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Dear Dr. Shimabukuro:

As the chief legal officers of our States of Louisiana, Montana and Alabama, we write to express our grave concerns about recent reports of myocarditis and pericarditis in young adults. Significantly more reports are surfacing in the short period since the press reported that the CDC opened an investigation into this adverse event. At that time, three short weeks ago, the CDC misleadingly stated that myocarditis and pericarditis were "rare," denied any causal connection, and incorrectly advised the incidence of myocarditis or pericarditis in young adult males was not higher than expected under ordinary circumstances. *See* CDC Notice, Myocarditis ad Pericarditis Following mRNA COVID-19 Vaccination, Updated May 27, 2021. The CDC further misleadingly stated "most patients with myocarditis and pericarditis who received care responded well to medicine and rest and quickly felt better." *Id.* The CDC has already walked back some of its statements as data mounts showing significantly higher-than-normal rates of this condition and a probable connection with the Moderna and Pfizer vaccines.[1] Indeed, the Committee you chair has now called an "emergency" meeting to examine the data. And as of today, press reports indicate more than 1,200 cases have been reported in people under 30 and the CDC Control & Prevention Advisory Committee on Immunization Practices has found a "likely association"

[1] The CDC initially called an "emergency" meeting to review heart complications in kids after vaccination, scheduling the meeting 11 days later and then delaying it even further due to the Juneteenth holiday. The discussion was added to the Advisory Committee on Immunization Practices' regularly scheduled meeting June 23-25. Dr. Marty Makary, a professor at Johns Hopkins School of Medicine and Bloomberg School of Public Health, said he thought the rescheduling was a "joke," given the seriousness of the risk. His recommendation is that children not get the 2d dose until these complications are properly reviewed. Marty Makary, MD, MPH, (@MartyMakary), June 18, 2021.

between these heart conditions and these vaccines in young adults.[2] We write to express several concerns.

First, current data is clearly insufficient to support the CDC's statements regarding the scope of risk. The CDC minimizes the occurrences of this adverse event even while the numbers of reported cases are growing rapidly. The early reported cases are likely the tip of the iceberg because the CDC only flagged the issue three weeks ago. The CDC's handling of this issue and its process for collecting data also indicates the incidence could be *severely* under-reported.[3]

The CDC has minimized – and continues to minimize – both the prevalence of this adverse event *and* its causal connection to these vaccines, both of which have contributed to under-reporting. *See*, CDC, Shimabukuro Report, Vaccines and Related Biological Products Advisory Committee (VRBPAC), June 10, 2021, https://www.fda.gov/media/150054/download. Additionally, the CDC's process for confirming reports and validating them is extremely slow and appears calibrated to *invalidate or confound* the causal links.

Widespread reporting of this problem is only beginning because knowledge of the problem is only starting to spread. Even so, available data reveals major red flags: over 800 reports of heart inflammation have been reported to VAERS by *May 31* (three weeks ago), and half of these (475) were confirmed to "meet the CDC working case definition," *see* CDC Shimabukuro Report. These cases involved the Pfizer-BioNTech vaccine (372 after the 2d dose) and 301 involved the Moderna vaccine, 201 of which were reported after the 2d dose). As of today, the CDC now reports more than 1,200 cases. The CDC Shimabukuro Report slices and dices data, but nevertheless still shows a dramatically higher incidence of observed myocarditis and pericarditis than expected in children between the ages of 16-17 and 18-24. The CDC report also confirms how limited the CDC's visibility is: the VAERS system has "inconsistent quality and completeness of information, reporting biases, and generally cannot determine cause and effect." *See* Shimabukuro Report. In addition the Vaccine Safety Datalink (VSD), upon which some of the analysis relies, only collects data from nine participating healthcare organizations located in a handful of states (WA, OR, CA, CO, MN, WI, GA, and MA). Based even on imperfect insight, however, the data indicates observed reports are far greater than expected.

Second, notwithstanding these warning signs regarding the scope of the problem, the CDC is minimizing the seriousness of myocarditis and pericarditis. The CDC report from the Vaccine Safety Team concluded the vast majority of myocarditis cases seen after vaccination have been "mild." Most pediatricians and pediatric cardiologists never use the terms "mild" and "myocarditis" in the same sentence. So, it is unclear what the committee's definition is of "mild" and it is grossly misleading. The CDC also further misleads the public in stating that children "responded well to anti-inflammatory medication" (also unclear what the CDC means here, as this

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[2] *CDC safety group says there's a likely link between rare heart inflammation in young people after Covid shot,* CNBC, June 23, 2021, posted at 11:13 a.m., https://www.cnbc.com/2021/06/23/cdc-reports-more-than-1200-cases-of-rare-heart-inflammation-after-covid-vaccine-shots.html .

[3] These heart inflammation conditions are not the only red flags that have surfaced. *See* Joseph A. Ladapo and Harvey A. Risch, Commentary, *Are Covid Vaccines Riskier Than Advertised? ,* The Wall Street Journal, June 22, 2021, https://www.wsj.com/articles/are-covid-vaccines-riskier-than-advertised-11624381749.

can involve expensive IV-administered IVIg infusions and treatment in Pediatric ICU), and individuals had "full recovery of symptoms." *See* Shimabukuro Report. This is *intentionally misleading, irresponsible, and undermines principles of informed consent that are necessary for parents to make the right decisions for their children.*

Third, the CDC's advice is not only flatly wrong and grossly irresponsible but potentially deadly. Myocarditis is a serious medical condition that can result in heart failure, heart attack or stroke, arrhythmias resulting from damage to the heart muscle, and sudden cardiac death. Both myocarditis and these consequences of having it can be *fatal* if not treated immediately, according to the Mayo Clinic, *see* Myocarditis, https://www.mayoclinic.org/diseases-conditions/myocarditis/symptoms-causes/syc-20352539. Similarly, pericarditis can last as long as three weeks and can also be recurring or chronic. It can lead to pericardial effusion, chronic constrictive pericarditis, and cardiac tamponade (a life-threatening condition that requires emergency treatment). Mayo Clinic, Pericarditis, https://www.mayoclinic.org/diseases-conditions/pericarditis/symptoms-causes/syc-20352510.

