Was the Standard for Informed Consent Met When COVID-19 Shots Were Administered to Pregnant and Breastfeeding Mothers?

An Injection of Truth: Healing Humanity

Dr. Byram W. Bridle, PhD
Associate Professor of Immunology and Virology

Disclosures

- Scientific Advisor for ImmunoCeutica Inc.
- Member of the Canadian Citizens Care Alliance
- Senior international fellow in virology and immunology for the Independent Medical Alliance
- Have held or hold grants from government and non-profit agencies
- Hold patents related to vaccines and viruses
- Received honoraria for events in which I gave presentations in my areas of expertise
- Have served as an expert witness in the areas of immunology and virology in international court cases
- Employed by University of Guelph (opinions expressed here are my own)
- In 2020, in recognition of my expertise, I received funding from the governments of Ontario (COVID-19 Rapid Research Fund, Ministry of Colleges and Universities) and Canada (Pandemic Response Challenge Program, National Research Council of Canada) for the development of vaccines against SARS-CoV-2
- The scope of my COVID-19 vaccine research was limited to the pre-clinical realm; funding expired in 2022, and I did not seek renewal nor additional funding due to substantial concerns that I had about incorrect public messaging about COVID-19 vaccines and the degree of censorship being imposed on anyone expressing such concerns
- I was a scientific contributor to a draft of the report on Alberta's response to the COVID-19 pandemic; this was done *pro bono*

Highlights of Qualifications

- I am an Associate Professor of Immunology and Virology who specializes in vaccinology
- I have a 107-page Canadian Common *Curriculum Vitae*
- I have been conferred the degrees: B.Sc. (biomedical sciences), M.Sc. (immunology), Ph.D. (immunology)
- I completed a post-doctoral fellowship in immunology and virology
- My areas of expertise overlap with the fields of public health and the study of infectious diseases
- I teach undergraduate, graduate and post-graduate immunology, virology, and cancer biology
- I have received multiple prestigious awards for teaching
- I have published extensively in the peer-reviewed scientific literature in my fields of expertise
- My research program involves developing vaccines to prevent infectious diseases, immunotherapies to treat cancers, and studies immune responses to viruses
- I am a member of the College of Reviewers for the Canadian Institutes of Health Research and have received multiple distinctions for being a top-tier reviewer

What Is Informed Consent?

The Alberta Medical Association refers to this definition…

From "*Consent: A guide for Canadian physicians*":

Standard of disclosure

Although obtaining a valid consent from patients has always involved explanations about the general nature of the proposed treatment and its anticipated effect, the Supreme Court of Canada, over two decades ago, imposed a more stringent standard of disclosure upon physicians. The adequacy of consent explanations is to be judged by the "reasonable patient" standard, or what a reasonable patient in the particular patient's position would have expected to hear before consenting.

https://www.cmpa-acpm.ca/en/advice-publications/handbooks/consent-a-guide-for-canadian-physicians#informed%20consent

What Where Pregnant and Breastfeeding Women Told About COVID-19 Shots?

Alberta Health Services

Healthy Albertans. Healthy Communities. Together.

Canada's Top 100 Employers 2021

MEMORANDUM

Date: September 13, 2021

To: Primary Care Providers and Primary Care Partners

From: Alberta Health Services

RE: COVID-19 Immunization and Pregnancy

Dr. Francois Belanger
Vice President, Quality and Chief Medical Officer

Dr. Linda Slocombe
Senior Medical Director, Primary Health Care

Dear colleagues,

You are no doubt answering questions from pregnant patients, or those considering pregnancy, about COVID-19 immunization. Thank you for continuing to encourage patients to be vaccinated as soon as possible. The fourth wave of COVID-19 and the Delta variant could have significant adverse effects on

The core message is that COVID-19 vaccines are safe and effective for pregnant individuals and their babies, with mRNA vaccines being the safest type of COVID-19 vaccine to get during pregnancy.

What's right for you?

- Different people have different feelings and concerns about the COVID-19 vaccine, and that's ok. But we should all have the same information and support each other to learn more.

