Presentation to the National Citizen's Inquiry

Alan Cassels

Langely BC,
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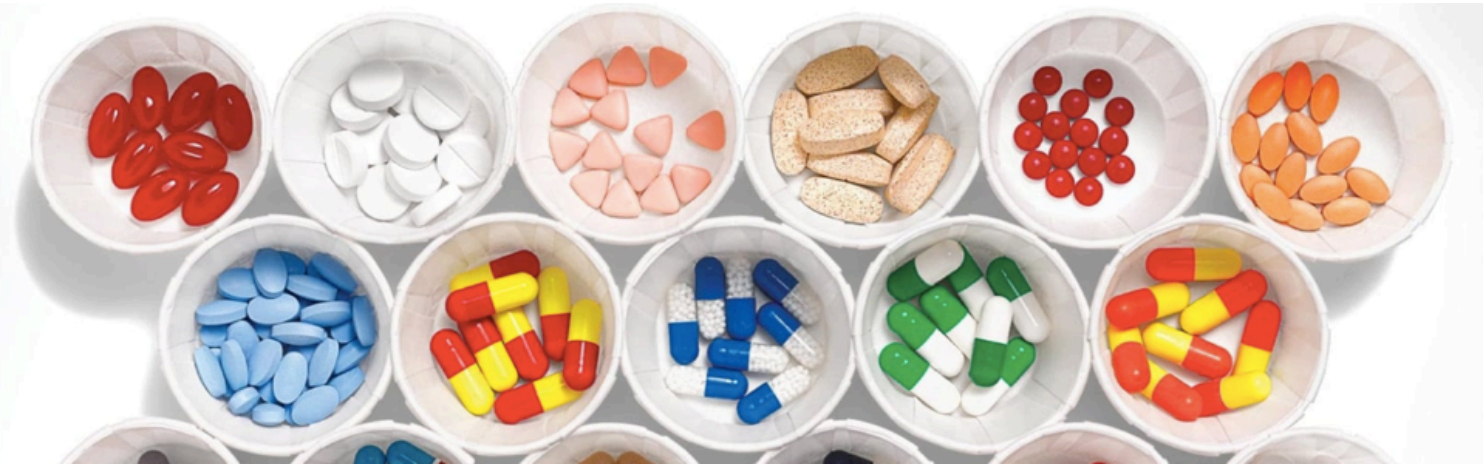
#AKECassels

Disclosures

- Former employee of the premier drug analysis group in Canada, UBC's Therapeutics Initiative.
- In 29 years I have never had any financial conflicts of interest with companies that manufacture or sell pharmaceuticals.
- Currently self-employed.
- Receive royalties from the sale of books I've written.



Who is Alan Cassels? Brief Bio

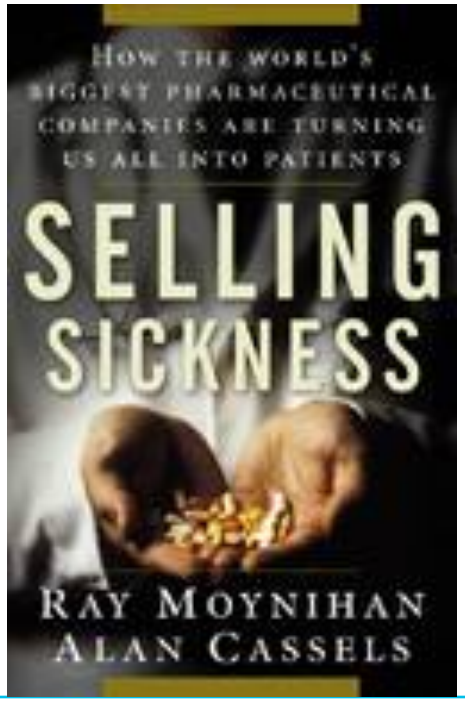
- Graduated from the Royal Military College with a degree in English.
- Served as a Naval Lieutenant in the Canadian Armed Forces on both coasts and in two UN missions (Cambodia and South Africa).
- Master's Degree in Public Administration, University of Victoria with a focus on pharmaceutical benefits policies.
- Have conducted, managed and published more than 20 research studies in pharmaceutical policy since 1994 (29 years) focusing on BC, Canada and overseas.

