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COVID-19 Vaccine and Myocarditis: New October 2023 Papers Raise Serious Concerns! The Good, the Bad and the Ugly Regarding Novavax “2023-2024 Formulation”

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COVID Intel

Theme: Science and Medicine

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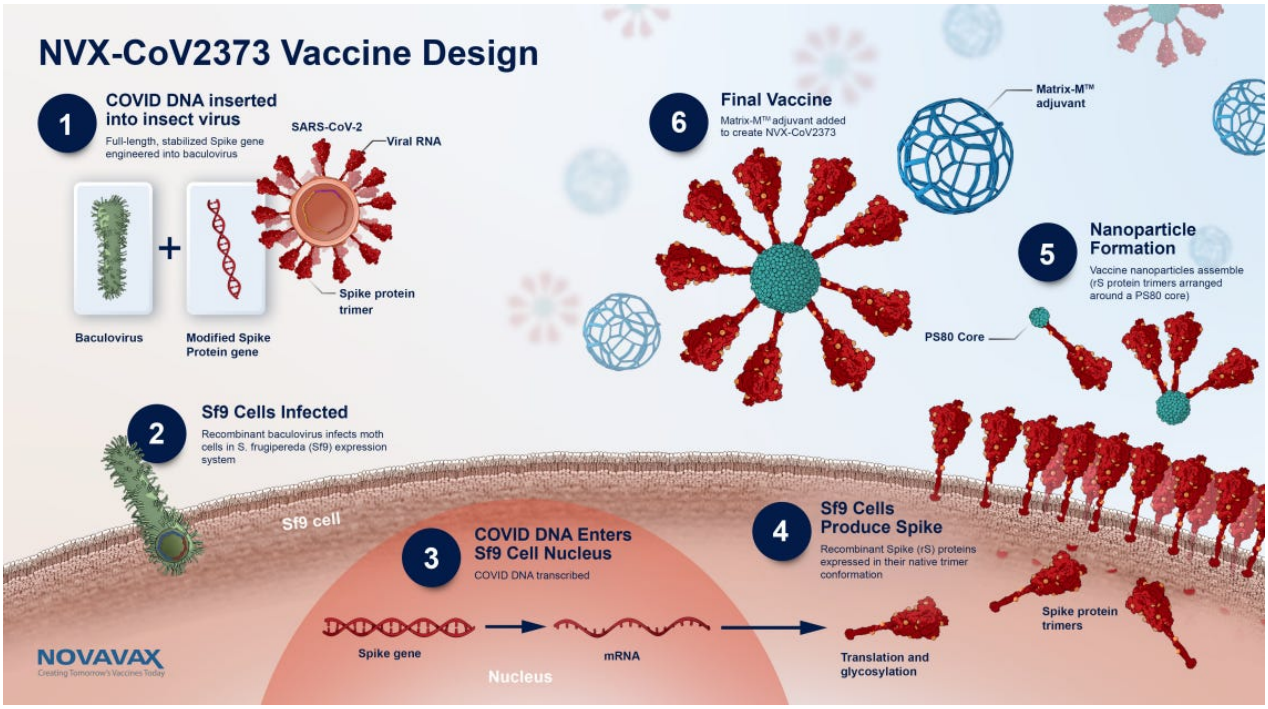
Papers Reviewed:

- Oct. 26, 2023 Wilkinson et al – A Brighton Collaboration standardized template with key considerations for a benefit/risk assessment for the Novavax COVID-19 Vaccine (NVX-CoV2373), a recombinant spike protein vaccine with Matrix-M adjuvant to prevent disease caused by SARS-CoV-2 viruses
- Oct. 18, 2023 – COVID-19 Update: New Novavax Vaccine Formulation for 2023-2024
- June 2023 Smith et al – Safety of the NVX-CoV2373 COVID-19 vaccine in randomized placebo-controlled clinical trials
- Feb. 2023 Saint-Gerons et al – Myopericarditis Associated with the Novavax COVID-19 Vaccine (NVX-CoV2373): A Retrospective Analysis of Individual Case Safety Reports from VigiBase
- Dec. 2022 Ahmad et al – Myopericarditis following both BNT162b2 and NVX-CoV2373
- June 7 2022 – U.S. Food and Drug Administration. Novavax COVID-19 vaccine (NVX-CoV2373) VRBPAC briefing document. Updated 2022



Oct. 26, 2023 Wilkinson et al – A Brighton Collaboration standardized template with key considerations for a benefit/risk assessment for the Novavax COVID-19 Vaccine (NVX-CoV2373), a recombinant spike protein vaccine with Matrix-M adjuvant to prevent disease caused by SARS-CoV-2 viruses.

