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Biden Risk-Benefit Analysis Hides 'Bad Data' on Moderna Shots for Kids

The U.S. Food and Drug Administration's risk-benefit document in connection with the Moderna mRNA shot in children 6 months to 5 years underscores the lack of data on the vaccine's effectiveness, high, chronic, nationally, disabling, fatal and medical injuries.

By Toby Rogers, Ph.D.

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Editor's Note: The U.S. Food and Drug Administration's vaccine advisory committee will meet June 15 to consider granting Emergency Use Authorization (EUA) of the Moderna and Pfizer-BioNTech COVID-19 vaccines for children under 5 years old, even though the Pfizer-Biontech vaccine is currently in a pending EUA under consideration for the vaccines aimed for teens and healthcare providers. Click here to sell your members of Congress to oppose EUA of these vaccines for young children.

The U.S. Food and Drug Administration (FDA) last week released its risk-benefit assessment of Moderna's Emergency Use Authorization (EUA) application to vaccinate children 6 months to 5 years old.

I've been reading it for the past two days and for me the things that stood out to me.

Introduction, a shell game to hide the bad data

The five-page document for Moderna is 180 pages-single-spaced. It was released two business days before the June 14-15 Vaccines and Related Biological Products Advisory Committee, or VRBAC meeting.

A similar risk-benefit assessment for Pfizer's EUA application for kids under 5 will be released today (just 24 hours the meeting).

This guarantees that NONE of the members of the VRBPAC will have read either of these documents before the meeting — which is exactly what the cartel wants.

One of the ways Moderna and the FDA rig the game is by adding endless layers of complexity to hide how bad the data really is.

This should have been four separate documents — Moderna in adolescents 12 to 17, Moderna in kids 6 to 11, Moderna in kids 2 to 5, and Moderna in kids 6 months to 23 months.

Looked at individually, the shot fails in each of these four age groups. But lumping them together creates data that makes it difficult to understand what's going on.

Another really pernicious thing that Moderna does is to further subdivide these populations into eight different subpopulations (Randomization Set, Full Analysis Set, Immunogenicity Subset, Per protocol Immunogenicity Subset, Per protocol Set for Efficacy, Modified Intention-to-Treat Set, MITT Set, Safety Set, Solicited Safety Set).

See what they did there? The public just wants to know — does the product work and what are the side effects?

By dividing the data into eight subcategories involving four different age groups how you have to wade through 32 different tables to try to make sense of what happened in the clinical trial.

They do something similar with the adverse events by dividing it across the tables i.e. four age groups × 20 adverse event tables = 80.

Subdividing the data in this way also allows Moderna to eliminate or hide data that it does not like.

This is what people call "massaging the data" and it is unethical and a violation of scientific norms. We'll return to this topic below.

No actual health benefits so Moderna/FDA use the immunobridging trick

The risks of COVID-19 are so low in the childhood population that there were 2090 severe cases of COVID-19 in either the treatment or the control group.

Therefore, the number needed to vaccinate, to prevent a single severe case of COVID-19 in the childhood population, is infinity. (Technically this undefined because you cannot divide by zero, but you take my point.)

The FDA and Centers for Disease Control and Prevention, or CDC, guidance documents for how to write a risk-benefit assessment state that one must provide a number needed to treat, the absolute risk reduction, and the relative risk reduction.

Moderna just skipped all that because the cartel makes its own rules.

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Moderna is a not-against natural immunity. But natural immunity has already sent because 16.2% of kids had natural immunity by February — so by now, the number is probably closer to 100%.

The God-given immune system in kids has already done its part to stop the pandemic and now the FDA wants to mess that up to stretch the cartel and keep the pandemic going forever.

Now you know why Moderna/FDA claim that this shot was "effective"? They use an unethical statistical trick called "immunobridging."

It makes me mad that I even have to explain it because it's such junk science. But we all need to know exactly how the FDA rigged the process so that we can explain to the jury at Nuremberg 2 why these monsters should be convicted so here goes.

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Remember, the Moderna shots produced NO reductions in severe outcomes because the risk of COVID-19 in this age group is infinitesimally small (see studies here, here, here, and here).

So Moderna ignored the actual health outcomes and switched to looking at antibodies in the blood. In the process, they engaged in two egregious sleights of hand.

First, Moderna claims that the sample size for each of the four subgroups of children is about 500 kids. But they then do a bait-and-switch because the "Per protocol" subset is only about 50% of the sample and only looked at the bloodwork of about 300 kids in each age group.

No explanation was given for the criteria they used to exclude 50% of the sample from their analysis. We know that up to 30% of kids have no antibody response at all (p.156) (I'm pissed perhaps they actually started with a much larger sample and then threw out the data that showed no effect from the shot)

The second sleight of hand is that **"no placebo recipients were included in the immunogenicity** Subset" (p. 26). Do you realize how huge this is? This is no longer an RCT at all — they did not include the bloodwork from anyone in the placebo group.

So the study cannot rule out the possibility that the increase in antibody levels was not from the vaccine at all but could have been from natural immunity. Just astonishing.

After these sleights of hand, Moderna then compares the antibody levels in the blood of about 10% of the children against the antibody levels in a sample of about 300 adults age 18 to 25 enrolled in a previous clinical trial. If the antibody levels are similar (which they are), Moderna claims, fand therefore it will present disease in the future is also likely!

A few problems with that claim:

The Moderna study only measured antibody levels two months after the second dose — the time period when the antibody levels are at their peak (what Bernstein calls "the happy valley"). But real-world experience with these vaccines shows that any efficacy quickly wanes to zero by six months and then goes NEGATIVE after that.