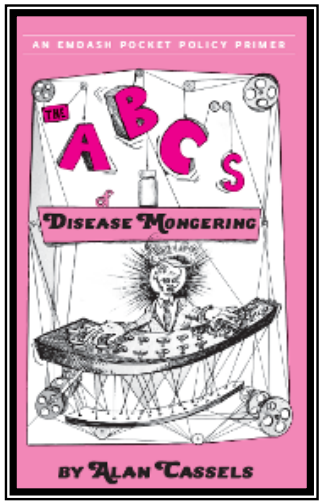
Who is Alan Cassels? Brief Bio

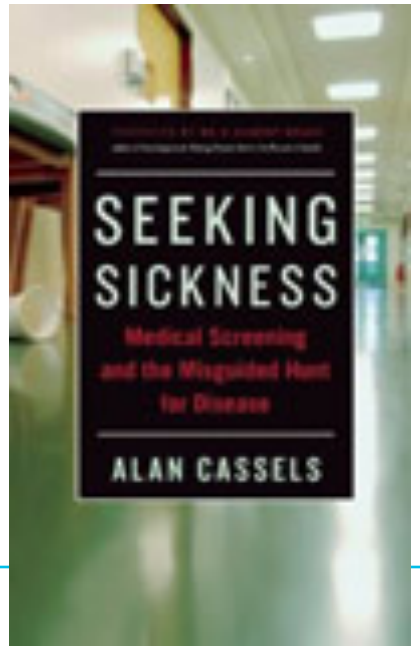
Writing and Lecturing:

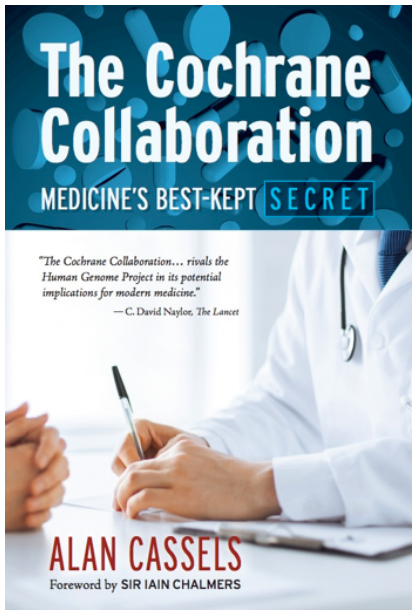
- I have published more than 30 peer reviewed articles and studies relating to drug benefits management, drug regulation and drug marketing.
- I have written and published more than 400 articles and opinion pieces on evidence-based medicine and four books (including an international bestseller and a Canadian bestseller.)
- I have lectured to university classes and professional societies in journalism, actuarial science, law, public administration, medicine, and pharmacy.
- In 2012, I received the Queen Elizabeth II Diamond Jubilee Medal, by MP Denise Savoie citing my *"exceptional work as an author, pharmaceutical policy researcher and consumer advocate for evidence-based medicine".*