Remember, the COVID-19 shots were mandated for pregnant and breastfeeding women!

Federal Order Paper Question 2163

- Order Paper Question 2163 asked:
- *"were randomized control trials used to obtain approval and support safety claims in pregnant and lactating women"*
- *"what is Health Canada's scientific basis was for claiming safety [of COVID-19 modRNA shots] in pregnant and lactating women"*

Government of Canada / Gouvernement du Canada

INQUIRY OF MINISTRY
DEMANDE DE RENSEIGNEMENT AU GOUVERNEMENT

PREPARE IN ENGLISH AND FRENCH MARKING "ORIGINAL TEXT" OR "TRANSLATION"
PRÉPARER EN ANGLAIS ET EN FRANÇAIS EN INDIQUANT "TEXTE ORIGINAL" OU "TRADUCTION"

QUESTION NO./Nº DE LA QUESTION	BY / DE	DATE
Q-2163	Mrs. Wagantall (Yorkton—Melville)	December 13, 2023

Reply by the Minister of Health
Réponse du ministre de la Santé

Signed by the Honourable Mark Holland

PRINT NAME OF SIGNATORY
INSCRIRE LE NOM DU SIGNATAIRE

SIGNATURE
MINISTER OR PARLIAMENTARY SECRETARY
MINISTRE OU SECRÉTAIRE PARLEMENTAIRE

QUESTION

With regard to Health Canada's COVID-19 vaccine safety monitoring and assessment for pregnant and lactating (P&L) women: (a) are observational trials and surveillance systems adequate to establish safety or must this be accomplished through randomized trials; (b) were randomized control trials (RCTs) used to obtain approval and support safety claims in P&L women, and, if so, what are the details, including, the (i) name of the trial, (ii) date of the trial; (c) did the trials in (b) (i) include all trimesters, (ii) include high risk pregnancies, (iii) include clinical and sub-clinical testing, (iv) include a trial group measured against a placebo control group, (v) include a control group which remained intact for multiple years to establish long term safety data, (vi) be sufficiently powered to detect common and rare side-effects; (d) if the answer to (b) is negative, what trials were used to evaluate the safety in the P&L population prior to approval in this cohort, including the (i) trial name, (ii) trial date, (iii) analysis of the trial; (e) did Health Canada (HC), the Public Health Agency of Canada, the National Advisory Committee on Immunization or Canadian Institute for Health Information inform pregnant and lactating women of the Pfizer monograph "No data are available yet regarding the use of COMIRNATY Omicron XBB.1.5 during pregnancy" or "No data are available yet regarding the use of COMIRNATY Omicron XBB.1.5 during breast- feeding. It is unknown whether COMIRNATY Omicron XBB.1.5 is excreted in human milk. A risk to the newborns/infants cannot be excluded"; (f) if the answer to (e) is affirmative, how were pregnant and lactating women advised of the Pfizer safety data; (g) what is HC's scientific basis for claiming safety of the XBB.1.5 mRNA product in P&L women; (h) what rigorous prospective studies, with active patient reporting and monitoring, is HC relying upon to support their safety claims in the P&L population for the use of Omicron XBB.1.5 product?

REPLY / RÉPONSE

ORIGINAL TEXT / TEXTE ORIGINAL [X]
TRANSLATION / TRADUCTION [ ]

Responses from Health Canada and the Public Health Agency of Canada

(b) None of the COVID-19 vaccine manufacturers sought indications for use in pregnant or lactating women or submitted RCTs in pregnant/lactating women for regulatory evaluation. The Product Monographs included statements about the uncertainties related to pregnancy and lactation. The product monographs can be accessed using the following link: COVID-19 vaccines and treatments portal (canada.ca).

(c) As indicated above, there were no RCTs in pregnant/lactating women submitted for regulatory evaluation as the vaccine sponsors did not seek an indication for use in pregnant and lactating women.

