Promoting Unlicensed Vaccines is Lawbreaking

Unlicensed healthcare products: No advertising or promotion allowed

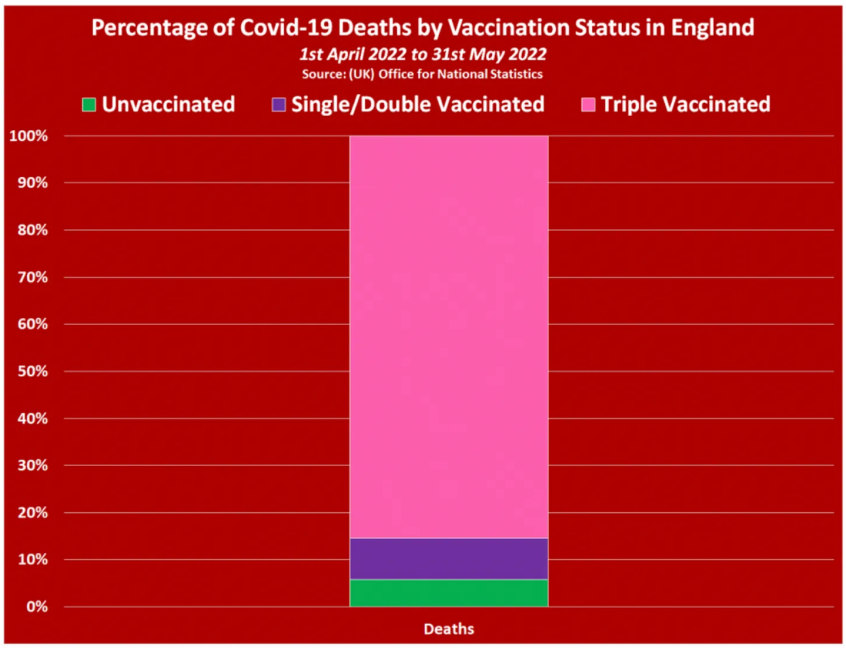
Robert W Malone MD, MS
Sep 1

As we barrel down the pike towards deployment and mandates (ironically after Labor day) involving yet more inadequately tested, Emergency Use Authorized genetic vaccine products (in other words, not licensed or market authorized), it seems an appropriate time to review the law concerning marketing of unlicensed medical products.

This is all about reducing the risk of hospitalization and death from Omicron BA.5, which (based on data from all over the world) appears to be most significant in the highly genetic “vaccinated” population.

clippings and attachments for today's Malone hit

Official figures published by the UK Government reveal the fully/triple vaccinated population have accounted for over 9 in every 10 Covid-19 deaths in England over the past year, 91% of all Covid-19 deaths since the beginning of 2022, and 94% of all Covid-19 deaths since the beginning of April 2022.



The FDA and CDC (and Dr. Barney Graham, on interview with the Washington Post) appear to have conceded that these vaccines are unlikely to do much for even slowing down infection, replication and spread of this virus. And in the opinion of many (including myself), these new products may well supercharge the development of even more sophisticated “vaccine escape mutant” viruses.

> “We may have gotten about as much advantage out of the vaccine, at this point, as we can get,” said Barney Graham, an architect of coronavirus vaccines" "“We can tweak it and maybe evolve it to match circulating strains a little better,” Graham said. “It will have a very small, incremental effect.”

Even Dr. Paul Offit, who seems to have never met a vaccine that he did not think should be jabbed into children, raised a red flag (or was it a white flag?) in his interview with TIME magazine:

> "Dr. Paul Offit, a member of the advisory committee, says this strategy makes him “uncomfortable” for several reasons. He notes that the data presented from Pfizer-BioNTech and Moderna in June involving their BA.1 booster shot, which focused on the levels of virus-fighting antibodies the vaccine generated, were underwhelming. “They showed that the neutralizing antibody titers were between 1.5- and two-fold

> greater against Omicron than levels induced by a booster of the ancestral vaccine," he says. "I'd like to see clear evidence of dramatic increase in neutralizing antibodies, more dramatic than what we saw against BA.1, before launching a new product. We're owed at least that."

I previously covered both the Fearporn and the reality of the clinical risk associated with Omicron BA.5 here on July 09, 2022.