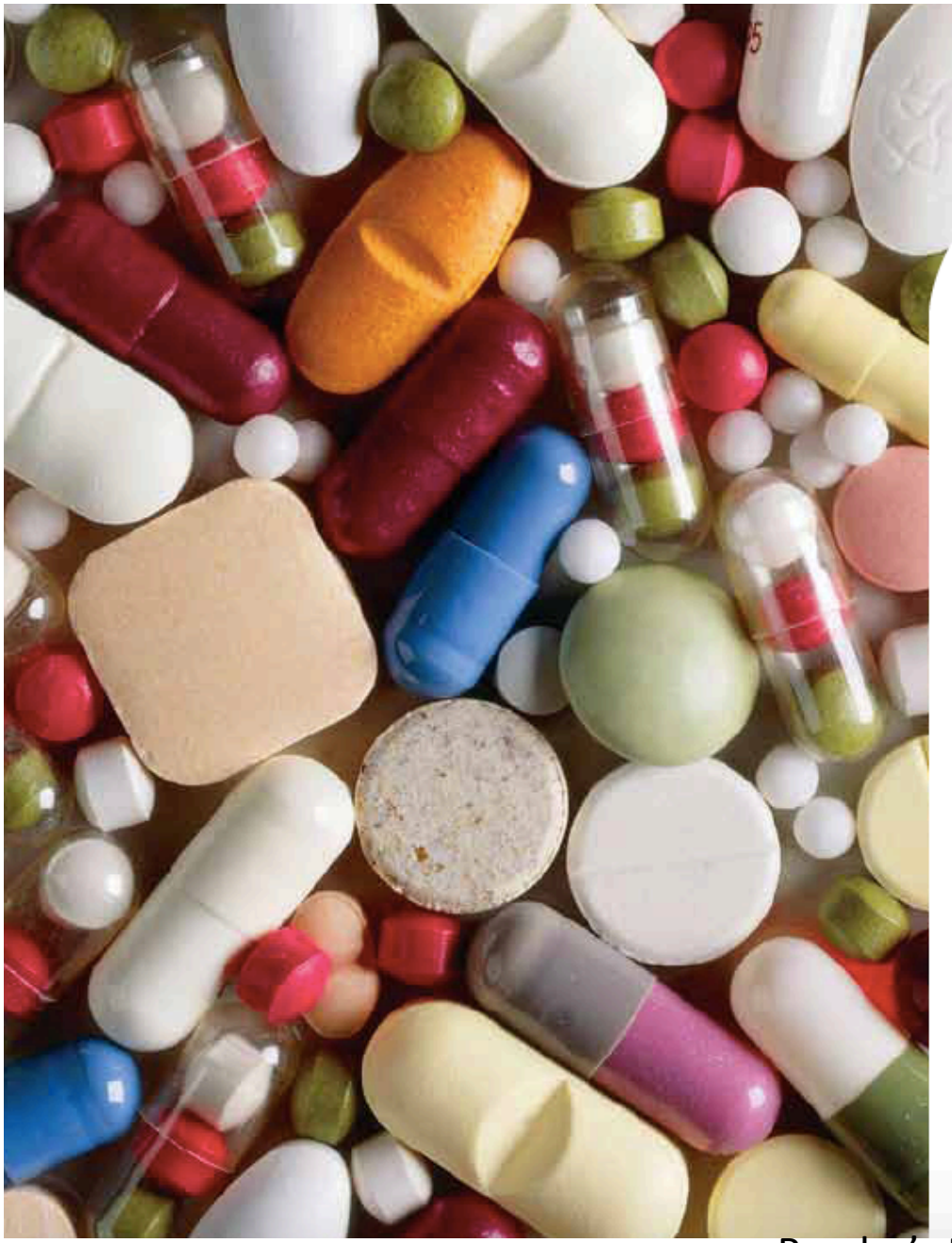
"Be careful of reading health books.
You may die of a misprint."
--Mark Twain











TOO MANY PILLS

Multiple-prescription drug use is on the rise among Canadian seniors. Are doctors too quick to prescribe medications to elderly patients?

BY ALAN CASSELS

Fervid Trimble was a contented, energetic 87-year-old who was enjoying life in a senior's residence in Seattle. With a daughter living nearby, and a son and daughter-in-law in Vancouver, she embraced her independence: She had her own apartment in the residence and was surrounded by her own belongings and a community of friends.

One morning, after waking up dizzy and disoriented, she was admitted to the building's health centre, a sort of in-house hospital, where doctors put her on several new drugs. That's when the real trouble began. Fervid's physical and mental health continued to deteriorate and as her hospitalization lengthened, her doctors added more meds to her regimen—digoxin for her heart, antibiotics for an infection and drugs for pain. Feeling lonely and isolated, she was also prescribed antidepressants and anti-anxiety pills. At one point she was on a total of nine different medications.

PHOTO: DEA/G.GIGOLINI/GETTY

Reader's Digest Canada, March 2011

The Therapeutics Initiative and Alan Cassels

- The Therapeutics Initiative (TI) at UBC is one of the best critical drug agencies in Canada evaluating drug evidence to advise physicians, pharmacists, and policymakers on the benefits and harms of drugs.
- The TI does not take money from the pharmaceutical industry and has been entirely funded by the BC Ministry of Health since 1994.
- Has a history of getting the evidence right on drugs. Its critical analysis of the C0X-II inhibitors, a class of drugs to treat arthritis, exposed fraudulent trial practices and hiding of drug harms. Subsequent drug benefits policies in BC around these drugs probably saved 500- to 1,000 lives in BC from avoidable heart attack deaths.
- Since 1994, I have worked alongside the TI began, occasionally on contract, writing therapeutics letters, and participating in drug benefits research projects.
- In 2018 I was hired as the Communications Director at the Therapeutics Initiative and received praise for my work, especially my efforts to include the perspective of consumers in our work.