(d) & (g) The regulatory basis for the decision taken by Health Canada are publicly available (https://covid-vaccine.canada.ca/), for each specific vaccine see Regulatory Decision Summary and Summary Basis of Decision documents.

As indicated in the specific Product Monographs, it is noted that the safety and efficacy of these vaccines in pregnant women have not yet been established. No indication for use in pregnant or lactating women was sought by the vaccine sponsors or authorized by Health Canada.

(h) Health Canada has not approved any safety claims with regard to pregnant and lactating women.

PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

COMIRNATY®

COVID-19 mRNA vaccine

Suspension for Intramuscular Injection

Single Dose Vial
30 mcg/0.3 mL
10 mcg/0.3 mL

Multiple Dose Vial
30 mcg/0.3 mL (6 doses/vial)
10 mcg/0.3 mL (6 doses/vial)
3 mcg/0.3 mL (3 doses/vial after dilution)

Single Dose Prefilled Syringe
30 mcg/0.3 mL

Active Immunizing Agent

Omicron KP.2 variant

ATC Classification J07BN01

COMIRNATY® [COVID-19 mRNA Vaccine] vaccine is indicated for:

- Active immunization against coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus in individuals 6 months of age and older.

COMIRNATY® [COVID-19 mRNA Vaccine] vaccine has been issued marketing authorization with Terms and Conditions that need to be met by the Market Authorization Holder to ascertain the continued quality, safety and effectiveness of the vaccine.

Patients should be advised of the nature of the authorization. For further information for COMIRNATY® [COVID-19 mRNA Vaccine] please refer to Health Canada's COVID-19 vaccines and treatments portal.

BioNTech Manufacturing GmbH
An der Goldgrube 12
Mainz, Rhineland-Palatinate, Germany 55131

Imported and distributed by:
Pfizer Canada ULC
17,300 Trans-Canada Highway
Kirkland, Quebec, Canada H9J 2M5

Submission Control Number: 284411

Date of Initial Authorization:
September 28, 2023

Date of Revision:

October 25, 2024

individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine.

7.1 Special Populations

7.1.1 Pregnant Women

No data are available yet regarding the use of COMIRNATY during pregnancy.

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/fetal development, parturition, or post-natal development (see 16 NON-CLINICAL TOXICOLOGY).

7.1.2 Breast-feeding

No data are available yet regarding the use of COMIRNATY during breast-feeding.

It is unknown whether COMIRNATY is excreted in human milk. A risk to the newborns/infants cannot be excluded.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for immunization against COVID-19.

7.1.3 Pediatrics

The safety and efficacy of COMIRNATY in children under 6 months of age have not yet been established.

7.1.4 Geriatrics

Clinical studies of COMIRNATY (Original) and COMIRNATY Original & Omicron BA.4/BA.5 included participants 65 years of age and older and their data contribute to the overall assessment of the safety and efficacy of COMIRNATY (See 8 ADVERSE REACTIONS and 14 CLINICAL TRIALS).

8 ADVERSE REACTIONS

8.1 Adverse Reaction Overview

The safety of COMIRNATY is inferred from safety data of the prior COMIRNATY (Original) and COMIRNATY Original & Omicron BA.4/BA.5 vaccines.

Safety data accrued with the COMIRNATY (Original) and COMIRNATY Original & Omicron BA.4/BA.5 formulations are relevant to the subsequent variant updated COMIRNATY vaccines because these vaccines are manufactured using the same process.

8.1.1 COMIRNATY Original & Omicron BA.4/BA.5 (15 mcg/15 mcg)

Participants ≥12 Years of Age – After a Dose of COMIRNATY Original & Omicron BA.4/BA.5 as a Second Booster (4th Dose)

Study C4591044 (Study 5) is an ongoing Phase 2/3 study to evaluate the safety, tolerability, and immunogenicity of new bivalent vaccines including COMIRNATY Original & Omicron BA.4/BA.5. In Cohorts 2 and 3 of the study 317 participants 12 years and older and 410 participants 18 years and older, respectively, received COMIRNATY Original & Omicron BA.4/BA.5 30 mcg (15/15 mcg) as a second booster dose following a previous primary series and one booster dose of COMIRNATY. The