And yet, here we are.

AXIOS: FDA authorizes Omicron boosters

> **Why it matters:** The updated shots, retooled to target the BA.5 strain that accounts for most cases in the U.S. today, are expected to become available after Labor Day.
>
> **Between the lines:** The reformulated mRNA shots got regulators' blessing without first being tested in humans.
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> - They are also the first to move ahead without an FDA advisory committee weighing in, marking a shift that more closely mirrors the annual flu shot approval process.
> - The Biden administration is prioritizing speed over having all the data on how the vaccines work in real life. Some experts warn that this could make some people leery about getting the reformulated shots.

According to Dr. Peter Marks, as we now know was previously the case with Dr. Deborah Birx, apparently the modern standard for granting Emergency Use Authorization for medical countermeasure products is "hope", although I am unable to find that as a condition for granting EUA in the current regulatory guidance documents. Perhaps that criteria will be added in upcoming revisions to the congressional authorization language.

Echoing prior similar comments by Dr. Birx, Dr. Marks has clearly stated that he "hopes" the updated "booster" injection will hold and not require "lots of vaccines" each year.

You can find the FDA justification for the new bivalent Pfizer/BioNTech and Moderna products here.

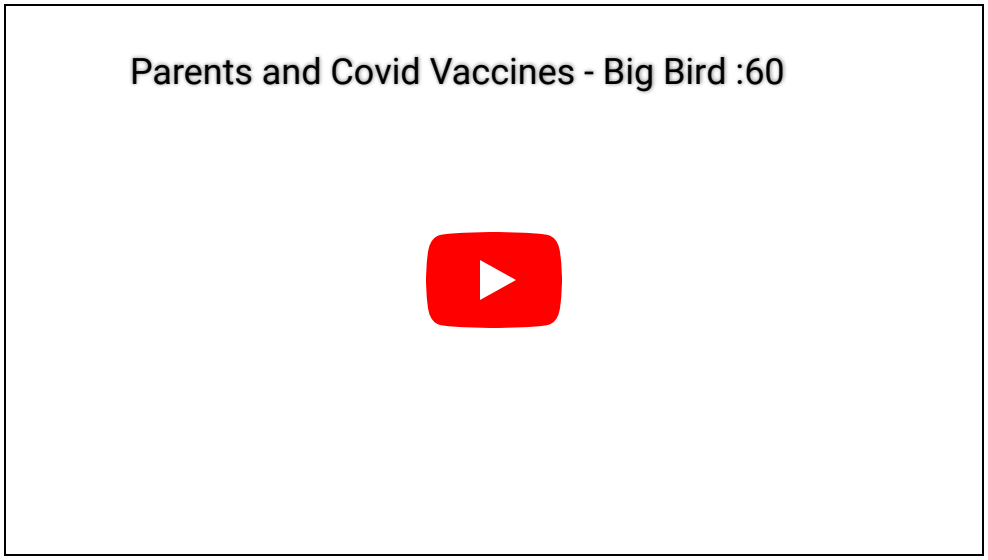
Note the FDA language buried at the very bottom of the statement:

> The **amendments to the EUAs** were issued to Moderna TX Inc. and Pfizer Inc.

These products have been added on by amendment to existing Emergency Use Authorizations by the FDA without any external review or comment. These products are NOT "licensed", they are experimental EUA authorized. If the US Federal COVID medical emergency declarations are lifted, these products can no longer be distributed. They are only authorized while there is a relevant declared medical emergency, and only while there remains no licensed alternative.

With the previously Emergency Use Authorized genetic COVID-19 / SARS-CoV-2 vaccines, a concerted and coordinated marketing campaign was deployed, and was funded by the US Government and may have included funding from non-governmental sources.

In the case of the infamous "Big Bird/Sanjay Gupta" CNN marketing campaign, according to Ad Week dot com, organizers responsible for this marketing to children and elderly of an unlicensed medical product included Sesame Workshop, WarnerMedia and the Ad Council.



What does US Federal and Canadian law have to say about marketing of unlicensed healthcare products?

For a nice summary, please see this link.