Alan Cassels published a 142 word letter to the Editor of the Globe and Mail on Feb 12, 2022

Re Driven By Misinformation (Opinion, Feb. 12, 2022): I don't see my unvaccinated friends, neighbours or colleagues as misguided, misinformed ignoramuses who spout conspiracy theories and propagandistic clichés. Maybe I don't get out enough.

They are mostly highly educated, a class that includes university professors, engineers, researchers, doctors, librarians and even some journalists. I find these are intelligent people with nuanced interpretations of science, who spend a lot of time reading the annoying small print of research studies and asking awkward questions. I therefore find it tiresome when they are labelled as misinformed ignoramuses who don't "follow the science."

Alan Cassels' 142 word letter continued…

In the drug-safety world there is a truism: Drug safety never leads, it always follows. It is a sentiment that might be best summed up by a line from the singer Tom Waits: "The large print giveth and the small print taketh away."

--Alan Cassels, Victoria BC

What happened next to Alan Cassels?

Several days later I was called into an office with the two co-Directors of the Therapeutics Initiative and told *"You can't be publishing letters like this critical of government policy."*

I explained that all my letter did was criticize the Globe and Mail's bigoted description of my unvaccinated friends and colleagues. (similar to the scornful condemnation of unvaccinated people by public officials including our Prime Minister). In the letter I didn't not make any mention of government policy, nor did I identify myself as a member of the Therapeutics Initiative.

I was told specifically: *"this could jeopardize our funding."*

Three months later, on June 14th,I was told to pack up my desk, hand in my computer and keys and leave immediately. This is called "fired without cause."

What does the research, indication or approved monograph say about Covid-19 vaccines?

- Quality research (double blind randomized trials)
- Indication: What is the drug/ vaccine approved to treat?
- The official Product Monograph (Health Canada Approved Label)
- Marketing claims

What is a Product Monograph?

"A Product Monograph is a factual, scientific document on a drug product that, devoid of promotional material, describes the properties, claims, indications and conditions of use of the drug and contains any other information that may be required for optimal, safe and effective use of the drug."

Health Canada, 2020

What is an “indication”?