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But this…

Date of Revision:

October 25, 2024

…postdates all the science by >1 year

- ModRNA from COVID-19 shots can spread throughout the body, including occasionally into human breast milk, where it is often fragmented
- This is not surprising since the systemic distribution of the lipid nanoparticles that carry the modRNAs has been known for more than a decade
- There is evidence that human milk exosomes and their microRNAs can survive digestion and be taken up by human intestinal cells
- The current model of modRNA biodistribution for breast milk is this:
  - Lipid nanoparticles carrying the modRNA systemically diffuse to mammary glands via the blood
  - The LNPs deliver the modRNAs into mammary cells
  - Mammary cells package the modRNAs into exosomes
  - Exosomes carrying the modRNAs get released from the mammary cells and get into the breast milk
- So, how can it be claimed that this science is “unknown”?

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Biodistribution of mRNA COVID-19 vaccines in human breast milk

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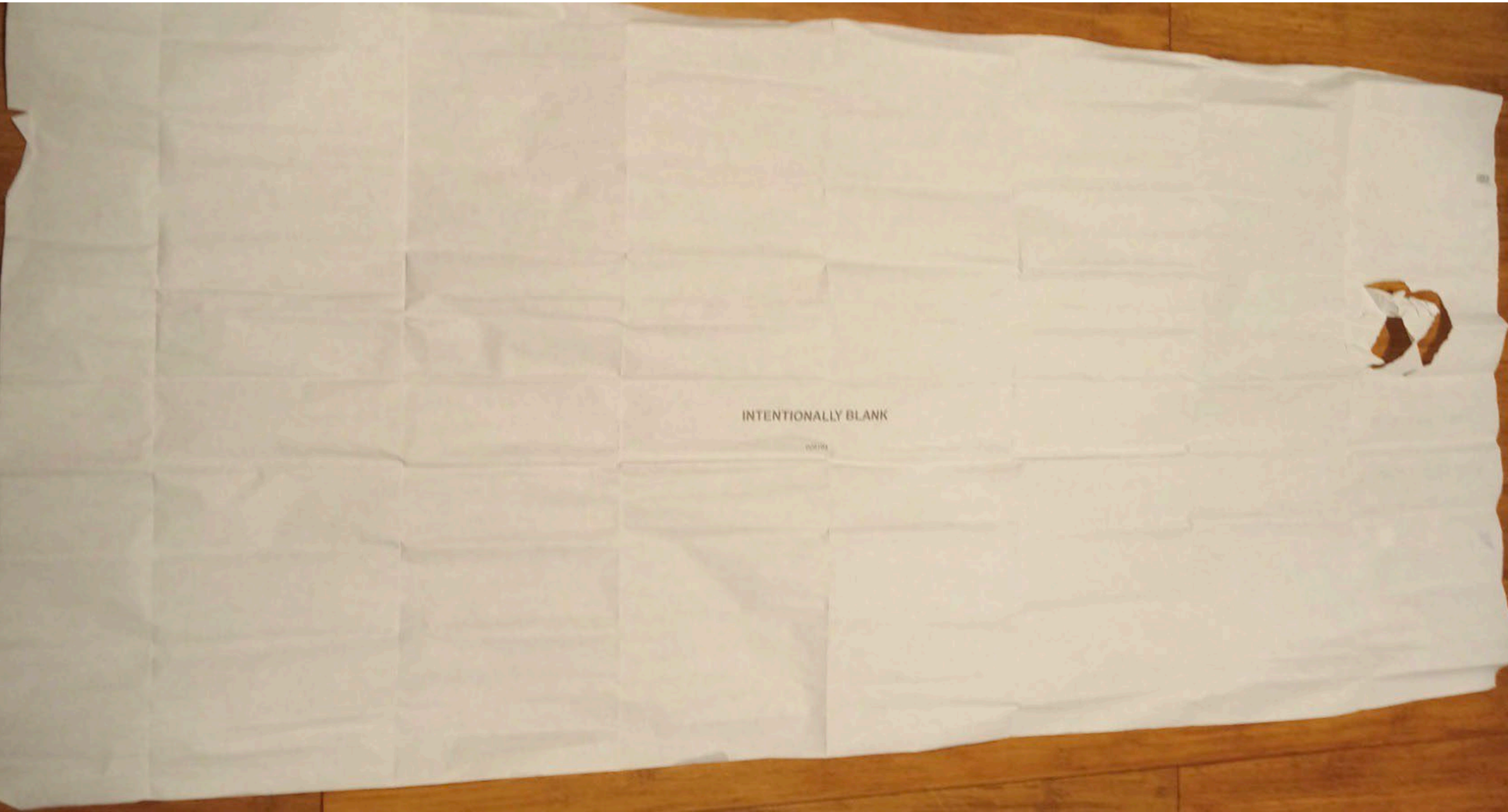
eBioMedicine 2023;96: 104800

