353–56 (2018).

[2] *See* Vanessa Rémy et at., *Vaccination: The Cornerstone of an Efficient Healthcare System*, 3 J. MKT. ACCESS & HEALTH POL'Y 1 (2015); Vanessa Rémy et al., *The Economic Value of Vaccination: Why Prevention is Wealth*, 3 J. MKT. ACCESS & HEALTH POL'Y 1 (2015); Mark Doherty et al., *Vaccine Impact: Benefits for Human Health*, 34 VACCINE 6707–14 (2016); Jason Schwartz & Adel Mahmoud, *When Not All That Counts Can be Counted: Economic Evaluations and the Value of Vaccination*, 35 HEALTH AFFS. 208–11 (2016).

[3] Amina Zafar, *Putting Off Kids' Vaccines During COVID-19 Heightens Risk of Other Outbreaks*, CBC NEWS (Apr. 24, 2020), https://www.cbc.ca/news/health/covid-19-child-immunizations-1.5543286.

[4] *WHO Coronavirus Disease (COVID-19) Dashboard*, WORLD HEALTH ORG. [WHO] (2021), https://covid19.who.int/.

which Canada contributed 778,972 cases and 20,032 deaths,[5] and the World Health Organization (WHO) has emphasized the human and social costs behind these numbers.[6] The global mortality rate for COVID-19 has placed intense pressure on governments to fast-track vaccine development and approval,[7] the accepted wisdom being that COVID-19 will only be controlled once safe and effective vaccines become widely available.[8] Developing, testing, delivering and administering, and monitoring these vaccines, however, presents a range of challenges for which public health frameworks are not consistently well-equipped. Difficulties arise because:

- different types of COVID-19 vaccines have been developed for use (i.e., killed, live attenuated, non-replicating adenovirus vector, protein subunit, replicating virus vector, mRNA and DNA);[9]
- the vaccines have different mechanisms of action, and safety and efficacy profiles;[10]
- supplies will be unevenly available;[11] and
- effective and equitable deployment of such large stocks create logistical and technical challenges (e.g., geography, cold-chain management).[12]

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[5] *Coronavirus Disease 2019 (COVID-19): Epidemiology Update*, GOV'T CANADA (Feb. 1, 2021), https://health-infobase.canada.ca/covid-19/epidemiological-summary-covid-19-cases.html?stat=num&measure=deaths&map=pt#a2.

[6] *Coronavirus Disease (COVID-19): Situation Report 204*, WORLD HEALTH ORG. [WHO] 1, 2 (2020), https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200811-covid-19-sitrep-204.pdf?sfvrsn=1f4383dd_2.

[7] Barney S. Graham, *Rapid COVID-19 Vaccine Development*, 368 SCIENCE 945 (2020).

[8] Marius Gilbert et al., *Preparedness and Vulnerability of African Countries Against Importations of COVID-19: A Modelling Study*, 395 LANCET 871 (2020).

[9] As of this writing, nine vaccines have been authorized for use. Jeff Craven, *COVID-19 Vaccine Tracker*, REGULATORY FOCUS (Mar. 11, 2021), https://www.raps.org/news-and-articles/news-articles/2020/3/covid-19-vaccine-tracker. The Pfizer-BioNtech Comirnaty BNT162b2 vaccine and the Moderna COVID-19 mRNA-1273 vaccine are approved in Canada. *Coronavirus Disease (COVID-19) Vaccines: Overview*, GOV'T CANADA (Mar. 5, 2021), https://www.canada.ca/en/public-health/services/diseases/coronavirus-disease-covid-19/vaccines.html.

[10] Jennifer A. Juno et al., *Humoral and Circulating Follicular Helper T Cell Responses in Recovered Patients with COVID-19*, NATURE MED. ONLINE (2020).

[11] Katie Dangerfield, *Canada's 'Slow' Rollout of Coronavirus Vaccine 'Embarrassing': Experts*, GLOBAL NEWS (Jan. 4, 2021), https://globalnews.ca/news/7553419/coronavirus-vaccine-canada-distribution-slow/; Rebecca Robbins, Frances Robles & Tim Arango, *Here's Why Distribution of the Vaccine Is Taking Longer Than Expected*, N.Y. TIMES (Jan. 11, 2021), https://www.nytimes.com/2020/12/31/health/vaccine-distribution-delays.html.

[12] Melinda C. Mills & David Salisbury, *The Challenges of Distributing COVID-19 Vaccinations*, LANCET (Dec. 8, 2020).

These difficulties can give rise to equity and prioritization issues, delays, failures, etc., which could, in turn, undermine confidence in the vaccines and the systems through which they are administered, and in public health institutions and actors generally. This would compound the uncertainty, caution, and even recalcitrance that has already been instigated by the highly compressed development and authorization processes of the COVID-19 vaccines;[13] while the traditional timeline for new vaccine development is fifteen to twenty years, COVID-19 vaccines have been developed and rolled out within a startling twelve to eighteen months.[14]

Given the above, the manner in which COVID-19 vaccines are authorized for use, and how well we can assess how they are performing will influence how both these vaccines and other (routine) vaccines are received by the public moving forward, our practices and processes can either encourage or undermine COVID-19 vaccine acceptance, and vaccine acceptance more generally in the longer term.[15] At *The Future of Global Healthcare Governance* conference, we were invited to consider how—in pursuit of the 'collective good' that is necessary in response to the pandemic—governments and law might positively influence vaccine confidence and acceptance.[16] In this paper, we examine how law is serving as a possible barrier to COVID-19 and post-COVID-19 immunization goals, with an emphasis on the Canadian situation, which is generally comparable to other high-income countries with similar regulatory systems.[17]

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[13] Angela Jung, *New Survey Finds More Canadians are Hesitant About Getting a Vaccine Against COVID-19, British Columbia*, CTV NEWS (Oct. 2, 2020), https://bc.ctvnews.ca/new-survey-finds-more-canadians-are-hesitant-about-getting-a-vaccine-against-covid-19-1.5131271; Tara Azimi et al., *COVID-19 Vaccines Meet 100 Million Uncertain Americans*, MCKINSEY & CO. (Dec. 18, 2020), https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/covid-19-vaccines-meet-100-million-uncertain-americans#; *Doubts About Vaccines in General and the Speed of Making the COVID-19 Vaccines Have Some Taking a Cautious View*, NORTON HEALTHCARE (Dec. 22, 2020), https://norton-healthcare.com/news/reaching-those-skeptical-about-covid-19-vaccines/. *See also COVID-19 Vaccine Deployment: Behaviour, Ethics, Misinformation and Policy Strategies*, ROYAL SOC'Y (Oct. 21, 2020), https://royalsociety.org/-/media/policy/projects/set-c/set-c-vaccine-deployment.pdf?la=en-GB&hash=43073E5429C87FD2674201CA19280A8E.

[14] Nicole Lurie et al., *Developing Covid-19 Vaccines at Pandemic Speed*, 382 NEW ENG. J. MED. 1969 (2020); Penny Heaton, *The Covid-19 Development Multiverse*, 383 NEW ENG. J. MED. 1986 (2020).

[15] In this regard, we note that the aim of "immunizations throughout the life-course," demands much greater attention to program integration and rationalization, and to adult immunization, a matter which the eventual immunization against COVID-19 will foreground. *Immunization Agenda 2030: A Global Strategy to Leave No One Behind*, WORLD HEALTH ORG. [WHO] 25 (Apr. 1, 2020).

[16] University of Georgia School of Law Dean Rusk International Law Center and *Georgia Journal of International and Comparative Law* Conference: The Future of Global Health Governance (Jan. 25, 2021), http://www.law.uga.edu/gjiclspring2021.

[17] This paper is an outcome of the *Trust, Acceptance and Sufficiency: Law as a Barrier to, and Enabler of, Routine and Responsive Immunization, Including COVID-19* project,

Specifically, we examine elements of the Canadian vaccine development and safety ecosystem, contending that the subject elements are characterized by shortcomings that combine to undermine trust in the system and the vaccines it makes available.

We begin by briefly outlining the vaccine development and safety ecosystem in Canada, identifying its key stages and mechanisms. We then explore in more detail two elements of that ecosystem. First, we examine the market authorization stage, focusing on how it was used in response to COVID-19. We argue that the manner in which it has functioned, both generally and throughout the COVID-19 pandemic, exhibits a systemic operational weakness, being a lack of sufficient and appropriate transparency. Second, we explore the post-deployment or clinical surveillance stage, arguing that its mechanisms aimed at identifying and reporting 'adverse events following immunization' (AEFIs) are characterized by an improper absence of standards, signifying design shortcomings. These shortcomings have been accentuated by the COVID-19 pandemic, and could, in turn, undermine actions taken in response to the COVID-19 pandemic.