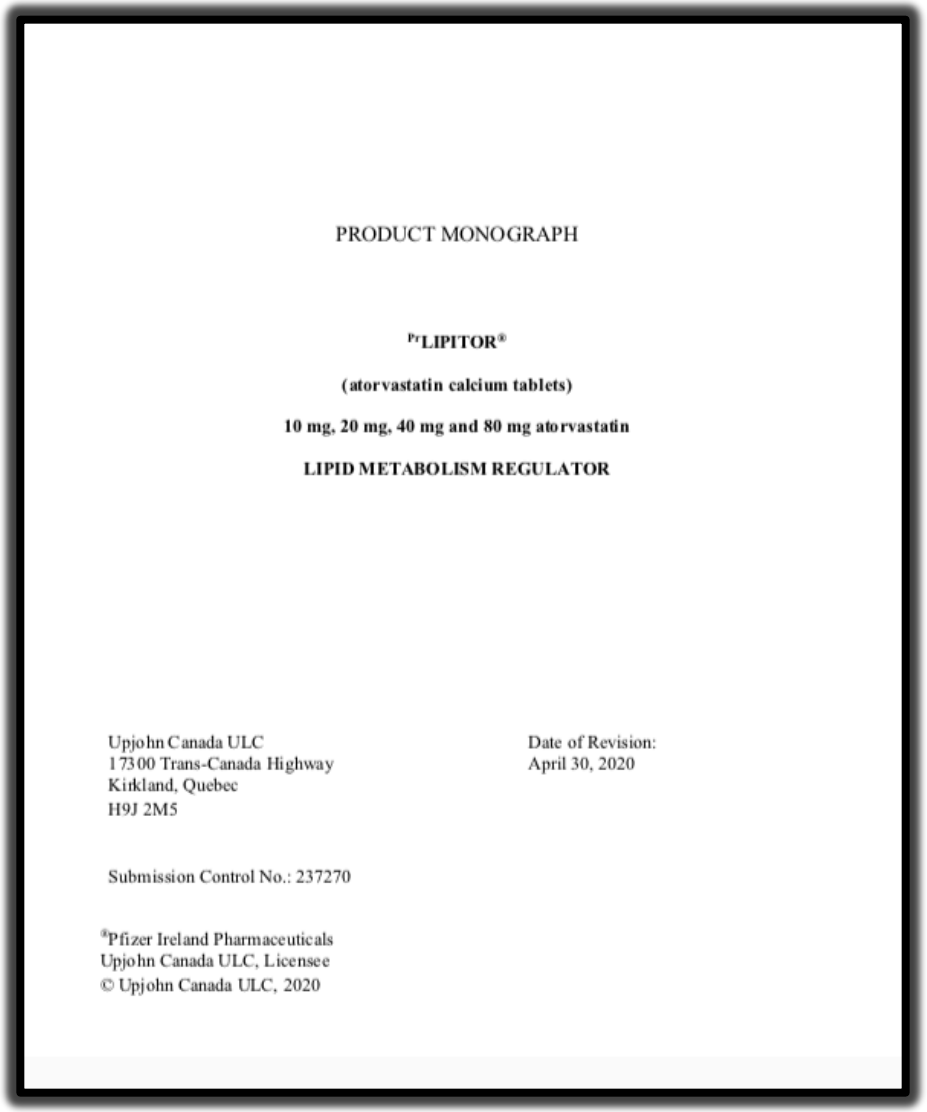
In medical terminology, an "indication" for a drug refers to the approved use of that drug for treating a particular disease.

- If Health Canada or the FDA determines that there is enough evidence to approve the drug for the indication (treatment of the disease), the indication becomes a labeled indication for the drug.
- Regulatory approval means that the company can include the information in their package insert (product label) regarding the use of the drug for that indication.
- The manufacturer can claim that the drug is effective for the approved indication and use this information to market their drug to patients and physicians.
- **Manufacturers are not allowed to market their drugs for indications that have not been approved by the FDA or Health Canada.**

Where is the gap between the evidence and the marketing? The example of atorvastatin.

Is this drug or other statins like it being used properly?, ie: for uses that have been scientifically proven, indicated on the label, and approved by the regulator?

Product Monograph: Atorvastatin (Lipitor)



PRODUCT MONOGRAPH

PrLIPITOR®

(atorvastatin calcium tablets)

10 mg, 20 mg, 40 mg and 80 mg atorvastatin

LIPID METABOLISM REGULATOR

Upjohn Canada ULC
17300 Trans-Canada Highway
Kirkland, Quebec
H9J 2M5

Date of Revision:
April 30, 2020

Submission Control No.: 237270

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Upjohn Canada ULC, Licensee
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This 56 page document
Can be found here

What is Lipitor “indicated” for?

- LIPITOR is indicated to reduce the risk of myocardial infarction in adult hypertensive patients without clinically evident coronary heart disease, but with at least three additional risk factors for coronary heart disease such as age >55 years, male sex, smoking, type 2 diabetes, left ventricular hypertrophy, other specified abnormalities on ECG, microalbuminuria or proteinuria, ratio of plasma total cholesterol to HDL-cholesterol >6, or premature family history of coronary heart disease.

- LIPITOR is also indicated to reduce the risk of myocardial infarction and stroke in adult patients with type 2 diabetes mellitus and hypertension without clinically evident coronary heart disease, but with other risk factors such as age ≥55 years, retinopathy, albuminuria or smoking.

- LIPITOR is indicated to reduce the risk of myocardial infarction in patients with clinically evident coronary heart disease.

Health Canada approved Product Monograph, p.4

So who should* take Lipitor?

- 85 year old man with high cholesterol but no history of heart disease?
- 70 year old woman who has normal blood pressure, but smokes and has high cholesterol?
- 50 yr old male bricklayer who has a stent in his heart?
- A 27 year old pregnant woman?
- A 32 year old woman who has toenail fungus?

* Should: would be indicated for taking Lipitor based on evidence of sufficient quality, and federal approval.