Published Online 19 September 2023
https://doi.org/10.1016/j.ebiom.2023.104800

Summary

Background **COVID-19 mRNA vaccines play a vital role in the fight against SARS-CoV-2 infection. However, lactating women have been largely excluded from most vaccine clinical trials. As a result, limited research has been conducted on the systemic distribution of vaccine mRNA during lactation and whether it is excreted in human breast milk (BM). Here, we evaluated if COVID-19 vaccine mRNA is detectable in BM after maternal vaccination and determined its potential translational activity.**

Information insert for the COVID-19 shot taken directly from a box at a clinic held in Victoria, BC, in February 2025:



ATIP: Release Package - A-2023-001138; Pfizer Monthly Safety Summary Report #7 (July 2021)
(Discusses the Research Management Plan required for authorization by interim order of the COVID-19 shot)

10.1 SUMMARY OF SAFETY CONCERNS

The summary of safety concerns for the Pfizer-BioNTech COVID-19 Vaccine can be found below. This summary includes ongoing safety concerns from the European RMP (EU RMP) version 2.0 dated 29 April 2021 and Canadian addendum to the EU RMP dated May 2021 (control no. 253040).

Important identified risk	Anaphylaxis
Important potential risk	Vaccine-Associated Enhanced Disease (VAED), including Vaccine-Associated Enhanced Respiratory Disease (VAERD)
Missing information	Use in pregnancy and while breast feeding
	Use in immunocompromised patients
	Use in frail patients with co-morbidities (e.g., COPD, diabetes, chronic neurological disease, cardiovascular disorders, active tuberculosis)
	Use in patients with autoimmune or inflammatory disorders
	Interaction with other vaccines
	Long-term safety data
	Use in paediatric individuals <12 years of age
	Vaccine effectiveness

Release Package - A-2023-001138; Pfizer Monthly Safety Summary Report #7 (July 2021)

10.1.3 Missing information

Missing information	Post-marketing case evaluation

MHPD – PROTECTED B ***Control # 254752***

Use in pregnancy and while breast feeding	There were 533 cases of use in pregnancy and 250 cases of use while breast feeding during the reporting period. Of the 250 cases of use while breast feeding, there were 193 cases of breast feeding baby and 57 cases of breast feeding mother. Among the 193 cases of breast feeding baby, 41 cases reported clinical events that occurred in the infant/child exposed to vaccine via breast feeding. Clinical events that were reported more than once were coded to the PTs Pyrexia (7), Diarrhoea, Malaise, Rash (5 each), Cough, Fatigue, Infantile vomiting, Vomiting (4 each), Agitation, Infant irritability, Rhinorrhoea (3 each), Crying, and Irritability (2 each). Among the 57 cases of breast feeding mother, 14 cases reported lactation issues. Other frequently reported (>5% of cases) events were coded to the PTs Maternal exposure during breast feeding (45), Product use issue (44), Off label use (43), Headache (10), Pyrexia (8), Fatigue (6), Breast pain, Heavy menstrual bleeding, Pain (5 each), Chills, Dizziness, Mastitis, Menstrual disorder, Myalgia, Pain in extremity (4 each), Axillary pain, Cough, Dysmenorrhoea, Peripheral swelling, Tenderness, and Vaccination site pain (3 each).