As a preliminary matter, we note that we accept the WHO definition of an AEFI as "any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine."[18] Common non-serious AEFIs include redness and swelling at the injection site or mild fever.[19] These will often be detected in the clinical trials, and they do not preclude vaccine approval so long as they are not excessively experienced. As such, they are not the sort of AEFIs that health authorities are interested in capturing; they are merely a mild and expected consequence of taking a compound designed to stimulate the immune system, and they should be addressed as a routine part of the usual consent and administering process. It is the serious AEFIs that the surveillance system is interested in capturing, for these have important consequences for the safety and efficacy profile of the vaccine, which in turn have potential implications for recommendations about routine use issued by national immunization advisory authorities, as well as the acceptance of the vaccine by the public.

We close by offering some recommendations on what governments can do to ensure that these stages of the vaccine development and safety ecosystem are more effectively working in pursuit of the collective good.

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[18] REPORT OF CIOMS/WHO WORKING GROUP ON VACCINE PHARMACOVIGILANCE, DEFINITION AND APPLICATION OF TERMS FOR VACCINE PHARMACOVIGILANCE 39 (2012).

[19] *Id.*

II. THE CANADIAN VACCINE DEVELOPMENT AND SAFETY ECOSYSTEM

In this section, we briefly describe the major components of what we consider to be the Canadian 'vaccine development and safety ecosystem.' This is the collection of post-innovation regulatory architectures and practices that is comprised of the pre-clinical stage, the market authorization stage, the routine use assessment stage, and the clinical surveillance stage of vaccine development, assessment, deployment, and reassessment.

Once a vaccine compound has been theorized and prepared, its further development and testing begins in the pre-clinical stage, where vaccines, like other therapeutic products, are expected to undergo laboratory-based safety and efficacy evaluations in animals and in humans. Phase I trials in humans involve 20-100 volunteers and focus on detecting serious side effects. Phase II trials generally involve hundreds of volunteers, and they are meant to determine the best dose and number of doses for effectiveness and safety. Phase III trials involve several thousand volunteers and undertake comparisons with placebos or already-licensed vaccines.[20] It is the responsibility of the vaccine sponsor/manufacturer to ethically generate at least threshold data that demonstrates that the proposed vaccine is safe and effective, after which it applies for a license from Health Canada's Biological and Radiopharmaceutical Drugs Directorate (BRDD).[21]

The pre-clinical stage is followed by the licensing stage, which gatekeeps market access. In keeping with other major frameworks in high-income countries and intergovernmental organizations (e.g., the European Union, Japan, the United Kingdom, the United States), Health Canada is responsible, under the *Food and Drugs Act* (FDA),[22] and the related *Food and Drug Regulations* (FDR),[23] for assessing therapeutic products. The law grants the Minister and his or her designees extensive powers, including those of inspection, the ordering of production, the seizure of material, and, ultimately, the issuing of licenses to import, manufacture, and sell therapeutic products in Canada.[24] It also requires

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[20] *Glossary of Common Terms*, NAT'L INSTS. HEALTH (NIH), https://www.nih.gov/health-information/nih-clinical-research-trials-you/glossary-common-terms (accessed June 14, 2021).

[21] *Biologic and Radiopharmaceutical Drugs Directorate*, GOV'T CANADA, https://www.canada.ca/en/health-canada/corporate/about-health-canada/branches-agencies/health-products-food-branch/biologics-genetic-therapies-directorate.html#wb-cont (last updated Oct. 20, 2020).

[22] R.S.C. 1985, c F-27, s. 21 (Can.).

[23] Food & Drug Regulations, C.R.C., c 870 (Can.).

[24] Food & Drug Act, R.S.C. 1985, c F-27, ss 22–30 (Can.).

sponsors or manufacturers to provide scientific evidence of the product's quality, safety, and efficacy.[25]

With respect to new drug submissions (NDS) for Schedule D drugs (biologic drugs for humans), the Centre for Biologics Evaluation (CBE), part of the BRDD, evaluates the research protocol, the conduct of the clinical trials and their data, the manufacturing protocols, and the purity and potency testing that has been undertaken.[26] In doing so, it tests and analyzes the products and conducts a risk-benefit analysis, taking into consideration internationally agreed-upon standards for good laboratory practices, good manufacturing practices, good clinical practices, etc.[27] It is also empowered to conduct on-site evaluations (OSE), which are product-specific assessments of the quality (chemistry and manufacturing) component of a drug submission to confirm the ability of the manufacturer to consistently produce a safe biologic drug.[28] If the evidence supports the submitter's quality, safety, and efficacy claims, and the benefits of the product outweigh the risks, Health Canada will issue a Notice of Compliance (NOC) and a Drug Identification Number (DIN), and the product can be sold in Canada through the Lot Release Program.[29]

Post-approval, the National Advisory Committee on Immunization (NACI) determines whether the product will be recommended for routine use in Canada.[30] This is a formal review conducted by independent experts in infectious

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[25] Food & Drug Regulations, C.R.C. c 870 (Can.), Div. 8. Division 5 deals with the import or sale of drugs for purposes of conducting clinical trials, addressing such issues as serious unexpected adverse reactions and the suspension or cancellation of trials. Food & Drug Regulations, C.R.C. c 870 (Can.), Div. 5.

[26] *Biologic and Radiopharmaceutical Drugs Directorate*, GOV'T CANADA (Oct. 20, 2020), https://www.canada.ca/en/health-canada/corporate/about-health-canada/branches-agencies/health-products-food-branch/biologic-radiopharmaceutical-drugs-directorate.html.

[27] *Guidance Document Non-Clinical Laboratory Study Data Supporting Drug Product Applications and Submissions: Adherence to Good Laboratory Practice*, HEALTH CAN. (Apr. 30, 2010), https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/non-clinical-laboratory-study-data-supporting-drug-product-applications-submissions-adherence-good-laboratory-practice.html. For more on these, see INTERNATIONAL CONFERENCE ON HARMONISATION, http://www.ich.org/home.html (last visited June 9, 2021).

[28] *See Biologic and Radiopharmaceutical Drugs Directorate*, GOV'T CANADA, https://www.canada.ca/en/health-canada/corporate/about-health-canada/branches-agencies/health-products-food-branch/biologics-genetic-therapies-directorate.html#wb-cont (last updated Oct. 20, 2020); *Regulatory Roadmap for Biologic (Schedule D) Drugs in Canada*, GOV'T CANADA, https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/regulatory-roadmap-for-biologic-drugs.html#wb-cont (last updated Feb. 19, 2021).

[29] GOV'T CANADA, *supra* note 26.

[30] *National Advisory Committee on Immunization (NACI): Membership and Representation*, GOV'T CANADA (Mar. 17, 2021), https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/naci-membership-representation.html.

diseases, public health, vaccine safety, epidemiology, paediatrics, nursing, and internal medicine. NACI reviews the safety and efficacy data on both new and existing vaccines on an ongoing basis. As new efficacy and safety data are reported post-licensure, recommendations are updated. NACI members are precluded from making recommendations for any vaccine if they have a conflict of interest.[31]

The last element of the vaccine development and safety ecosystem is clinical surveillance, or 'pharmacovigilance.' This is about the detection, assessment, understanding, prevention, and communication of AEFIs and 'vaccine failures,'[32] or any other vaccine- or immunization-related issues. Pre-clinical trials are not usually large enough to detect rare (>0.01% and < 0.1%) and very rare (< 0.01%) AEFIs, nor those where onset is much delayed.[33] These are only detected when very large numbers of people have been immunized (i.e., after the vaccine has been approved for use and deployed widely). Under the *Food and Drug Regulations*, responsibilities are imposed on vaccine manufacturers (or market authorization holders) regarding post-market safety monitoring, reporting, and, in some cases, specific safety studies,[34] and they are expected to submit safety update reports that contain all global data related to the use of their product.

In the following sections, we argue that the Canadian vaccine development and safety ecosystem, like similar systems in other jurisdictions, is either operating or is designed, depending on the issue, sub-optimally. While a number of elements could be examined to demonstrate this claim, we focus on insufficient transparency in the market authorization stage (being an operational shortcoming), and insufficiently clear and harmonized standards in the clinical surveillance stage (being a design shortcoming). Combined, these shortcomings serve

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[31] Shalini Desai et al., *Canada's National Advisory Committee on Immunization: Celebrating 50 Years*, CAN. J. INFECTIOUS DISEASES & MED. MICROBIOLOGY 126 (May–June 2015).

[32] A vaccine failure is confirmed when the target disease is detected in individuals vaccinated for that disease. A vaccine failure would typically constitute an AEFI. With respect to COVID-19, identifying vaccine failures requires a systematized way of tracking that a person who is testing positive for COVID-19 has previously been vaccinated against COVID-19. Making such a determination is difficult if there exists no central data system that healthcare workers can access to identify a patient's immuno-status, as is the case in Canada.

[33] CIOMS/WHO WORKING GROUP ON VACCINE PHARMACOVIGILANCE, *supra* note 18.