Health Canada approved Product Monograph, p.4

Who should take Lipitor?

The answer to all these patients is NONE.

- These are all off-label indications. Ie: the drug does not have sufficient evidence to demonstrate benefit in these patients, AND has not been approved by our regulator to be used in them. Doctors can still prescribe the drug for anyone they want to but those uses are not sufficiently tested, scientifically–supported, or federally-approved indications.
- Drug companies CANNOT MARKET THEIR DRUGS FOR OFF-LABEL PURPOSES. It is illegal to do so.

Health Canada approved Product Monograph, p.4

This is why drug companies don't market "off-label"

THE UNITED STATES DEPARTMENT of JUSTICE

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JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE — Wednesday, September 2, 2009

Justice Department Announces Largest Health Care Fraud Settlement in Its History

Pfizer to Pay $2.3 Billion for Fraudulent Marketing

WASHINGTON – American pharmaceutical giant Pfizer Inc. and its subsidiary Pharmacia & Upjohn Company Inc. (hereinafter together "Pfizer") have agreed to pay $2.3 billion, the largest health care fraud settlement in the history of the Department of Justice, to resolve criminal and civil liability arising from the illegal promotion of certain pharmaceutical products, the Justice Department announced today.

Pharmacia & Upjohn Company has agreed to plead guilty to a felony violation of the Food, Drug and Cosmetic Act for misbranding Bextra with the intent to defraud or mislead. Bextra is an anti-inflammatory drug that Pfizer pulled from the market in 2005. Under the provisions of the Food, Drug and Cosmetic Act, a company must specify the intended uses of a product in its new drug application to FDA. Once approved, the drug may not be marketed or promoted for so-called "off-label" uses – *i.e.*, any use not specified in an application and approved by FDA. Pfizer promoted the sale of Bextra for several uses and dosages that the FDA specifically declined to approve due to safety concerns. The company will pay a criminal fine of $1.195 billion, the largest criminal fine ever imposed in the United States for any matter. Pharmacia & Upjohn will also

Covid-19 Vaccines Product Monograph (the example of Comirnaty[tm])

Pfizer About Us Science Our Products Community Support News Contact Us CA EN | FR

PFIZER-BIONTECH COVID-19 VACCINE (COVID-19 mRNA Vaccine)

On September 16, 2021, Health Canada granted full approval (Notice of Compliance or NOC) for COMIRNATY™. The vaccine was initially authorized for use in Canada under an Interim Order Authorization on December 9, 2020 under the name Pfizer-BioNTech COVID-19 Vaccine.

COMIRNATY™ and the Pfizer-BioNTech COVID-19 Vaccine have the same formulation, and are considered interchangeable by Health Canada. For additional information, please refer to the Health Canada approved Product Monograph for COMIRNATY™ (available here).

Although the vaccine's brand name is now COMIRNATY™, Canada will continue to receive vials of the vaccine labeled as Pfizer-BioNTech COVID-19 Vaccine and a transition to new labeling in Canada with the COMIRNATY™ name will occur at a later date. This approval has no impact on any vials of the Pfizer-BioNTech COVID-19 Vaccine currently in Canada and these are usable until their expiry date. As a reminder, vials of Pfizer-BioNTech COVID-19 Vaccine with an expiry date of August 2021 through February 2022 printed on the label may remain in use for 3 months beyond the printed date as long as all approved storage conditions have been maintained.

This 83 page document is here

Comirnaty Approved Product Label: Indication

PART I: HEALTH PROFESSIONAL INFORMATION
INDICATIONS
COMIRNATY (COVID-19 Vaccine, mRNA) is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS- CoV-2) in individuals 6 months of age and older. (page 5)

The primary endpoint was defined as any symptomatic COVID-19 case confirmed by Reverse Transcription-Polymerase Chain Reaction (RT-PCR). (p.62)

Case definition defined by the protocol: (at least 1 of) fever, new or increased cough, new or increased shortness of breath, chills, new or increased muscle pain, new loss of taste or smell, sore throat, diarrhea or vomiting.

Health Canada approved product monograph for Comirnaty

Skill Testing Question: What was the Cominarty^{tm} vaccine indicated for?

Did it?