I was raked over the coals for suggesting this might be a POTENTIAL concern!!!

21.2% of cases of breast feeding by a vaxxed mom resulted in clinical events!

24.6% lactation issues!

- Failing to acknowledge the non-inferiority of naturally acquired immunity in pregnant and breast-feeding women makes the evidence against proper informed consent even more egregious
- As of 1.5 years ago, there were 108 published papers showing the superiority of naturally acquired immunity

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Hard Questions That Demand Answers

- Supreme Court of Canada says the standard for informed consent is to be measured by what a reasonably thinking pregnant or breastfeeding woman would have expected to hear before consenting
- Would a pregnant or breastfeeding Mom have reasonably expected disclosure that "*Health Canada has not approved any safety claims with regard to pregnant and lactating women*"?
    - …that the manufacturers never asked for their shots to be given to these women?
    - …that no data were submitted to support giving these women the shots?
    - …that Health Canada was investigating early post-marketing surveillance data showing that for breastfeeding Moms that had inadvertently received the shots, 21.2% of the suckling infants had clinical issues?
        - …and 24.6% of the Moms had lactation issues?
    - …should evidence of naturally acquired immunity been accepted as reasonable evidence of immunity for these women?
- Based on the evidence, was the standard for informed consent met for pregnant and breastfeeding women?
- Are these kinds of questions worth discussing in transparent public forums or should those posing them be gaslighted and subjected to dangerous *ad hominem* attacks and censorship?

Public Dissemination of Misinformation About Alberta's Report

Calgary Watch

Alberta COVID-19 report widely criticized

A UCP government-funded COVID-19 pandemic review has critics up in arms over its suggestion that vaccination should stop immediately. Teri Fikowski reports.

This misrepresents Alberta's report, which stated, "*Immediately halt the use of all COVID-19 vaccines* ***without full disclosure to patients regarding both the safety and efficacy issues by their physician***."

Timothy Caulfield ✓
@CaulfieldTim

🚨 More anti-science horror in Alberta? 🚨

Alberta task force recommends halt of COVID vaccines in new report
theglobeandmail.com/canada/article...

Recommended (as reported by @globeandmail):
- "...COVID-19 vaccines be halted"
- "protect 'public discussion of alternative medical treatments'"
- "value of drugs such as ivermectin..."

Dark Age 2.0? by @alanna_smithh @CarrieTait cc @TheBreakdownAB @UbakaOgbogu @AntibioticDoc @DrShazmaMithani @ryanjespersen @Albertadoctors @AHS_media @UAlbertaSPH @UAlberta_FoMD