- "Novavax, Inc. has developed a recombinant protein vaccine formulated with the saponin-based Matrix-M™ adjuvant (referred to as NVX-CoV2373) against SARS-CoV-2"
- "SARS-CoV-2 recombinant spike (rS) nanoparticle consists of a highly purified protein constructed from the full-length, wild-type SARS-CoV-2 spike. This protein is based on the spike gene sequence from the original Wuhan-Hu-1 strain and is produced using a baculovirus expression system in an insect cell line that is derived from Sf9 cells of the *Spodoptera frugiperda* species"
    - "Notably, the flexibility of this step allows for the use of alternative genetic constructs as needed, such as the S-proteins from new SARS-CoV-2 variants"
    - "recombinant spike protein was modified to contain amino acid substitutionsin the S1/S2 furin cleavage and two proline substitutions in the S2 domain to confer protease resistance and to produce a stable prefusion conformation"
    - "the recombinant baculovirus is replicated in Sf9 cells and NVX-CoV2373 spike gene is transcribed, translated, and post-translationally modified (i.e. glycosylated), resulting in high-yield production of the recombinant SARS-CoV-2 S-protein in a native trimer conformation. Next, the trimers are harvested, purified by column chromatography and filtration, and dialyzed into a detergent-containing buffer solution wherein they self-assemble into ~60 nanometer particles arranged around a polysorbate 80 core."
    - In the final step, the S-protein nanoparticles are formulated with Matrix-M saponin-based adjuvant (Matrix-M™)
    - "formulation with Matrix-M, a potent and stable adjuvant studied in over 37,000 individuals, allows for antigen dose sparing and

enhanced immune responses while maintaining a favorable safety profile"

- In over 40 countries, NVX-CoV2373 is either authorized for emergency use or has received full approval
- SAFETY: "NVX-CoV2373 safety has been assessed throughout the comprehensive non-clinical and clinical development programs and in post authorization safety surveillance. No risks were identified in the nonclinical development program while data supported the dose and regimen approved for human use. The NVX-CoV2373 safety profile indicates this vaccine is well tolerated as demonstrated by data from over 31,000 participants receiving NVX-CoV2373 across 5 randomized controlled clinical trials."
- Novavax = 5 ug (Wuhan strain spike protein) + 50 ug Matrix-M
    - "there is paucity of evidence about the longevity of the antibody response to COVID-19 infection…therefore, reinfection with COVID-19 is possible"
    - The Matrix-M adjuvant is manufactured by mixing defined, partially purified extracts of the bark of the *Quillaja saponaria* Molina tree, termed Fraction A and Fraction C, with cholesterol and phosphatidylcholine in the presence of a detergent.
    - The resulting spherical immune stimulating complexes are particles of approximately 40 nm diameter, are remarkably stable, held together by the strong affinity between saponin and cholesterol. The particle also provides chemical stability to the fragile saponin molecules under conditions where free saponins degrade quickly.
    - Matrix-M adjuvant administration was generally well tolerated in humansand animals. Toxicology data from animal studies to evaluate Matrix-M adjuvant, alone or co-administered with different vaccine antigens, did not demonstrate relevant systemic or organ-specific toxicities. There were transient and inconsistent reductions in body weight and red cell mass parameters
    - Matrix-M has been tested with Influenza, RSV and Ebola nanoparticle vaccines
    - "immunostimulation from Matrix-M adjuvant may also contribute to immunotoxicity"
    - biodistribution studies of Matrix-M have been done in rodents
    - biodistribution of nanoparticle-spike hasn't been done – WHY? – "We anticipate that the co-formulated vaccine will follow a conventional protein antigen trafficking pathway following intramuscular administration: the antigen taken up by dendritic cells will migrate to the draining lymph node where it is processed and presented to T cells by antigen-presenting cells and initiate the immune response. Therefore, we expect that detectable antigen distribution would mostly be limited to local lymph nodes"
    - No studies have been performed to measure persistence in local or distal tissues due to the very low microgram doses of antigen, it will be difficult to detect in serum and tissues.
    - delivery in the context of a saponin adjuvant is designed to facilitate transport to the draining lymph nodes rather than formation of a local depot.
    - "Novavax expects a low potential for serious unwanted effects and

toxicities in neonates, infants, and children"

- "Novavax expects a low potential for serious unwanted effects and toxicities in pregnant women and fetuses"
- "Novavax does not believe there are other special populations which would be more susceptible for serious unwanted effects and toxicities"

Oct. 18, 2023 – COVID-19 Update: New Novavax Vaccine Formulation for 2023-2024.