[34] *Vaccine Safety Basics Learning Manual,* WORLD HEALTH ORG. [WHO] 28 (2013), https://www.who.int/vaccine_safety/initiative/tech_support/Vaccine-safety-E-course-manual.pdf ("[V]accines may undergo clinical trials after licensure to assess the effects of changes in vaccine formulation, vaccine strain, age at vaccination, number and timing of vaccine doses, simultaneous administration and interchangeability of vaccines from different manufacturers on vaccine safety and immunogenicity . . . ."); *see also id.* (further explaining that "to improve detection of AEFIs that are not detected during pre-licensure trials, some vaccines have undergone formal Phase IV Surveillance Studies with cohorts as large as 100,000 and durations of 4–6 years.").

to undermine trust in the system, its actors, and its outcomes, and thereby contribute to vaccine hesitancy,[35] and to COVID-19 vaccine hesitancy in particular.

III. THE MARKET AUTHORIZATION STAGE: INSUFFICIENT TRANSPARENCY AND PERCEPTIONS OF SAFETY

To begin, transparency has not been a hallmark of therapeutic product market approval processes in Canada. Prior to the modernization of the therapeutic products regulatory system through the adoption of the *Protecting Canadians from Unsafe Drugs Act* (Vanessa's Law),[36] Health Canada had been subject to repeated and scathing criticisms in relation to its information use and disclosure, its perceived culture of secrecy, and its regulatory capture by the pharmaceutical industry.[37] Vanessa's Law had the dual objectives of providing a modern platform upon which to support an emergent biotechnology sector and improving confidence in the oversight of therapeutic products by strengthening safety oversight, improving reporting of serious adverse drug reactions by certain health

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[35] Martin Letendre, *The Montreal Tuberculosis Outbreak Revisited*, VERITAS IRB (Apr. 11, 2016), https://researchethicssimplified.com/the-montreal-tuberculosis-outbreak-revisited/; Emilie Karafillakis et al., *HPV Vaccination in a Context of Public Mistrust and Uncertainty: A Systematic Literature Review of Determinants of HPV Vaccine Hesitancy in Europe*, 15 HUM. VACCINES & IMMUNOTHERAPEUTICS 1615 (2019).

[36] S.C. 2014, c 24 (Can.) (amending the FDA and FDR).

[37] Matthew Herder, *Unlocking Health Canada's Cache of Trade Secrets: Mandatory Disclosure of Clinical Trial Results*, 184 CANADIAN MED. ASS'N J. 194 (2012); Andrew Prayle et al., *Compliance with Mandatory Reporting of Clinical Trial Results on ClinicalTrials.gov: Cross-sectional Study*, 344 BMJ d7373 (2012); Joel Lexchin, *Health Canada and the Pharmaceutical Industry: A Preliminary Analysis of the Historical Relationship*, 9 HEALTHCARE POL'Y 22 (2013); Matthew Herder, *A New Bill Will Make Health Canada's Drug Approvals More Transparent. In Theory, Anyway*, NAT'L POST (Nov. 5, 2014), https://nationalpost.com/opinion/matthew-herder-a-new-bill-will-make-health-canadas-drug-approvals-more-transparent-in-theory-anyway; Matthew Herder, *Denaturalizing Transparency in Drug Regulation*, 8 MCGILL J. L. & HEALTH S57 (2015); Joel Lexchin, *Private Profits vs. Public Policy: The Pharmaceutical Industry and the Canadian State*, U. TORONTO PRESS (2016). With respect to the opacity around decisions relating to COVID-19 vaccines, see Cormac MacSweeney, *Trudeau Government Silent on Drug Manufacturer Liability for COVID-19 Vaccines*, CITYNEWS (Dec. 8, 2020), https://www.citynews1130.com/2020/12/08/trudeau-government-liability-covid-19-vaccines/. *See also* Sandra J. Bean, *Emerging and Continuing Trends in Vaccine Opposition Website Content*, 29 VACCINE 1874 (2011); David Broniatowski et al., *Weaponized Health Communication: Twitter Bots and Russian Trolls Amplify the Vaccine Debate*, 108 AM. J. PUB. HEALTH 1378 (2018); John D. Lee, *The Utter Familiarity of Even the Strangest Vaccine Conspiracy Theories,* ATLANTIC (Jan. 11, 2021), https://www.theatlantic.com/ideas/archive/2021/01/familiarity-strangest-vaccine-conspiracy-theories/617572/.

care institutions, and increasing transparency.[38] It enabled Health Canada, for the first time, to:

- compel further testing on products, including when issues arise with at-risk populations;
- require label and package changes when serious risks are identified;
- recall unsafe products; and
- impose tougher penalties for unsafe products.

However, by 2017, Health Canada had not yet exercised its new authority despite cases where it might have justifiably done so,[39] and it was not until December 2019 that it had adopted regulations, through which much of the amendments work.[40]

The pre-existing frustration over Health Canada's lack of transparency has been compounded by the pandemic, during which therapeutic products (including vaccines) have entered the pre-clinical and market authorization stages, and in some cases clinical use, with little reliable information furnished to the public,[41] or indeed little reliable information at all.[42] With respect to COVID-19 related clinical trials, the following has been observed:

> [T]rials are being rapidly authorized and misinformation about merits of various experimental interventions is prevalent. Delaying disclosure of clinical trial designs, correspondence between regulators and sponsors about those designs, and the basis for crucial decisions to be made by [data safety monitoring boards] about whether to halt or modify a trial at the point of interim analysis until after the decision to authorize or approve the

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[38] Katherine Fierlbeck, *Reforming the Regulation of Therapeutic Products in Canada: The Protecting of Canadians from Unsafe Drugs Act (Vanessa's Law)*, 4 HEALTH REFORM OBSERVER, ART. 5 (2016).

[39] Adrienne Schnier, *The Protecting Canadians from Unsafe Drugs Act: What is Happening with Vanessa's Law?*, 90 OBITER DICTA 9 (2017).

[40] *Id.*

[41] For example, while Health Canada discloses a fairly significant amount of information through its Clinical Information Portal, launched in March 2019, much of the safety and efficacy data is disclosed post-approval, and that data is comprised primarily of the Clinical Study Reports, not the agency review itself (other than a high-level summary of decisions taken). Sterling Edmonds et al., *Transparency Too Little, Too Late? Why and How Health Canada Should Make Clinical Data and Regulatory Decision-Making Open to Scrutiny in the Face of COVID-19*, 19 J. L. & BIOSCIENCES 7 (2020), https://academic.oup.com/jlb/article/7/1/lsaa083/5991911.

[42] *Id.* Health Canada authorized remdesivir, a COVID-19-targeting drug, on the basis of study protocols and preliminary or topline results; the CSRs that normally accompany an NDS were not provided.

> intervention pre-empts the correction of potential flaws in trial designs and limits the opportunity to build public understanding of the knowledge and uncertainties behind a given COVID-19 intervention.[43]

Lack of transparency around the relationship that exists between regulators and regulatees, the evidence that is generated during vaccine development and testing, and the evidence relied on to grant market access is a particularly pernicious problem in the vaccine setting because vaccine acceptance is persistently hampered by concerns around insufficient evidence, secrecy, and government-pharma 'coziness' and conspiracies.[44]

In the market authorization stage, Health Canada bases its level or intensity of regulatory oversight—testing or protocol review and compliance monitoring—on the degree of risk felt to be associated with the product.[45] Neither the reasons for this variability of scrutiny, nor indications as to when it is in play and what standard is being applied, are well communicated to the public, nor are the other market access flexibilities.[46] The most opaque flexibility—discretionary use of

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[43] *Id.*

[44] A search in CanLII using the terms "vaccine" and "vaccination" and "conspiracy" turns up fifty-seven court cases. A common scenario is that estranged parents are in conflict over the immunization of the children of the marriage, and the vaccine-refusing parent introduces into evidence opinions about government-pharma conspiracies. *See, e.g.*, *A.P. v. L.K.*, [2021] ONSC 150 (2021).

[45] *Regulatory Roadmap for Biologic (Schedule D) Drugs in Canada*, GOV'T CANADA (July 2020), https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/regulatory-roadmap-for-biologic-drugs.html#wb-cont; *Compliance and Enforcement Policy for Health Products (POL-0001)*, HEALTH CANADA (Dec. 2018), https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/policies-standards/compliance-enforcement-health-products.html.