From theglobeandmail.com

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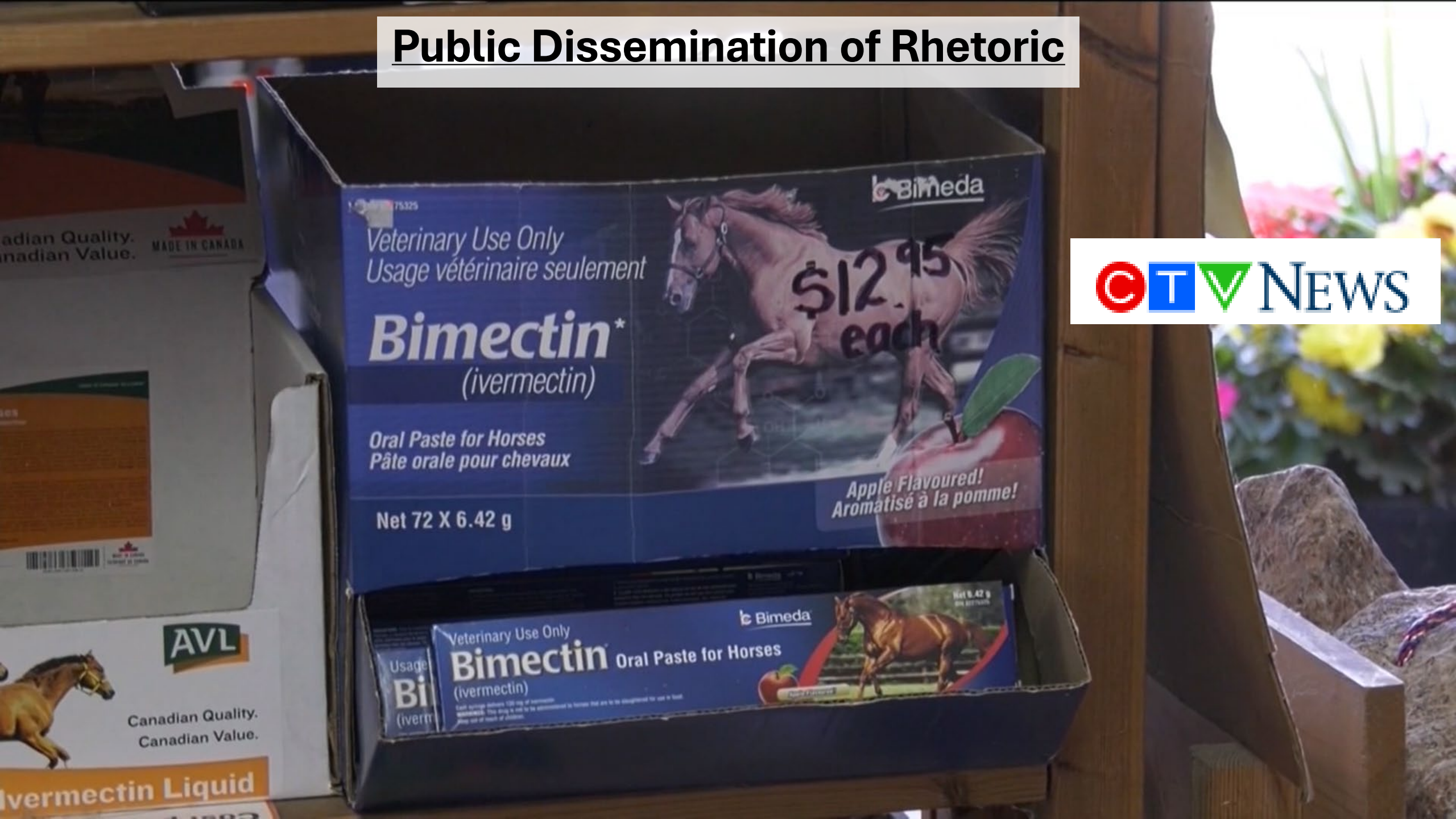
Public Dissemination of Rhetoric and *Ad Hominem* Attacks