- original formulation of Novavax vaccine is no longer authorized for use in US
- 2023-2024 formulation of the Novavax vaccine contains the spike protein of the XBB.1.5 Omicron strain of SARS-CoV-2.
- No clinical studies evaluating the SAFETY or effectiveness of the 2023-2024 Novavax vaccine are available
- "The updated Novavax COVID-19 vaccine is indicated for use in persons ≥12 years old who have not already received another 2023-2024 COVID-19 vaccine formulation"
- WARNING: "Those who have not previously been vaccinated against COVID-19should receive 2 doses; the product labeling recommends that they be given 3 weeks apart, but according to the CDC, an 8-week interval between doses might be optimal for some patients (especially adolescent and young adult males) to reduce the risk of myocarditis and pericarditis"

Table 1. Vaccination Recommendations for Updated 2023-2024 COVID-19 Vaccines[1,2]

Age	Dose/Vial Color	Not Previously Vaccinated	Previously Vaccinated
Pfizer/BioNTech Vaccine *(Comirnaty)* – mRNA vaccine			
6 months-4 years[3]	3 mcg/0.3 mL; yellow cap and label	3 doses: 1st at week 0, 2nd at week 3, 3rd ≥8 weeks after dose 2	▶ **1 previous Pfizer dose:** 1 dose ≥3 weeks later and 1 dose ≥8 weeks after dose 2 ▶ **2 previous Pfizer doses:** 1 dose ≥8 weeks after last dose ▶ **3 previous Pfizer doses:** 1 dose ≥2 months after last dose
5-11 years	10 mcg/0.3 mL; light blue cap and label	1 dose	▶ 1 dose ≥2 months after last dose of any mRNA COVID vaccine
≥12 years	30 mcg/0.3 mL; gray cap and label	1 dose	▶ 1 dose ≥2 months after last dose of any COVID vaccine
Moderna Vaccine *(Spikevax)* – mRNA vaccine			
6 months-4 years[3]	25 mcg/0.25 mL; dark blue cap/ green label	2 doses 1 month apart	▶ **1 previous Moderna dose:** 1 dose ≥1 month after last vaccine ▶ **≥2 previous Moderna doses:** 1 dose ≥2 months after last vaccine
5-11 years	25 mcg/0.25 mL; dark blue cap/ green label	1 dose	▶ 1 dose ≥2 months after last dose of any mRNA COVID vaccine
≥12 years	50 mcg/0.5 mL; blue cap and label	1 dose	▶ 1 dose ≥2 months after last dose of any COVID vaccine
Novavax Vaccine – adjuvanted protein subunit vaccine			
≥12 years	5 mcg (plus 50 mcg adjuvant)/ 0.5 mL; blue cap and label	2 doses 3 weeks apart[4]	▶ 1 dose ≥2 months after last dose of any COVID vaccine

1. The updated 2023-2024 formula vaccines include a monovalent component that corresponds to the Omicron variant XBB.1.5. Previous bivalent Moderna and Pfizer/BioNTech and monovalent Novavax vaccines are no longer authorized for use in the US. The Johnson & Johnson (Janssen) vaccine is no longer available in the US.
2. For immunocompetent persons. Persons with moderate or severe immunocompromise may receive additional doses of the 2023-2024 COVID-19 formula vaccines based on the clinical judgement of a healthcare provider and personal preference and circumstances; additional doses should be given ≥2 months after the last 2023-2024 COVID-19 vaccine dose.
3. Includes children who would turn 5 years old during the vaccination series. All doses should be from the same manufacturer.
4. According to the CDC, an 8-week interval between doses might be optimal for some patients, especially adolescent and young adult males, to reduce the risk of myocarditis and pericarditis (https://bit.ly/3KgPdxl).