> Internationally, regulations exist to prohibit the advertising or promotion of unlicensed healthcare products. In Canada, Section 9(1) of the *Food and Drugs Act* states that, "*no person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its composition, merit or safety.*" Since the terms and any proposed indication of unlicensed healthcare products have not been established, advertising such products is not permitted.1
>
> Similar provisions are laid out in the US Code of Federal Regulations (CFR), Title 21, section 312.7(a) and 812.7(a)—the promotion of any investigational drug or medical device (including a new use under investigation for an existing device) is expressly prohibited.2,3

1. Department of Justice Canada. (2012, August 16). *Food and Drugs Act*, Section 9.
2. United States Code. (2012, April 1). Title 21, Part 312, *Investigational New Drug Application.*
3. United States Code. (2012, April 1). Title 21, Part 812, *Investigational Device Exemptions*.

To continue with the example, AdWeek has this to say about the "Campaign", which was clearly and explicitly an advertising campaign prepared and distributed by the advertising industry group "The Ad Council".

CAMPAIGNS

Big Bird and Granny Bird Share Their Covid-19 Vaccine Experiences

By Kyle O'Brien on Dec. 8, 2021 - 7:00 AM

When Big Bird announced on his Twitter feed that he had been vaccinated against Covid-19 in November, it was a big step to convince parents to think about vaccinations. It also, however, rankled conservative politicians who blamed the character for brainwashing kids and using the platform for propaganda.

> Well, an 8'2" bird doesn't back down after a few negative comments and the large yellow beaked one even brought Granny Bird along to talk about their vaccine experiences and assure parents and children that getting the vaccine is the right thing to do.
>
> In a new campaign by Sesame Workshop, WarnerMedia and the Ad Council, Big Bird and Granny Bird talk about how getting the shot may have made his wing hurt a little, but it was the right thing to do to keep everyone safe and healthy.

> It's part of the Ad Council's massive Covid-19 Vaccine Education Initiative.

All indications are that we going to see more lawless marketing of these "new" EUA-authorized and unlicensed medical products in the near future. What is wrong with this, you ask?

Why the promotion or advertising of unlicensed healthcare products is prohibited

> The primary concern about the promotion or advertising of unlicensed healthcare products or off-label uses is that a healthcare provider may form an opinion about a product's use on the basis of the claims made by its company before it receives regulatory approval, and that opinion may be incorrect relative to the pending regulatory approval. Such an erroneous opinion on the part of the healthcare provider could lead to incorrect use of the licensed product, thus using the product off-label.4

When disseminating information on unlicensed healthcare products may be deemed acceptable

> Although companies that develop healthcare products are not allowed to promote unlicensed products or off-label uses, disseminating information about an investigational product may be acceptable under certain circumstances, as outlined below.

Scientific information: Medical conferences and continuing medical education

> The US 21 CFR section 213.7(a) recognizes that the prohibition of promoting investigational healthcare products is not intended to restrict the full exchange of scientific information concerning such a product, including presenting scientific findings in scientific or lay media. Additionally, it is recognized by the EU Advertising Directives that without industry sponsorship of scientific meetings and attendance by doctors at such meetings, the medical community would be less well informed.

> Companies that develop healthcare products commonly sponsor medical conferences, continuing medical education (CME) or events for the exchange of scientific information (for example, a poster presentation of a disease state at a medical conference). All sponsorships should be developed in line with the following:
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> Distinguish the critical difference between the provision of information, and promotional material (advertising). Evaluate whether the material is informational or promotional. Do not distribute information if it is promotional in nature.
>
> Avoid "unduly influencing" speakers to disseminate off-label information.
>
> Clearly label the marketing status of the product so that you do not mislead your audience. (For example, you may encounter a situation where a product is approved in some jurisdictions but not in the country of a conference, or that in that particular country is has a different approved indication of use).
>
> To ensure compliance, companies may establish internal programs, procedures and policies that follow industry guidelines regarding CME events and the exchange of scientific information. For instance, the Accreditation Council for Continuing Medical Education (ACCME) has strict accreditation requirements to which CME providers must adhere when holding an event and providing related educational materials. 1,2

From a regulatory/legal standpoint, these EUA products remain under "clinical investigation". So what are the rules for that?