[46] Presently, the Canadian regulatory framework contains two regular accelerated pathways for drug approval and access. The first is the Extraordinary Use New Drugs (EUND), which allows the authorization of drugs based on non-clinical information and limited clinical information, and which is available in circumstances where sponsors cannot reasonably provide substantial evidence to demonstrate the safety and efficacy of a new drug in humans due to logistical or ethical challenges in conducting the appropriate human clinical trials. While extensive data from clinical trials is absent, there are requirements for rigorous post-marketing surveillance. The second is the Special Access Program (SAP), which is open to seriously-ill patients for whom conventional therapies have failed, are unsuitable, or are unavailable. Supported by ss C.08.010 and C.08.011 of the *Food and Drug Regulations*, it is triggered by a healthcare professional request, and it authorizes a manufacturer to sell a drug that cannot otherwise be sold or distributed in Canada. The antiviral remdesivir was accessed under the SAP up to July 27, 2020, after which it was approved by Health Canada, subject to conditions that the company provide data from the trials conducted to date as well as periodic safety reports. *Remdesivir Authorized with Conditions for the Treatment of Patients in Canada with Severe COVID-19 Symptoms*, HEALTH CANADA (July 28, 2020),

Interim Orders—was adopted in relation to the approval process for the COVID-19 vaccines. The Minister exercised the discretion to make Interim Orders containing any provision that may be contained in a regulation made under the Act if the Minister believes that immediate action is required to deal with a significant risk, direct or indirect, to health, safety, or the environment.[47]

On May 23, 2020, the Minister issued an *Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19 (2020)*,[48] which reduced administrative requirements when assessing the use of existing marketed products as possible COVID-19-related therapies; permitted alternate means of obtaining patient consent; broadened the criteria for qualified health professionals who can carry out qualified investigator duties at remote sites; and expanded the range of applicants able to apply for medical device clinical trial authorizations. Health Canada emphasized that it remained committed to prioritizing the review of all COVID-19 clinical trial applications within fourteen days, both through the usual pathway and this alternative regulatory pathway.[49]

On September 16, 2020, the Minister issued an *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19 (2020)*,[50] which created an expedited pathway to market approval for drugs and vaccines aimed at COVID-19.[51] Health Canada stated that its "objective was to expedite the authorization for the importation, sale, and advertising of drugs used

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https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2020/73621a-eng.php. For more on these accelerated pathways, see *Guidance Document: Submission and Information Requirements for Extraordinary Use New Drugs (EUNDs)*, GOV'T CANADA (May 16, 2014), https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/pdf/brgtherap/applic-demande/guides/eund-dnue-eng.pdf; *Health Canada's Special Access Program: Request a Drug*, GOV'T CANADA, https://www.canada.ca/en/health-canada/services/drugs-health-products/special-access/drugs.html.

[47] Food & Drugs Act, R.S.C. 1985, c F-27 at 30.1(1). In addition, the Governor-in-Council can make regulations that it considers necessary for the purpose of preventing shortages of therapeutic products in Canada, or for alleviating those shortages or their effects, in order to protect human health. Food & Drugs Act, R.S.C. 1985, c F-27 at 30(1.4) (repealed 2020).

[48] *See* MINISTER OF HEALTH, INTERIM ORDER RESPECTING CLINICAL TRIALS FOR MEDICAL DEVICES AND DRUGS RELATING TO COVID-19 (2020), https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/interim-order-respecting-clinical-trials-medical-devices-drugs.html.

[49] *Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19: Notice*, GOV'T CANADA (May 27, 2020), https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/interim-order-respecting-clinical-trials-medical-devices-drugs/notice-interim-order.html#wb-cont.

[50] MINISTER OF HEALTH, INTERIM ORDER RESPECTING THE IMPORTATION, SALE AND ADVERTISING OF DRUGS FOR USE IN RELATION TO COVID-19 (2020), https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/interim-order-import-sale-advertising-drugs.html.

[51] *Drugs and Vaccines for COVID-19: Overview*, GOV'T CANADA (Sept. 13, 2020), https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/authorization.html.

in relation to COVID-19 and establishment licensing, while taking into consideration urgent public health needs[.]"[52] It went on to state that market authorization will be:

> predicated on the Minister's determination that the evidence provided supports the conclusion that the benefits outweigh the risks associated with the drug, taking into account the uncertainties related to the benefits and risks, as well as the urgent public health need caused by COVID-19. This includes weighing the risks of modifying certain requirements for information to support the safety and effectiveness of a drug, such as allowing consideration of a foreign regulatory approval, against the benefits of having it available to Canadians quickly.[53]

Ultimately, the Interim Order introduced three mechanisms for Health Canada to expedite the availability of COVID-19 drugs in Canada:

- Reduced Data: Authorizing a drug, including those not yet licensed in Canada or other jurisdictions, based on a modified set of application requirements (with the potential for a "rolling" submission of information as it becomes available);
- Foreign Approval: Authorizing a drug included on The List of Foreign Drugs based on certain elements being approved by a trusted foreign regulatory authority (e.g., Europe's European Medicines Agency, or regulators from Australia, Japan, Singapore, Switzerland, the United Kingdom and the United States) where they have been shown to provide some benefit in the context of COVID-19;
- Expanded Indications: Expanding the indication for an already approved drug to include a COVID-19 indication based on known evidence, with or without an application from the market authorization holder (i.e., an expanded age group or population compared to that in the existing NOC).[54]

The Interim Order also introduces a mechanism whereby drugs that show promise for treating or preventing COVID-19 can be imported and "pre-positioned" or placed in Canadian facilities before their authorization to allow for

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[52] *Explanatory Note: Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19*, GOV'T CANADA, https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/interim-order-import-sale-advertising-drugs/note.html (last visited Mar. 10, 2021).

[53] *Id.*

[54] MINISTER OF HEALTH, *supra* note 50.

quicker distribution after authorization.[55] The use of pre-positioning is restricted to promising COVID-19 drugs for which the Government of Canada has entered into a Procurement Agreement with the manufacturer.[56] When proceeding under the Interim Order, applications are not subject to the fees that apply when operating under the regular regime.[57] The Interim Order is only valid for a one-year term and product authorizations issued under it are only valid while the Interim Order is in effect, but Health Canada is developing transition measures to avoid disruptions when the Interim Order ends.[58]

The COVID-19 response has accentuated the pre-existing concerns around transparency insofar as it has eased standards around both clinical trials and regulatory approval for importing and selling without clearly indicating how this has happened and what its potential consequences are. A lack of transparency around clinical trial data poses potentially significant risks to trial participants and patients, it jeopardizes clinical trial quality, and it could undermine trust in key actors and thereby contribute to vaccine hesitancy. This easing of standards must be understood against a background of demonstrated reporting bias in relation to trial outcomes,[59] and a general reluctance on the part of key actors to release relevant data in a timely fashion.[60] Ultimately, the scrutiny to which vaccine candidates are subject varies, and the effective functioning of the safety system has been criticized on this point.[61] On this point, it has been argued that, to begin with, decisions have been made on less-than-ideal amounts of data:

> In the context of the current pandemic . . . Health Canada has shown a willingness to accept data on a piecemeal basis and even approved one drug (remdesivir) without the benefit of CSRs [Clinical Study Reports]. Until those CSRs are submitted to Health Canada little to no information about remdesivir's safety and efficacy is likely to be published via the [Clinical

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[55] Alice Tseng & Nancy Pei, *New Interim Order for COVID-19 Drugs Has Wide-reaching Impact, Allowing Minister to Unilaterally Expand Indication for Non-COVID-19 Drugs*, SMART & BIGGAR (Sept. 29, 2020), https://www.smartbiggar.ca/insights/publication/new-interim-order-for-covid-19-drugs-has-wide-reaching-impact-allowing-minister-to-unilaterally-expand-indication-for-non-covid-19-drugs.

[56] MINISTER OF HEALTH, *supra* note 50, s 27(c).

[57] Tseng & Pei, *supra* note 55.

[58] *Id.*

[59] Natalie McGauran et al., *Reporting Bias in Medical Research: A Narrative Review*, 11 TRIALS 1–15 (2010).

[60] Matthew Herder et al., *Against Vaccine Assay Secrecy*, 11 HUMAN VACCINES & IMMUNOTHERAPEUTICS 498, 498–503 (2015); *see also* Aaron Fellmeth, *Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data under the TRIPS Agreement*, 45 HARV. INT'L L. J. 443, 443-503 (2004).

[61] Janice Graham et al., *Capacity for a Global Vaccine Safety System: The Perspective of National Regulatory Authorities*, 30 VACCINE 4953, 4953–59 (2012).

> Information] Portal. With the Interim Order's introduction of a new expedited "rolling application" process it is unclear how much data Health Canada will have to release at the time of market authorization.[62]

In addition to relying on less data, governments also shared with the public insufficient amounts of information with the public about both the regulatory process and decision-making, and the details of the vaccine candidates. While sharing less information might theoretically limit fears relating to potential AEFIs, the current process:

> echoes government-driven vaccine races from the past, such as the one developed for the forecasted 1976 influenza pandemic, the side effects of which helped to propel anti-vaccination movements to this very day. A COVID-19 intervention that is administered to whole swaths of the world's population—without full transparency about its safety and efficacy—may engender lasting distrust not only against COVID-19 vaccines but a range of other infectious disease interventions with more established safety and efficacy profiles. The best way to prevent that outcome is to ensure high quality clinical trials, independent scrutiny of the resulting findings, and an unprecedented level of regulatory candour about experimental COVID-19 interventions in real-time. Enhanced transparency should be a marker of the intervention's trustworthiness—an expression of the regulatory system's effort to convey what is known, to open that knowledge and judgment up to outsiders, and to invite critical reflection about whether a particular drug or vaccine will help us to re-emerge from COVID-19.[63]

Though the Minister has discretion with respect to releasing certain types of data under certain conditions to certain parties,[64] previous Ministers have proven reluctant to share data, particularly if there was a concern that it could be classified as confidential business information.[65] Again, this reflects the culture of non-disclosure that exists in this stage of the vaccine development and safety ecosystem.