June 2023 Smith et al – Safety of the NVX-CoV2373 COVID-19 vaccine in randomized

placebo-controlled clinical trial.

- 4 Clinical Trials with 30,058 getting Novavax, 19,892 getting placebo
- 11.4% had a Grade 3+ systemic reaction within 7 days (3.6% for placebo)
- 21 deaths or 0.07% (12 deaths or 0.06% in placebo)
- "Grade 3–4 events were more frequent in vaccine recipients than placebo recipients, which is not unexpected for an adjuvanted vaccine compared to a saline placebo. SAE rates reported by participants who received NVX-CoV2373 or placebo were similar"
- "Following marketing authorization of NVX-CoV2373, reports of myocarditis and pericarditis were received from several regions, including Australia and the European Union. Based on a review of the cumulative post-authorization reports, myocarditis and pericarditis are now considered identified risks for NVX-CoV2373"
- "It is unclear what specific mechanism causes the cardiac tissue inflammation."

Feb. 2023 Saint-Gerons et al – Myopericarditis Associated with the Novavax COVID-19 Vaccine (NVX-CoV2373): A Retrospective Analysis of Individual Case Safety Reports from VigiBase.

- 61 safety reports for myocarditis and pericarditis reported to regulators, 24 serious, 19 required hospitalization, 3 were life threatening, 1 disabling, none were fatal
- median age 36 years old, 62%, 38% women
- 70% had chest pain
- median period to onset 3 days after jab
- only 13% recovered
- "disproportionality signal was found for NVX-CoV2373 (Novavax) vaccine in line with the mRNA vaccines, and the Pfizer-BioNTech vaccine in particular"
- AstraZeneca had elevated risk of myocarditis but only 1/10th that of Pfizer or Novavax.
- "More research would be needed to understand the role of nanoparticles in the potential risk of vaccine-induced myocarditis."
- Interpretation: Novavax has myocarditis risk comparable to Pfizer mRNA

Dec. 2022 Ahmad et al – Myopericarditis following both BNT162b2 and NVX-CoV2373.

- This case report presents 2 cases of pericarditis and myocarditis recurrence within 1 week following booster dose vaccination with NVX-CoV2373
- both cases has similar clinical presentations:
    - both subjects had mirroring events following their BNT162b2 and NVX-CoV2373 vaccinations
    - As young individuals who had reactions within 7 days of a non-first dose vaccination, both also fit the same demographic usually seen in post-mRNA vaccine myopericarditis
    - Both fulfill the criteria of myopericarditis, with presentations of pleuritic chest pain and ECG
- Theory:
    - Pfizer myocarditis – immunogenicity of the lipid nano particle (LNP) sheath required to deliver mRNA to host cells – potential cause for

either direct damage to the myocardial cells, or as another trigger for immune dysregulation.
- nanoparticles are also used in the NVX-CoV2373 vaccine, which is required for incorporation of the S-protein into the host

June 7 2022 – U.S. Food and Drug Administration. Novavax COVID-19 vaccine (NVX-CoV2373) VRBPAC briefing document. Updated 2022.

Table 18. Potential Immune-Mediated Medical Conditions Reported in the Pre-Crossover Period, Study 301

Preferred Term	NVX-CoV2373 N=19735 Number of Subjects (%)	Placebo N=9847 Number of Subjects (%)
Alopecia areata	1 (0.005)	0 (0)
Ankylosing spondylitis	1 (0.005)	0 (0)
Autoimmune thyroiditis	1 (0.005)	1 (0.01)
Basedow's disease	2 (0.01)	0 (0)
Bell's palsy	3 (0.015)	1 (0.01)
Crohn's disease	1 (0.005)	0 (0)
Erythema nodosum	1 (0.005)	0 (0)
Lichen planus	0 (0)	1 (0.01)
Neuropathy peripheral	3 (0.015)	3 (0.03)
Polymyalgia rheumatica	1 (0.005)	1 (0.01)
Psoriasis	1 (0.005)	1 (0.01)
Rheumatoid arthritis	2 (0.01)	1 (0.01)
Seizure	3 (0.015)	2 (0.02)
Thrombocytopenia	2 (0.01)	1 (0.01)
Uveitis	2 (0.01)	2 (0.02)

Source: Source: EUA 28237 Amendment 15, ADAE dataset generated using MAED.
N=number of subjects in cohort

Of the 25 PIMMCs in the NVX arm, 12 events reported by 11 participants were considered related to vaccination by the investigator, including alopecia areata, Basedow's disease, Bell's palsy, psoriasis, and thrombocytopenia (n=1 each); neuropathy peripheral, rheumatoid arthritis (n=2 each); and uveitis (n=3). In the placebo arm, 2 events reported by 2 participants were considered related to vaccination by the investigator, including peripheral neuropathy and seizure.