Public Dissemination of Rhetoric



CTV NEWS

Public Dissemination of Rhetoric and *Ad Hominem* Attacks

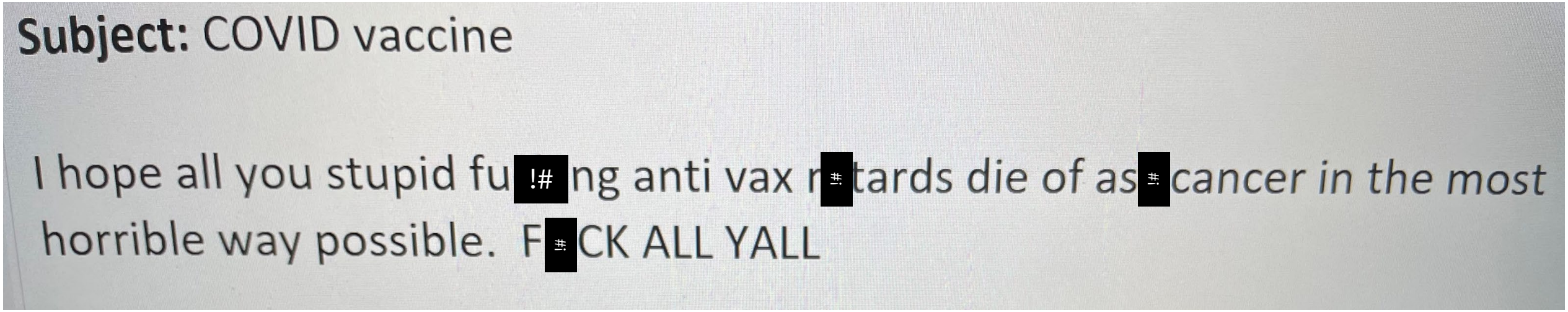
https://www.ctvnews.ca/calgary/video/2025/01/28/alberta-covid-19-report-widely-criticized/

- Dr. Shelley Duggan, President, Alberta Medical Association
- Claimed the report "*contains misinformation*", "*and we all know that misinformation is a huge problem right now and* ***people die because of it***"
- Instead of providing a dissenting view backed by evidence, Dr. Duggan made an *ad hominem* attack, accusing experts that contributed to the report of killing people
- This event required heightened security for the speakers because of the public promotion of this kind of dangerous rhetoric
- Dr. Duggan's approach is harmful and unprofessional, and Albertans should consider whether such people are fit to lead their medical association

- To people like Dr. Duggan: feel free to come to the table and engage in reasonable, transparent, objective, and evidence-based discussions of health science
- We won't treat you like you treat us

An example of why public promotion of *ad hominem* attacks is dangerous.

The following email was sent to MLA Eric Bouchard and was directed at everyone involved with the report...



...this is merely one example of what those of us that are speaking today, and many others, have been chronically exposed to for the past four years.

How Do We Move Forward?

Immediately stop the COVID-19 shots for children, and pregnant and breastfeeding Moms

Consider placing a moratorium on all RNA-based vaccine technologies, especially self-amplifying RNA, for humans and the animals we eat until the science and deceit can be untangled

Ad hominem attacks must stop; treat others the way you would want to be treated; grant opportunities for exchanges of ideas instead of rendering judgements based on assumptions

- This includes leadership at Alberta Health Services, Alberta Medical Association, Canadian Medical Association, most of the membership of ScienceUp First, and much of the legacy media, and many more; fundamental changes are needed

Censorship, especially under the guise of 'combating health misinformation', must end

- Organizations like ScienceUpFirst, which is run out of Alberta by Prof. Timothy Caulfield and senator Stan Kutcher, needs to be investigated
- How can those who disseminate a substantial amount of misinformation be granted the authority to determine what truth is for the rest of us, especially those with superior expertise?

Unfair and unbalanced messaging by media outlets needs to end; many need to be investigated to assess whether they have contravened their own editorial conduct polices

How Do We Move Forward?

We need transparency within our health institutions; they have profound financial conflicts of interest with big pharm; their leadership needs to be evaluated because there are a growing number of examples of deceit and even lying, which has predictably broken public trust

Health agencies in Canada need to stop using PCR testing as the sole basis for diagnosing diseases, they need to incorporate functional testing to assess true risk of transmission, and they need to promote monitoring of acquisition of immunity, whether naturally acquired or vaccine-induced, while recognizing the validity of the former

Canada's health policies must be internally derived to best serve the interests of Canadians; serving the interests of global entities of questionable integrity must stop

Judges need to stop granting judicial notice to health agencies; health officials must be compelled to show up in courts to defend their statements just like all other subject matter experts

Careers need to be restored for all those who were 'left to the wolves' while negligent health regulators sat on data that confirmed the concerns being expressed

Alberta's report has reignited debate about the handling of the COVID-19 pandemic

- One side continues to refuse to come to the table to have a discussion
- The sitting Government of Alberta needs to compel experts on both sides to testify under oath in a formal parliamentary hearing