- Prevent hospitalizations?
- Prevent death?
- Prevent heart attacks, strokes or cancers?
- Prevent viral transmission?

NO: It showed a reduction in Covid-19 symptoms with a confirmed PCR test.

Skill testing question #2: How many of the six Federally Approved Covid-19 Vaccines in Canada are **Indicated** to prevent viral transmission?

- Pfizer/BioNTech; (Comirnaty)
- Moderna (Spikevax)
- Janssen and Johnson & Johnson (Jcovden)
- AstraZeneca. (Vaxsevria)
- Medicago (Covifenz)
- Novavax (Nuvaxovid)

How many are Indicated to prevent transmission?

- Pfizer/BioNTech; (Comirnaty)
- Moderna (Spikevax)
- Janssen and Johnson & Johnson (Jcovden)
- AstraZeneca. (Vaxsevria)
- Medicago (Covifenz)
- Novavax (Nuvaxovid)

NONE

Of the six Federally Approved Covid-19 vaccines in Canada how many even mention the word "transmission" in the product monograph?

NONE

The word 'transmission' or any of its correlates indicating viral conveyance to another person, does not appear in ANY Covid-19 product monograph, therefore the *manufacturers are prevented BY LAW from claiming their vaccine prevents viral transmission to other people.*

Why focus on Transmission?
Because the key marketing strategy for the vaccine focused on people's sense of altruism: *"I'm getting vaccinated to protect grandma…."*

- None of the approved Covid-19 vaccines in Canada have been shown to prevent the transmission of COVID-19.
- None of them have been studied to prevent transmission (no randomized trials).
- None have been approved or indicated to prevent transmission.
- Whether you were vaccinated or not made no difference to grandma.

Following the Science: Where are the research studies demonstrating that Covid Vaccines prevent viral transmission?

Not Available

Why is this important? We saw that belief trumps evidence, and regulatory protection.

- Public health measures in Canada segregating people and discriminating against them on their basis of their vaccine status, caused deep rifts in our society.
- The “transmission myth” enacted into law removed peoples’ rights to public spaces, sporting facilities, travel, visiting relatives in care facilities and hospitals to no benefit.

Colonial era version of the “vaccine passport” sign restricting who can enter an establishment.

Covid Vaccines and Transmission: Not reinforced by epidemiologic studies

Numerous epidemiologic studies conducted in the US, Germany, Vietnam, and Israel indicate that vaccinated individuals are equally able as unvaccinated people to transmit the virus to others.

This research means that both vaccinated and unvaccinated persons are vectors for disease, and the vaccine does not provide any additional reduction in rates of viral transmission.

My summary: Covid Vaccines and Transmission

- Based on my review of studies underlying the approval of the six Covid-19 vaccines in Canada, I believe that there exists zero randomized trials of the approved Covid-19 vaccines in Canada showing any effect on viral transmission.
- Covid-19 vaccines have only been studied in randomized trials to show an impact on developing symptomatic Covid-19, not whether the product has any effect on the likelihood that it can affect transmitting the virus to others.

Comirnaty Post Market Adverse Reactions

8.5 Post-Market Adverse Reactions

The following adverse reactions have been identified during post authorization use of COMIRNATY.

Cardiac Disorders: myocarditis and/or pericarditis (see **WARNING AND PRECAUTIONS** section)

Immune System Disorders: severe allergic reactions, including anaphylaxis

Musculoskeletal and Connective Tissue Disorders: pain in extremity (arm)

Nervous System Disorders: Facial paralysis / Bell's Palsy, hypoesthesia, paresthesia, dizziness

Skin and subcutaneous tissue disorders and other hypersensitivity reactions: skin rash, pruritus, urticaria, angioedema, erythema multiforme

Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to product exposure. They are included because: a) they represent reactions that are known to occur following immunizations generally; b) they are potentially serious; or c) on the basis of their frequency of reporting.

Health Canada approved product monograph for Comirnaty
https://www.pfizer.ca/files/COMIRNATY_PM_EN.pdf Page 53.

Alan and his mom

- Transmission was an invalid justification for vaccine mandates because such mandates MAY ONLY be justified if there is proper scientific support that the vaccinated were not able to transmit the virus to others.
- We know this is false, yet we allowed this misinformation to nearly destroy our society.

How to contact me

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