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In summary, the events of myocarditis/pericarditis are concerning for a causal association with NVX-CoV2373 for the following reasons: 1) five events were reported within 2 weeks of vaccination, 2) only 1 event had a clearly identified alternative etiology (COVID-19) strongly associated with myocarditis, and other events had only circumstantial evidence of potentially plausible alternative etiologies, and 3) four of the events occurred in young men, a subject population known to be at higher risk for mRNA COVID-19 vaccine-associated myocarditis. Additionally, identification of multiple potential vaccine-associated cases in a premarket safety database of ~40,000 vaccine recipients raises concern that if causally associated, the risk of myocarditis following NVX-CoV2373 could be higher than reported during post-authorization use of mRNA COVID-19 vaccines (for which no cases were identified in pre-authorization evaluation).

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My Take...

The "Good News"

- It's not an mRNA COVID-19 vaccine
- It doesn't have a Pfizer or Moderna Lipid Nanoparticle
- it has a finite quantity of spike protein that is alleged to be 5 ug

- No “DNA contamination” (hopefully)
- according to the company it has an “acceptable safety profile”

The Bad

- It uses Wuhan spike protein
- 1:1400 died in Novavax Clinical Trials (21 deaths from 30,000 participants)
- myocarditis and pericarditis are now considered identified risks for NVX-CoV2373
    - There were 5 cases of myocarditis/pericarditis in the Novavax Clinical Trials, 4 were “serious” and hospitalized
    - Company doesn’t know the specific mechanism that causes cardiac tissue inflammation (myocarditis/pericarditis)
- Study by Saint-Gerons et al analyzed 61 cases of myocarditis/pericarditis reported to regulators, 62% men
    - rate of myocarditis similar to Pfizer mRNA COVID-19 vaccines (suggesting nanoparticle involvement)
    - only 13% recovered
- FDA Briefing Document (June 2022)
    - Immune mediated medical conditions related to Novavax: Alopecia, autoimmune thyroid disease, Bell’s Palsy, psoriasis, thrombocytopenia, peripheral neuropathy, rheumatoid arthritis, uveitis (these are all associated with spike protein damage seen with mRNA vaccines after systemic distribution of LNP/mRNA!)
    - according to FDA, risk of myocarditis after Novavax could be higher than mRNA COVID-19 vaccines

The Ugly

original Novavax is no longer on the market in the US

2023-2024 formulation of Novavax with XBB.1.5 spike protein has no clinical studies evaluating safety or effectiveness

- Spike proteins are mixed in a detergent solution where they “self-assemble” around a Polysorbate-80 core
    - “polysorbate 80 is not an inert compound and has been implicated in a number of systemic and injection- and infusion-site adverse events (ISAEs)”
- ALSO contains a saponin-based Matrix-M adjuvant (40nm nanoparticle, remarkably stable, held together by saponin-cholesterol interactions” (in rodents causes decreased body weight and red cell mass) – “may contribute to immunotoxicity”
- biodistribution of Novavax nanoparticle-spike has never been done and company “assumes” that it “mostly” stays in local lymph nodes because it should behave like a “conventional protein antigen” (it’s NOT, it’s a nanoparticle)
- No studies have been performed to measure nanoparticle-spike persistence in local or distal tissues
- “Novavax expects a low potential for serious unwanted effects and toxicities in neonates, infants, and children” (they don’t know)
- “Novavax expects a low potential for serious unwanted effects and toxicities in

pregnant women and fetuses" (they don't know)
- "Novavax does not believe there are other special populations which would be more susceptible for serious unwanted effects and toxicities" (they don't know)