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[62] Edmonds et al., *supra* note 41, at 19.

[63] *Id.* at 28.

[64] *See* Food & Drugs Act, R.S.C. 1985, c 3.3, 21.2(3)(a) (Can.).

[65] *Cf. Regulatory Transparency and Openness Framework and Action Plan 2015-2018*, GOV'T CANADA, https://www.canada.ca/en/health-canada/corporate/transparency/regulatory-transparency-and-openness/regulatory-transparency-openness-framework-action-plan-2015-2018.html (last modified June 23, 2015).

The realities of the COVID-19 pandemic combined with the compressed nature of COVID-19 vaccine development has made Health Canada's historical 'closed shop' approach more susceptible to distrust from the public. In an approval process that is sensitive to transparency—whether the development and approval process is normal or accelerated and compressed—Health Canada would make information such as trial design, raw safety and efficacy data, outcome measures, researcher and regulator correspondence, and patient-level data (i.e., blinding and randomization protocols, serious adverse events within trials, etc.) available in real-time, or at least a timely fashion. Under current practices, they are often released late, and in some cases not at all, which seriously hampers the capacity of third-parties to re-analyze trials or to effectively assess the data on which regulatory decisions have been made.[66] In the past, such re-analyses have revealed discrepancies between reported findings and actual trial results.[67] Quite simply, far too much remains non-transparent with the consequence that questions arise as to who actually benefits. Trust in the system, which is already criticized as being too cozy as between the regulators and the for-profit regulatees, who wield too much power, is undermined, and vaccine acceptance is reduced.

IV. THE CLINICAL SURVEILLANCE STAGE: AN ABSENCE OF STANDARDS FOR AEFIS

In this section, we turn to another stage in the vaccine development and safety ecosystem, namely that of clinical surveillance. Public tolerance of safety shortfalls in vaccines is significantly lower than that related to medicines administered to persons who are already sick because, where most pharmaceutical products are administered to ill persons for curative purposes, vaccines are usually given to healthy persons for preventative purposes.[68] This lower risk tolerance translates into a need for an obviously robust and joined-up governance ecosystem that is sensitive to safety from development to deployment. While the above discussion suggests that the existing ecosystem does exhibit concern for safety, this concern is not realized through effective mechanisms in the clinical surveillance stage.

As indicated, the pre-clinical stages of the ecosystem are unable to furnish complete safety profiles for vaccine candidates. The real-world safety and effectiveness of vaccines can therefore only be known following widespread use and

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[66] Edmonds et al., *supra* note 41.

[67] Johanna Le Noury et al., *Restoring Study 329: Efficacy and Harms of Paroxetine and Imipramine in Treatment of Major Depression in Adolescence*, 351 BMJ h4320 (2015).

[68] *Vaccine Safety Basics Learning Manual*, *supra* note 34, at 14.

epidemiological tracking for AEFIs. In the case of COVID-19 vaccines, safety and effectiveness will likely vary from one vaccine to another, by age group, by medical condition, and potentially by geographic diversity[69] and temporal remoteness from immunization, making the systematic collection of reliable data at this stage doubly important. Ideally, such data would be available to national authorities like Canada's NACI in real-time so it can determine which vaccines are the most effective for different populations and fine-tune its COVID-19 recommendations in a vaccine-specific manner. In short, there is a pressing need to consistently and reliably (1) identify serious AEFIs, (2) report serious AEFIs, (3) assess serious AEFIs, and (4) support individuals who experience serious AEFIs causally connected to the vaccine or vaccine administering system.

However, as a result of design deficiencies in the Canadian regulatory framework, there exists a barrier to effective practice in the first step: identifying serious AEFIs. There is no contained standard or even harmonized understanding of this core concept; there is no single, sufficiently specific and compelling definition of an AEFI. Every province and territory in Canada has a public health promotion statute of some kind, and all of them address immunization to some degree. However, seven Canadian jurisdictions simply do not legislatively define what constitutes a reportable AEFI (e.g., Newfoundland & Labrador (NL), Nova Scotia (NS), New Brunswick (NB), Prince Edward Island (PEI), Saskatchewan (SK), North West Territories (NWT), Yukon (YK)).[70] Both Quebec (QC) and

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[69] The interim analysis of Johnson & Johnson's COVID-19 vaccine Phase III trial, released January 29, 2021, showed 72% efficacy in the United States but just 57% in South Africa. *Jansen Investigational CPVID-19 Vaccine: Interim Analysis of Phase 3 Clinical Data Released*, NAT'L INST. HEALTH (Jan. 29, 2021), https://www.jnj.com/johnson-johnson-announces-single-shot-janssen-covid-19-vaccine-candidate-met-primary-endpoints-in-interim-analysis-of-its-phase-3-ensemble-trial.

[70] Some of these jurisdictions may offer a non-legal definition at the policy or guidance level. For example, the *Nova Scotia Immunization Manual* stipulates that serious AEFIs should be reported by healthcare professionals, offering reasons why this is so, and how it should be done. It does not clearly articulate a definition for AEFIs, but states that, an "Adverse Event Following Immunization" should be reported when the event:

- Has a temporal association with a vaccine: Please refer to the Summary of Reporting Criteria. Temporal association alone (i.e. onset of an event following receipt of vaccine) is not proof of causation.
- Has no other clear cause at the time of reporting: A causal relationship between immunization and the event that follows does not need to be proven and submitting a report does not imply or establish causality. Sometimes the vaccinee's medical history, recent disease, concurrent illness/condition and/or concomitant medication(s) can explain the event(s).
- Is serious in nature: A serious adverse event is one that is life threatening or results in death, requires hospitalization (≥24 hours) or prolongation of an existing hospitalization, results in residual disability or associated with a congenital malformation.
- Is unusual or unexpected: An event that has either not been identified previously or one that has been identified previously but is being reported at an increased frequency. For

Nunavut (NU) have definitions, but they are vague, imprecise, seemingly overbroad, or otherwise provide little practical guidance for AEFI reporting. Those with a precise or relatively clear definition of what constitutes a reportable AEFI—Ontario (ON), Manitoba (MB), Alberta (AB), British Columbia (BC)—all conflict to varying degrees as to what constitutes a reportable AEFI. For the legislative definitions in operation, see **Table 1**.

Table 1
Legal Definitions of AEFIs

P/T	Statute	Definition
NL	*Public Health Protection and Promotion Act*, SNL 2018, c. P-37.3	No Definition Found
NS	*Health Protection Act*, SNS 2004, c. 4	No Definition Found
PEI	*Public Health Act*, RSPEI 1988, c. P-30.1	No Definition Found
NB	*Public Health Act*, SNB 1998, c. P-22.4	No Definition Found
QC	*Public Health Act*, c. s-2.2	**s 69** [a]n unusual clinical manifestation, temporally associated with vaccination, in a person having received a vaccine or a contact of that person and [where the physician] suspects a link between the vaccine and the unusual clinical manifestation.
ON	*Health Protection and Promotion Act*, RSO 1990, c. H.7	**s 38(1)** "reportable event" means, (a) persistent crying or screaming, anaphylaxis or anaphylactic shock occurring within forty-eight hours after the administration of an immunizing agent, (b) shock-like collapse, high fever or convulsions occurring within three days after the administration of an immunizing agent, (c) arthritis occurring within forty-two days after the administration of an immunizing agent, (d) generalized urticaria, residual

additional information regarding unusual or unexpected events, please refer to the Canadian Immunization Guide.

- Clusters of events: known or new events that occur in a geographic or temporal cluster (e.g. 6 in a week, or 6 in a zone) that require further assessment, even if the total number of AEFIs may not be higher than expected.