The second problem — and this is unmistakable and instantly disqualifying for Moderna — is that on the April 6 meeting of the FDA's "expert advisory committee" one member after another acknowledged that there are no "correlates of protection" for these vaccines.

What that means in plain English is that you cannot use antibodies (or B-cells, T-cells, or any other proxy) to predict whether someone is immune or not.

Eric Rubin, who serves on that committee and is also the editor of the New England Journal of Medicine (NEJM) stated it bluntly:

"We know what kind of antibody response can be generated, we just don't know if it works."

You can watch it yourself in the video below.

The third problem is that the Moderna study was completed back in mid-2021 — when the Delta variant was the dominant strain of coronavirus. Since then, the Omicron variants have totally replaced the original strains and real-world data show that both Moderna and Pfizer shots are not effective against the Omicron strains.

So in spite of all of the charming (disarming) 99% of the sample, immunobridging, claiming correlates of protection that are not valid Moderna cannot show any evidence that this shot will be effective against SARS-CoV-2 as it exists now.

It's all harms

Let's talk about harms from this shot (and remember, it's all harms in this population because the shot made no difference in real-world health outcomes). And there, things get really weird really fast.

The median study follow-up duration was just 53 days after dose 2. After that, they wiped out the control group. Here's how they justified it (p. 35):

"Following authorization of an alternative COVID-19 vaccine for this age group on May 13, 2021, participants in the study were permitted to unblind to study treatment. Crossover participants with mRNA-1273 participants initially randomized to placebo began in October 2021."

For each age category, Moderna spreads the adverse events across 5 different tables to increase the noise to hide the signal. But the bottom line is that the vaccine caused more harm than it did. The adolescent population (p. 91) had more adverse incidents reported at least one adverse reaction after any injection with 25.3% reporting a reaction that was Grade 3 or higher (p. 56).

Holy sh*t! Those numbers are high. Grade 3 means unable to return to work or school the next day because the person is so sick.

A different ISR outlier must have written the summary statements for the other three age groups because they don't say it's likely that the adverse event rates are similar across all of the children.

This adverse event data is so high it's disqualifying.

But then things get even weirder — the adverse event rates in the placebo group were also very high in many, but not all, categories. Moderna used this to say, well yes, the adverse event rate in the treatment group was higher than anything anyone has ever seen before but the rates were also somewhat high in the placebo group and so, therefore, nothing to worry about here.

My strong suspicion is that Moderna rigged the placebo. Why wouldn't they — the FDA has no regulations concerning the contents of placebos (see Gotlieb, 1997 and Golomb et al. 2018).

The dirty little secret of the vaccine program is that manufacturers almost always use rigged placebos to create an artificially high "background" rate to hide adverse events.

The brilliant quantitative analyst Jessica Rose made a similar observation yesterday in her analysis of the FDA risk-benefit document:

"I still have a very strong suspicion that these 'placebos' are not saline and rather empty LNPs. [Lipid nanoparticles — the delivery vehicle that Moderna uses to get mRNA into the cell]. An empty LNP would be the nanoparticles without the mRNA antigen.)"

The above certain this is what Moderna did. In the 2 through 5 year-old age group, 37.5% of the placebo recipients reported at least one adverse reaction after any injection (p. 91). Those recipients (see p. 139). A number that high in the placebo group would have been impossible if Moderna had used an inert saline placebo.

It's Time to Follow the Science: Join our Campaign!

Pfizer-BioNTech Vaccine Trial Data Is Unusually Similar

I know that this article is already long but I need to flag one more essential point.

FDA review of the Moderna mRNA shot in adolescents has been held up for a year because the Moderna shot causes myocarditis in this age group — particularly in boys.

So I was curious to see how the FDA would attempt to get around this. And it's all right there on pages 9 and 35. It's one of the most chilling things I've ever read. The FDA's argument goes like this:

"Yes, by the spring and summer of 2021 there were already seven high-quality studies from around the world showing that mRNA shots increase myocarditis risk. By the fall of 2021, the Centers for Disease Control, the Food and Drug Administration, and Nordic countries showing a 2x to 7x increased risk of myocarditis from mRNA shots.

"Yes, the CDC's own study of the Vaccine Safety Datalink showed a 2x higher risk of myocarditis from Moderna shots. By May, we have additional studies from the United States, Germany, several Nordic countries, Italy, and France showing a 3x to 7x increased risk of myocarditis from the Moderna shot.

In all, the FDA cited TWENTY SIX STUDIES showing that mRNA shots in general, and Moderna in particular, increase myocarditis.

But now to worry! The FDA announces in the next sentence:

The FDA, CDC, and Kaiser Permanente put their fears on the case in February and March of this year and found that the Pfizer-BioNTech shot in adolescents aged 12 to 17 years old, "rarely causes myocarditis and even those results were reassured to make sure that they were not statistically significant, so nothing to see here!"

It was the same fears who they deep-six — Tom Shimabukuro and John Su — whose entire job is making vaccine safety signals disappear. Those guys are absolutely going to hell.

So that's the FDA announcement. Just ignore those 26 high-quality studies from around the world showing an increased risk of myocarditis. Our friends laundered the data for Moderna so we're all good.

What is to be done

Children's Health Defense just launched an excellent 1-click call to action that I highly encourage you to do (and please share it with all of your friends).

Up until tonight (June 13) at 11:59 p.m. Eastern time, you can officially register your profound displeasure with the FDA by submitting a formal comment (1-click). Look the Ask Comment Button in the upper left corner of the website — 125,397 comments have already been received. Let's see if we can get that number above 140,000.

If you want to write to public health political appointees, FDA staff, and VRBPAC members, all of their email addresses are here:

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