Concluding Thoughts

- Novavax is made of 2 nanoparticles, a 60nm Polysorbate-80/Wuhan-spike rosette and 40nm Matrix-M (saponin-cholesterol)
- it seems they got away with not calling Matrix-M a nanoparticle by calling it an "adjuvant" instead, something that's added to stimulate an immune response, but it's a nanoparticle.
    - Matrix-M is a nanoparticle: "The Matrix-M adjuvant consists of two distinct fractions of saponins purified from the *Quillaja saponaria* Molina tree, combined with cholesterol and phospholipids to form 40-nm open cage-like nanoparticles"
- Both are made in detergent solutions, and the Polysorbate-80 core and the Matrix-M are not inert – both could cause immunotoxicity and adverse events – these risks have not been studied
- Novavax causes myocarditis comparable to Pfizer, only 13% recover!
- Novavax never did a biodistribution study on the Polysorbate-80/Wuhan-spike but it's proven to get in the bloodstream and go systemic because the FDA Briefing document outlines many immune adverse events all over the body.
- Novavax also never did studies on persistence of spike in local or distant tissues and organs.
- Novavax – no data on safety in neonates, infants, children
- Novavax – no data on safety in pregnancy
- 11.4% had a Grade 3+ systemic reaction within 7 days with no long term safety data.

Novavax is a dual nanoparticle vaccine with toxic original Wuhan spike protein, with very serious adverse events (myocarditis, systemic immune injury), very serious potential risks (never-studied systemic distribution of two nanoparticles causing spike protein injury with potential additional toxicity of Polysorbate-80 and Matrix-M) and far too many unknowns.

Does any of this sound "safe" to you?

Caveat Emptor!

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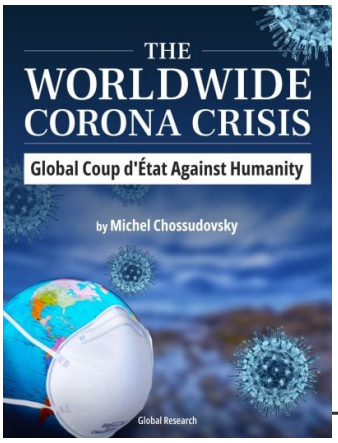
Dr. William Makis is a Canadian physician with expertise in Radiology, Oncology and Immunology. Governor General's Medal, University of Toronto Scholar. Author of 100+ peer-reviewed medical publications.

Featured image is from Children's Health Defense



The Worldwide Corona Crisis, Global Coup d'Etat Against Humanity

by Michel Chossudovsky

Michel Chossudovsky reviews in detail how this insidious project "destroys people's lives". He provides a comprehensive analysis of everything you need to know about the "pandemic" — from the medical dimensions to the economic and social repercussions, political underpinnings, and mental and psychological impacts.

"My objective as an author is to inform people worldwide and refute the official narrative which has been used as a justification to destabilize the economic and social fabric of entire countries, followed by the imposition of the "deadly" COVID-19 "vaccine". This crisis affects humanity in its entirety: almost 8 billion people. We stand in solidarity with our fellow human beings and our children worldwide. Truth is a powerful instrument."

Reviews

This is an in-depth resource of great interest if it is the wider perspective you are motivated to understand a little better, the author is very knowledgeable about geopolitics and this comes out in the way Covid is contextualized. —Dr. Mike Yeadon

In this war against humanity in which we find ourselves, in this singular, irregular and massive assault against liberty and the goodness of people, Chossudovsky's book is a rock upon which to sustain our fight. –Dr. Emanuel Garcia

In fifteen concise science-based chapters, Michel traces the false covid pandemic, explaining how a PCR test, producing up to 97% proven false positives, combined with a relentless 24/7 fear campaign, was able to create a worldwide panic-laden "plandemic"; that this plandemic would never have been possible without the infamous DNA-modifying Polymerase Chain Reaction test – which to this day is being pushed on a majority of innocent people who have no clue. His conclusions are evidenced by renown scientists. —Peter Koenig

Professor Chossudovsky exposes the truth that "there is no causal relationship between the virus and economic variables." In other words, it was not COVID-19 but, rather, the deliberate implementation of the illogical, scientifically baseless lockdowns that caused the shutdown of the global economy. –David Skripac

A reading of Chossudovsky's book provides a comprehensive lesson in how there is a global

coup d'état under way called "The Great Reset" that if not resisted and defeated by freedom loving people everywhere will result in a dystopian future not yet imagined. Pass on this free gift from Professor Chossudovsky before it's too late. You will not find so much valuable information and analysis in one place. –Edward Curtin

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