It goes on to state that most vaccines reactions are mild and self-limited and local (e.g., tenderness or redness at injection site) or systemic (e.g., fever, joint or muscle pain) but are minor in severity, and those outlined in the vaccine product monograph do not need to be reported. PROVINCE OF N.S., NOVA SCOTIA IMMUNIZATION MANUAL 87 (2019), https://novascotia.ca/dhw/cdpc/documents/Immunization-Manual.pdf.

		seizure disorder, encephalopathy, encephalitis or any other significant occurrence occurring within fifteen days after the administration of an immunizing agent, or (e) death occurring at any time and following upon a symptom described in clause (a), (b), (c) or (d).
MB	*Immunization Regulations*, M Reg. 36/2009, adopted under the *Public Health Act*, CCSM c. P210	**s 2(1)** For the purposes of the definition "reportable event" in s 56 of the Act, a reportable event means an adverse event set out in subsection (2) that is temporally associated with an immunizing agent, cannot be attributed to a co-existing condition, and that meets at least one of the following criteria: (a) the event is life-threatening, could result in permanent disability, requires hospitalization or urgent medical attention, or for any other reason is considered to be of a serious nature; (b) the event is unusual or unexpected, including, without limitation, (i) an event that has not been previously identified, or (ii) an event that has been previously identified but is being reported at an increased frequency; (c) at the time of the report there is nothing in the patient's medical history—such as a recent disease or illness, or the taking of medication—that could explain the event. **s 2(2)** The following are 'adverse events' for the purpose of subsection (1): (a) a local reaction at or near the injection site; (b) anaphylaxis; (c) an allergic reaction of any of the following types: (i) skin or mucosal, either at or near the injection site or generalized, (ii) cardiovascular, (iii) respiratory, (iv) gastrointestinal; (d) one or more of the following: (i) seizures, (ii) meningitis*, (iii) Guillain-Barré Syndrome*, (iv) Bell's Palsy*, (v) paralysis other than Bell's Palsy*, (vi) encephalopathy* or encephalitis*, (vii) hypotonic or hyporesponsive episode (age less than two years), (viii) persistent crying (continuous and unaltered for more than three hours), (ix) rash, (x) arthritis, (xi) intussusception*, (xii)

		thrombocytopenia*, (xiii) parotitis, (xiv) oculo-respiratory syndrome; * as diagnosed by a physician (e) a serious event not described in clauses (a) to (d).
SK	*Public Health Act*, SSK 1994, c. P-37.1	No Definition Found
AB	*Immunization Regulation*, AB Reg. 182/2018, adopted under the *Public Health Act*, RSA 2000, c. P-37	**s 1(2)** For the purposes of this Regulation and s 18.4 of the Act, "adverse event following immunization" means an unfavourable health occurrence experienced by a patient that (a) follows immunization, (b) cannot be attributed to a pre-existing condition, and (c) meets one or more of the following criteria, as determined by a health practitioner: (i) the health occurrence is life-threatening, could result in permanent disability, requires hospitalization or urgent medical attention, or for any other reason is considered to be of a serious nature; (ii) the health occurrence is unusual or unexpected, including, without limitation, an occurrence that (A) has not previously been identified, or (B) has previously been identified but is being reported at increased frequency; (iii) the health occurrence cannot be explained by anything in the patient's medical history, including, without limitation, a recent disease or illness, or consumption of medication.
BC	*Reporting Information Affecting Public Health Regulation*, BC Reg. 167/2018, adopted under the *Public Health Act*, SBC 2008, c. 28	**s 5(1)** "adverse event following immunization" means a negative change in a person's health that (a) occurs after the person receives an immunization, (b) is serious, unusual or unexpected, or for which medical attention is sought, and (c) cannot clearly be attributed to a cause other than the immunization.
NU	*Reporting and Disease Control Regulations*, NU Reg 051-2019, adopted under the *Public Health Act*, SNu 2016, c. 13	**s 1** "adverse event following immunization" means an adverse medical event which has a temporal association, but not necessarily a causal association, with the administration of an immunizing agent and which cannot be clearly attributed to other causes.

NWT	*Public Health Act*, SNWT 2007, c. 17	No Definition Found
YK	*Public Health and Safety Act*, RSY 2002, c. 176	No Definition Found

This patchwork of definitions poses challenges for effective clinical surveillance. A jurisdiction with a broader definition of an AEFI would likely report higher AEFI rates than provinces with a narrower definition. Those provinces with no legal definition would rely on healthcare providers to articulate and act upon their own definition. Thus, even if there is no real difference in the safety profile of a vaccine from one jurisdiction to another, the opposite may appear to be the case based on reported AEFIs. In addition to obscuring *actual* jurisdictional differences in vaccine safety, this reality could undermine a national understanding of the real-world safety and efficacy of a vaccine, and it could frustrate reliable comparisons with other countries. It could also negatively and inappropriately skew public perceptions of vaccine safety. A common and clear Canada-wide definition which aligns with an international standard would allow for meaningful comparisons between AEFI rates in different sub-national jurisdictions and internationally, and it would allow for more accurate and easily aggregated data across jurisdictions to detect safety signals.[71]

The second element of a clinical surveillance system is to ensure consistent and timely reporting of AEFIs to health authorities. The Canadian vaccine development and safety ecosystem contains several clinical surveillance systems, being the following:

- Canadian Adverse Events Following Immunization Surveillance System (CAEFISS): Managed by the Public Health Agency of Canada (PHAC), CAEFISS is a federal, provincial, territorial collaboration commencing in 1987 the objectives of which are to: (1) continuously monitor the safety of marketed vaccines in Canada; (2) identify increases in the frequency or severity of recognized AEFIs; (3) identify previously unknown AEFIs that may be related to a vaccine; (4) identify areas that require further investigation or research; and (5) provide timely information for analysts and policy-makers on AEFI profiles for vaccines in Canada.[72] CAEFISS receives reports from physicians, nurses, or pharmacists who provide immunizations, or

[71] *See Vaccine Safety Basics Module 3: Adverse Events Following Immunization, Classification of AEFIs*, WORLD HEALTH ORG. [WHO], https://vaccine-safety-training.org/classification-of-aefis.html (last visited March 8, 2021).

[72] *Canadian Adverse Events Following Immunization Surveillance System (CAEFISS)*, GOV'T CANADA, https://www.canada.ca/en/public-health/services/immunization/canadian-adverse-events-following-immunization-surveillance-system-caefiss.html (last visited Mar. 8, 2021).

who care for individuals with AEFIs. The causal assessment is usually undertaken by the reporting healthcare provider, and the system is passive insofar as it relies on individuals to identify an issue and engage with the system.[73]

- Immunization Monitoring Program ACTive (IMPACT): Overseen by the Canadian Paediatric Society and funded by PHAC, IMPACT is a more active system that feeds into CAEFISS. Nurse monitors in twelve paediatric hospitals across Canada (which handle some 90% of all paediatric tertiary care admissions) systematically search their admissions records for vaccine-preventable diseases and selected infectious diseases in children that are (or will soon be) vaccine-preventable, vaccine failures, or AEFIs.[74] When select medical events are found to be temporally linked to immunization, they are reported to CAEFISS, as well as to local and provincial and territorial health officials. Provided there is sufficient information on which to make a determination, PHAC undertakes a causality assessment using international practices and principles.[75]
- Canada Vigilance Program (CVP): This is an infrastructure organization and platform which passively receives and then assesses reports from health professionals and consumers about suspected adverse reactions to health products marketed in Canada, including prescription and non-prescription medications, natural health products, biologics (including vaccines), radiopharmaceuticals, and disinfectants and sanitizers. While the CVP provides a variety of tools for health professionals and consumers to report suspected adverse reactions, reporting is voluntary.[76]
- MedEffect: Under the Therapeutic Access Strategy (TAS), the Marketed Health Products Directorate developed the MedEffect website, which is meant to: (1) simplify completion and filing of adverse reaction reports via web, phone, fax, or mail; (2) build awareness about the importance of reporting adverse reactions, and how this

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[73] *Id.*

[74] *IMPACT*, CANADIAN PAEDIATRIC SOCIETY, https://www.cps.ca/en/impact (last updated Nov. 10, 2020).

[75] *Causality Assessment of an Adverse Event Following Immunization (AEFI): User Manual for the Revised WHO Classification*, WORLD HEALTH ORG. [WHO] (2d ed. 2018), https://www.who.int/vaccine_safety/publications/aefi_manual.pdf?ua=1.

[76] *Canada Vigilance Program*, GOV'T CANADA, https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/canada-vigilance-program.html#wb-cont (last modified July 12, 2018). *See also* HEALTH CANADA, REPORTING ADVERSE REACTIONS TO MARKETED HEALTH PRODUCTS—GUIDANCE DOCUMENT FOR INDUSTRY (2018), https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/reports-publications/medeffect-canada/reporting-adverse-reactions-marketed-health-products-guidance-industry/reporting-adverse-reactions-marketed-health-products-guidance-industry.pdf.

information is used to identify and communicate potential risks; and (3) provide centralized public access to health product safety information (e.g., Health Canada's Advisories, Warnings, and Recalls, the Canadian Adverse Reaction Newsletter (CARN), and the Canadian Adverse Drug Reaction Monitoring Program (CADRMP)).[77]

- Canadian Immunization Research Network (CIRN): To help manage affairs when an AEFI is discovered, and to help overcome concomitant reluctance on the part of patients, parents, and healthcare workers, the CIRN established thirteen special immunization clinics (SICs) staffed by paediatric and adult infectious disease specialists and allergists experienced in dealing with challenging situations (i.e., high-risk patients, etc.), which cases are logged into a central registry to enable review of further immunization outcomes for people with similar AEFIs, as well as to better evaluate management protocols.[78]

Unfortunately, these systems do not coalesce into a comprehensive or harmonized framework for the systematic reporting and collection of immune-relevant data, including that around AEFIs; they are mostly voluntary, they do not capture all of the places and avenues where AEFIs might be discovered and relevant data collected, and those sources that are captured are not integrated.[79] Contrary to these largely passive (or voluntary, report-driven) mechanisms, the regulatory framework, in a breathtaking disjunct, imposes—albeit unevenly—mandatory AEFI reporting.