Clinical investigation

> When a new drug or medical device, or a new use of a licensed product, is under investigation, any claims of safety and effectiveness about such healthcare products are prohibited unless the company is seeking to recruit clinical investigators or enroll patients in a study.1 Permissible activities may include:
>
> "Institutional ads" in which a company states that it is conducting research in a certain therapeutic area to develop a new product, but does not mention the proprietary or established name of the product

> "Coming soon" advertisements, which state the name of the product, but make no representation about the new product's safety, efficacy or intended use

1. Drake, K.L. (2009). Chapter 9. FDA regulation of the advertising and promotion of prescription drugs, biologics, and medical devices. In Pisano, D.J., Mantus, D.S. (Eds.), *FDA regulatory affairs. A guide for prescription drugs, medical devices, and biologics* (2nd ed.). NY: Informa Healthcare.
2. de Wet, C. (2009). Chapter 12. Information and promotion. In Griffin, J.P. (Ed.) *The textbook of pharmaceutical medicine* (6th ed.). West Sussex: John Wiley & Sons Ltd.

Dr. Peter Marks, director of the formerly respected FDA Center for Biologics Evaluation and Research (CBER), "hopes" that these modified bivalent vaccines will work, but my understanding of the literature concerning immune imprinting/original antigenic sin in the context of the current SARS-CoV-2 genetic vaccines strongly suggests that the approach being employed with these products will only exacerbate the problems of immune imprinting. Based on their comments (or lack thereof) concerning these new, inadequately tested genetic "vaccine" products, Dr. Marks and his colleagues appear to be willfully ignorant of this literature and the associated implications.

Just to be completely clear, this peer reviewed literature, published in many of the highest profile scientific journals, is easily found with simple pubmed search terms. I have previously reviewed many of these studies here and here, and have testified about the risks and issues in my testimony to the Texas State Senate on June 26, 2022. I mention these things just to make that point that this information has been readily available for FDA, CDC and anyone else to review for quite some time.

In my opinion, the FDA and CDC have continued to bypass well established regulatory norms and have permitted outright lawless activities (including prohibited marketing of

unlicensed medical products) in their rush to deploy genetic vaccine products for a disease which is readily managed using a wide variety of early clinical treatment protocols.

I hope my predictions about these rushed and largely untested "new" bivalent vaccine products are wrong, and they do not make the immune imprinting/original antigenic sin problems worse. However, I fear that this is what the current data appear to indicate is likely to happen.

But at a minimum, the recent political spin angle that this "vaccine" mess is all the fault of the Trump administration based on operation warp speed bypassing normal vaccine development procedures can no longer carry water. With deployment of these bivalent vaccines based on "hope" rather than clinical data demonstrating safety and effectiveness, the current executive branch administration is now guilty of precisely the sin which they **j'accuse** the prior Republican administration of.

I "hope" that we will not see yet more lawless marketing of unlicensed medical products. I suspect that my "hope" will be as worthless as that of Dr. Birx and Dr. Marks have been.

We could call this cartoon "Hope", and not be too far off the mark for todays (and tomorrow's) US HHS COVID-19 vaccine policies. Personally, I prefer science and evidence based medicine and public health policies. But for now, hope is apparently the new normal at HHS under this administration.

108 Comments

Write a comment...

Kathleen Writes Kathleen Devanney's Newsletter Sep 1 ❤ Liked by Robert W Malone MD, MS

I guess laws don't matter when outlaws are in charge. We the People will need to take matters into our own hands. Thanks.

♡ 98 Reply Collapse

6 replies

Aimee Sep 1

California Has Made Honest Medical Speech Illegal

AB 2098 Promises to Suspend the Licenses of Physicians Who “Spread Misinformation”

“Specifically, it would punish any doctor for speaking honestly about the so-called “vaccines,” PCR testing, forced masking, or the nature of the virus itself. This would destroy the doctor-patient relationship and criminalize public speech by all California physicians. It will also lead to the loss of every decent medical doctor and redefine a physician’s allegiance toward his patient, replacing it with allegiance with the state.”

https://markmcdonaldmd.substack.com/p/california-has-made-honest-medical?

♡ 41 Reply Collapse

7 replies by Robert W Malone MD, MS and others

106 more comments…