The *Regulations Amending the Food and Drug Regulations (Serious Adverse Drug Reaction Reporting—Hospitals)*,[80] which came into effect in December 2019, give effect to s 21.8 FDA. Under Regulation C.01.020.1(1), only hospitals are "prescribed health care institutions" obligated to provide to the Minister

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[77] *MedEffect Canada*, GOV'T CANADA, https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html (last modified Mar. 5, 2021).

[78] Karina Top et al., *Canadian Paediatricians' Approaches to Managing Patients with Adverse Events Following Immunization: The Role of the Special Immunization Clinic Network*, 19 PAEDIATR CHILD HEALTH 310–14 (2014).

[79] Nor are they linked to a fully integrated patient-centered health information system designed to facilitate the determination of background rates and other relevant factors. Panorama—the Provincial Public Health Information System Panorama, an electronic health record system that stores and allows authorized providers access to public health services received in the province—was supposed to deliver this data accessibility, but after some twenty years of evolution it remains only partially useful because it does not capture all the health data relevant for making sound assessments and decisions. For more, see *An Audit of the Panorama Public Health System*, AUDITOR GEN. BRITISH COLUMBIA (Aug. 2015), https://www.bcauditor.com/sites/default/files/publications/reports/OAGBC_PanoramaReport_FINAL.pdf.

[80] SOR/2019-190 (Can.).

information that is in their control about a "serious adverse drug reaction."[81] Regulation C.01.020.1(2) identifies the 'prescribed information' that hospitals must provide to the Minister within 30 days. However, because surveillance is limited to hospitals, the Regulation neglects significant sources and avenues of information, such as that arising from physicians, nurses, or nurse practitioners working in family or general practices, in clinics, or in congregate living facilities, as well as information that may be held by health authorities, and their data are not being systematically collected, aggregated, or assessed. Even with respect to hospitals, Regulation C.01.020.1(3) FDR states that a hospital is exempt from s 21.8 FDA with respect to reporting this information if, inter alia, the information relates to a vaccine that was administered under a routine immunization program of a province.

Given the above, one must turn to the provinces and territories for further guidance on reporting. Eleven of Canada's thirteen sub-national jurisdictions impose mandates; Newfoundland & Labrador and Yukon are without mandatory AEFI reporting. In all cases where mandates exist, there are potentially significant penalties for failure to report, which suggests that, as a policy matter, governments recognize that tracking AEFIs is important. Ontario goes farthest regarding mandates and penalties, stipulating that the healthcare provider administering a vaccine must inform the patient of the importance of immediately seeking healthcare should an AEFI occur.[82]

Table 2
Mandatory AEFI Reporting & Penalties

P/T	Statutory and Regulatory Provisions	Mandate	Penalty
NL	NA	No	
NS	*Health Protection Act*, SNS 2004, c. 4, ss 31(1), 71(1);	Yes	Fine: $2,000 Prison: 6 months

[81] C.R.C., c. 870 C.01.020.1(1). Under Regulation C.01.020.1(4), the term "hospital" means

> a facility (a) that is licensed, approved or designated as a hospital by a province in accordance with the laws of the province to provide care or treatment to persons suffering from any form of disease or illness; or (b) that is operated by the Government of Canada and that provides health services to in-patients.

[82] Province of Ontario *Health Protection and Promotion Act*, R.S.O. 1990, c. H.7, s 38(2). It is not clear what effect, if any, this interaction has on patients (i.e., whether it causes patients to seek medical attention more quickly, or whether it causes anxiety and unnecessary healthcare visits); *see also infra* 18 tbl. 2 (providing the penalty for non-compliance with mandatory AEFI reporting).

	Reporting of Notifiable Diseases and Conditions Regulations, NS Reg 195/2005, s 11(1).		
PEI	*Public Health Act*, RSPEI 1988, c. P-30.1, s 66(1); *Immunization Regulations to the Public Health Act*, s 4.	Yes	Fine: $1,000 ($10,000 for 3+ offences) Prison: 6 months
NB	*Public Health Act*, SNB 1998, c. P-22.4, ss 27(1)(c) and 52(1); *Reporting and Diseases Regulations*, s 18; *Provincial Offences Procedure Act*, s 56(3).	Yes	Fine: $1,100 ($2,100 for 2+ offences) (Category C offence)
QC	*Public Health Act*, c. s-2.2, ss 69 and 138.	Yes	Fine: $1,200
ON	*Health Protection and Promotion Act*, RSO 1990, c. H.7, ss 38 and 100(2).	Yes	Fine: $5,000
MB	*Public Health Act*, CCSM c. P210, ss 59 and 90.	Yes	Fine: $50,000 Prison: 6 months
SK	*Public Health Act*, SSK 1994, c. P-37.1, ss 23(1) and 61.	Yes	Fine: $75,000 ($100,000 for 2+ offences)
AB	*Public Health Act*, RSA 2000, c. P-37, ss 5(1) and 73(3).	Yes	Fine: $100,000 ($500,000 for 2+ offences)
BC	*Public Health Act*, SBC 2008, c. 28, ss 12 and 99(1)(d); *Reporting Information Affecting Public Health Regulation*, BC Reg 167/2018, s 5.	Yes	Fine: $25,000 Prison: 6 months
NU	*Public Health Act*, SNu 2016, c. 13, ss 12 and 80(1); *Reporting and Disease Control Regulations*, NU Reg 051-2019, s 2(2)(b).	Yes	Fine: $50,000 ($100,000 for 2+ offences) Prison: One year
NWT	*Public Health Act*, SNWT 2007, c. 17, ss 3(2) and 49(1)(a).	Yes	Fine: $10,000 ($25,000 for 2+ offences) Prison: 6 months (1 year for 2+ offences)
YK		No	

However, it is questionable the extent to which these mandates are enforced. There is no information available on enforcement, but the authors' practical knowledge of, and engagement with, this field, combined with a legal search of reported cases, suggests a general absence of attention to mandate enforcement and imposition of statutory penalties. Ultimately, there are no strong motivators

for healthcare providers to vigilantly report AEFIs (assuming they can determine that the condition they are seeing is following or associated with a vaccination). On this point, the Canadian Medical Protective Association has noted that adverse events reporting across Canada remains uneven, in part due to non-harmonized legal obligations, and it recommends a consistent approach to reporting.[83] Standardized reporting protocols combined with reporting to a central (national) database would permit factual information to be gathered and would support system-wide data collection and analysis, including meta-analysis of incident and occurrence trends.

We recommend that Canada (and other countries) adopt mandatory reporting of serious AEFIs, imposing reporting obligations on all healthcare professionals who administer vaccines or are expected to treat patients post-immunization. In short, mandates need to exist on those who perform healthcare duties in hospital-based, clinic-based, and congregated care-based contexts, which includes individuals such as physicians, family physicians, public health nurses, nurse practitioners, and pharmacists. Obviously, this reporting must be imposed not only on and through hospitals, but also on individual healthcare providers in a range of care settings, and on health authorities.

The third element in a clinical surveillance system is to ensure consistent, reliable, and timely assessment of serious AEFIs. Given the relatively low levels of attention paid to public health and preventative medicine both generally and in healthcare training (and specifically in medical schools), it is unclear the extent to which healthcare providers are uniformly equipped to consistently identify, much less reliably assess, AEFIs. Many healthcare providers who administer vaccinations (e.g., nurses and pharmacists), and many who may see patients for health-related events post-vaccination (e.g., family physicians), will not have the training or experience to confidently assess whether an event is causally related to vaccination.

Further, both these healthcare providers and more suitable assessors will be further stymied by the fact that there exists no single repository for storing immunization status or AEFI data. Data that will be important to collect from patients experiencing a medically significant event include: their demographic information (i.e., age, sex, ethnicity, location, etc.); their immunization history and status; their general health condition, including medications and allergies; the

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[83] CMPA, *Medical-Legal Handbook for Physicians in Canada*, Version 8.3 (2020), https://www.cmpa-acpm.ca/en/advice-publications/handbooks/medical-legal-handbook-for-physicians-in-canada#harm-from-healthcare-delivery. For more on the inadequacy of post-market surveillance regulation, see Joel Lexchin, *Health Canada's Use of its Notice of Compliance with Conditions Drug Approval Policy: A Retrospective Cohort Analysis*, 49 INT'L J. HEALTH SERVS. 294–305 (2019). For a critic of the U.S. system, see Joshua D. Wallach et al., *Postmarket Studies Required by the U.S. Food and Drug Administration for New Drugs and Biologics Approved Between 2009 and 2012: Cross Sectional Analysis*, BRIT. MED. J. 1 (Apr. 16, 2018).

existence of any previous adverse reactions to vaccination; whether a COVID-19 vaccine was received, and which one; when and where the vaccine was received, and how was it delivered; and how the vaccine was tolerated at the time of inoculation.

However, as noted, Canada relies on multiple-discontinuous-electronic personal health information (PHI) platforms, and there is no widely-shared access point for retrieving existing AEFI data in real time (i.e., there are few links between hospital data, community clinic office data, and immunization registry data such that reliable data can be aggregated in pursuit of reliable assessments). Without access to such data—very granular data easily accessed by assessors—neither reliable *vaccine safety (AEFI occurrence) determinations* nor reliable *vaccine effectiveness determinations* can be made because they will rely on an incomplete or inaccurate evidentiary base considered by individuals not in a position to robustly assess the data. Under the present system, not all positive cases will be queried with respect to the multiple issues that are pertinent, including prior receipt of a COVID-19 vaccine (and then which vaccine, when and where it was received, how it was delivered and tolerated, etc.). Such details are particularly important for differentiation of effectiveness of one vaccine versus another, and for answering such practically significant questions as:

- Is the failure or event directly due to a storage and handling, diluent, or other program error, or is it more probably linked to an element or action of the specific vaccine?
- Are failures or events being seen amongst others who received that specific vaccine during that time period?
- Are there underlying clinical reasons that may have altered response to that specific vaccine?

To properly evaluate these questions when a patient presents with a possible AEFI, the assessor requires access to significantly more data than is currently collected by the fragmented systems that exist.

We recommend that each national jurisdiction should found a single, central, independent, and interdisciplinary body which is tasked with assessing for causation all reported serious AEFIs. Only through reliance on a single expert body can decision-makers be assured that a consistent analysis using common factors, like evidence and national standards, is being applied. This body could then classify post-immunization medical events as vaccine-related, program-related, or unrelated AEFIs. To do this effectively, there should also exist a 'large linked database' (LLDB).[84] Although some countries have successfully implemented

[84] *Vaccine Safety Basics: Learning Manual*, *supra* note 34, at 28. This Learning Manual notes that LLDBs are discrete administrative databases created independently from each other that are linked to enable the sharing of data across platforms. *Id.* With sufficient integration,

relatively low-cost, patient-centered, and integrated health information systems that can be searched in real-time,[85] Canada has not done so.

The final element of a comprehensive clinical surveillance system, and one that may additionally impact public trust and acceptance of vaccines, is support for those patients who have experienced a serious AEFI related to the program or the vaccine. Such support should come in the form of a Vaccine Injury Compensation Program (VICP), which programs are not uncommon in the many high-income countries. As of 2011, the only G8 countries without a national VICP were Canada and Russia,[86] and currently, twenty-four countries and the province of Quebec have such programs.[87] VICPs are typically instituted based on a belief that governments have a special responsibility to those injured by properly manufactured and administered vaccines used in public health programs; they are increasingly seen as an important component of vaccination programs.[88] They are particularly important given the abysmal success of tort claims relating to vaccine injuries.[89] VICPs have produced positive experiences,[90] with the existence of such programs contributing to:[91]

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they can detect very rare ARs and AEFIs, and can provide an economical and rapid means of conducting post-licensure studies of the safety of drugs and vaccines. *Id.* They can also facilitate the testing of hypotheses when signals or allegations create suspicions of a possible vaccine safety issue. *Id.*

[85] Michael Graven et al., *Decline in Mortality with the Belize Integrated Patient-Centred Country Wide Health Information System (BHIS) with Embedded Program Management*, 82 INT'L J. MED. INFORMATICS 954–63 (2013); *see also* Michael Krausz et al., *Emergency Response to COVID-19 in Canada: Platform Development and Implementation for eHealth in Crisis Management*, 6 JMIR PUB. HEALTH & SURVEILLANCE e18995 (2020) (outlining the triage, monitoring, and service-provision platform).

[86] Roger Collier, *No-Fault Compensation Program Overdue, Experts Say*, 183 CANADIAN MED. ASS'N J. E263 (2011), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3060206/.

[87] Randy G. Mungwira et al., *Global Landscape Analysis of No-Fault Compensation Programmes for Vaccine Injuries: A Review and Survey of Implementing Countries*, 15 PLOS ONE 1, 4 (2020), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0233334. For more on the Quebec program, see Eve Dubé et al., *Vaccine Injury Compensation Programs: Rationale and an Overview of the Québec Program*, 46 CAN. COMMUNICABLE DISEASE REP. 305–08 (2020).

[88] Geoffrey Evans, *Vaccine Injury Compensation Programs Worldwide*, 17 VACCINE S25–S35 (1999).

[89] For a now dated U.K. examination, see Stephanie Pywell, *A Critical Review of the Recent and Impending Changes to the Law of Statutory Compensation for Vaccine Damage*, 246 J. PERS. INJ. LITIG. ONLINE 4 (2000). The Canadian setting exhibits a similar trend.

[90] *See* Ruth Tindley, *A Critical Analysis of the Vaccine Damage Payments Scheme*, 19 EUR. BUS. L. REV. 321 (2008) (providing the U.K. experience with VICPs); *see* Laine Rutkow et al., *Balancing Consumer and Industry Interests in Public Health: The National Vaccine Injury Compensation Program and its Influence During the Last Two Decades*, 111 PENN ST. L. REV. 681 (2006) (examining the U.S. experience with VICPs); Katherine Cook & Geoffrey Evans, *The National Vaccine Injury Compensation Program*, 127 PEDIATRICS S74 (2011).

[91] Kimberly M. Thompson et al., *Performance of the United States Vaccine Injury Compensation Program (VICP): 1988–2019*, 38 VACCINE 1, 6 (2020); *see also* H. Cody Meissner,

- better evidence around vaccine safety;
- better evidence around the nature of injuries relating to (specific) vaccines; and
- greater confidence in vaccines.

Ultimately, in addition to representing important supports for people who have been injured, such programs signal to the public that the government and health authorities are confident in the products being delivered. In this way, these programs are one of the many tools needed to combat vaccine hesitancy.

All told, the prevailing vaccine surveillance system in Canada is neither designed nor sufficiently powered to encourage justified trust in the vaccines administered, even when they are in fact safe and effective. A significant barrier to a more robust, comprehensive, and harmonized system is the persistent insinuation into framework development efforts of the many vested interests across Canada and of provinces and territories. As an example, consider the 2003 National Immunization Strategy, a multi-million-dollar plan to align vaccination schedules and expand access across Canada, which ultimately failed due to the jurisdictional differences in epidemiology, vaccine delivery systems, and financial means.[92]

V. CONCLUSIONS

Both market authorization and AEFI reporting are part of Canada's vaccine development and safety ecosystem. However, they exhibit operational and design shortcomings which may well undermine public trust in the actors and systems, and public acceptance of the vaccines.

With respect to the market authorization stage, while useful flexibilities exist to facilitate rapid development and authorization, the process for doing so is not at all transparent, veiling substantial amounts of data, and obscuring the assessment process undertaken by regulators. To remedy this, the Minister should exercise the discretion granted under the FDA and FDR to expand Health Canada's data-sharing practices in relation to vaccine approvals, and to move those expanded sharing practices further upstream in the authorization process. Greater public trust cannot be achieved without transparent access to the raw data on which decisions to approve and recommend vaccines are based.

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et al., *The National Vaccine Injury Compensation Program: Striking a Balance Between Individual Rights and Community Benefit*, 321 J. AM. MED. ASS'N 343, 344 (2019).

[92] Wayne Kondro, *Progress Report on the National Immunization Strategy*, 176 CANADIAN MED. ASS'N J. 1811–13 (2007).

With respect to the clinical surveillance stage, which is aimed at determining the *real-world safety and effectiveness* of vaccines, there is much that governments can do to improve identification, reporting, and assessment of AEFIs, and to better support patients who have been injured as a result of vaccines or actions taken within vaccine programs. In the Canadian context, preventative medicine must feature more prominently in healthcare provider education, AEFI reporting must be made mandatory in all Canadian jurisdictions and with respect to all pertinent actors, with robust enforcement of such mandates, and reporting and data systems must be strengthened (or implemented). Also, there should exist an independent national expert body (equivalent to the NACI) that is tasked with conducting causality assessments with respect to AEFIs. This would facilitate quality of the causality assessment by injecting consistency in the standards applied, the factors taken into account, and the specific biological actions of the subject vaccine.

Ultimately, the fragmented approach that prevails in Canada in relation to key aspects of the vaccine development and safety ecosystem creates a sub-optimal immunization environment that will not encourage justified trust and high rates of vaccine acceptance. Long-term neglect of public health prior to the COVID-19 pandemic has left systems under-resourced. The pandemic has simultaneously highlighted both the fragility and the indispensability of public health in this country and others. Strong action now—in advance of mass distribution of COVID-19 vaccines and their possible inclusion in routine immunization programs—will strengthen national public health systems and better prepare them for the next pandemic.