The CDC's selective emphasis on the clearing of "*symptoms*" in its efforts to downplay the seriousness of these conditions and promote vaccines in children could cause serious damage and death in young adults and children. While *symptoms* of these conditions may be alleviated, the *condition* can cause permanent heart damage and death. And for *months* after an acute event both conditions leave young adults and children at deadly risk when engaging in ordinary physical activities. Children routinely engage in activities that elevate their heart rates, some at greater stress levels than others. Indeed, some student athletes will begin two-a-day football practices this summer before football season begins and others are training for and competing in a variety of other sports. This heightened physical activity is *expressly* contraindicated and discouraged by pediatric cardiologists after myocarditis for *at least* six months due to the increased risk of cardiac arrest and death. Pericarditis can become chronic. The CDC misleadingly advises, however, that "most patients who received care responded well to medicine and rest and quickly felt better" and that "patients can usually return to their normal activities when their symptoms improve." *See* CDC advisory, Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html, last updated May 27, 2021 (last accessed June 11, 2021). And as to parents and clinicians, it negligently advises that the "CDC continues to recommend COVID-19 vaccination for everyone 12 years of age and older….". *Id. See also* CDC, Clinical Considerations: Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults, https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html. No parent can conceivably exercise informed consent based upon this type of flatly false and misleading information. "We didn't know," when the CDC *does know* of the seriousness of these conditions and knows the restrictions on activity for kids, will be cold comfort to the parents of children who may lose their child due to complications of myocarditis.

Fourth, treatment and long term care for children with these conditions is expensive. Not only do these conditions require immediate emergency medical attention, they can result in expensive hospitalizations and costly specialized testing and treatment. The CDC does not pay for

treatment or testing and the federal government has conveniently placed itself last in line to pay as a "payer of last resort." *See* Health Resources & Services Administration, Countermeasures Injury Compensation Program (CICP), https://www.hrsa.gov/cicp/, and set up a complex and difficult to navigate system for obtaining the limited compensation offered. Indeed, the statistics from the government's website indicate compensation is highly restricted. As of June 1, 2021, the CICP has only ever found 39 of 1,360 filed claims and still had 869 pending claims. *See* CICP Data, https://www.hrsa.gov/cicp/cicp-data. Notably, a claimant must request and then be sent a claim form to even submit a claim. Within a year of the event the claimant also must file the claim and supply a full year of medical records.

All of the currently used COVID-19 vaccines were approved pursuant to an FDA *emergency use authorization* (EUA). For the FDA to issue an EUA for a vaccine, the FDA "must determine that the known and potential benefits outweigh the *known* and *potential* risks of the vaccine." U.S. FDA, Emergency Use Authorization for Vaccines Explained, https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained. But the rush to approve them limits the time for clinical testing, the populations tested, and the size and nature of the populations tested. EUA approval involves a major trade-off: far more limited clinical testing, especially with regard to our youth. Young adults under the age of 18 were only recently approved, and the authorization for 12-15 year olds was granted as recently as mid-May based upon testing of *only 2,000* U.S. volunteers. Nevertheless, the CDC, even today, is comparing these adverse events to the *total* number of all vaccinated persons. That is grossly misleading.

We urge the CDC not to dismiss these red flags and to re-evaluate the dismissive, misleading, and deadly advice it is providing regarding these serious life-threatening conditions.

Myocarditis has been cited as the reason for sudden cardiac death in 5-22% of athletes under 35 years of age. *See* Mathias Frick, Otmar Pachinger, and Gerhard Polzl, Myocarditis and sudden cardiac death in athletes. Diagnosis, treatment, prevention, https://pubmed.ncbi.nlm.nih.gov/19575161/ (original in German). A recent article published in Pediatrics in Review, the official journal of the American Academy of Pediatrics, acknowledged that the diagnosis of myocarditis and pericarditis has often been delayed because they are uncommon diseases in pediatrics and because "symptoms in the early stages may be overlooked," but that it is important to identify "because the disease process can rapidly become life-threatening." *See* Hari Tunuguntia, Aamir Jeewa, and Susan W. Denfield, *Acute Myocardits and Pericarditis in Children,* Pediatrics in Review (January 2019). The authors further note that "prompt referral to the emergency department, with access to specialists with expertise in the care and support of these patients, is *imperative*." (Emphasis added.)

In summary, the rise in incidents of myocarditis and pericarditis in young adults and children is extremely concerning. Its connection to the Pfizer and Moderna mRNA vaccines should not be diminished in an effort to achieve herd immunity or some targeted percentage of vaccinated individuals.

Parents deserve complete and accurate information – not misleading and grossly incorrect advisories which undermine informed consent. The CDC's current dismissive approach to this problem could lead to sudden cardiac arrest in significant numbers of youth. While in a "cost-benefit" analysis of overall numbers of vaccinated persons, the CDC may conclude that this risk is outweighed by its benefits, it will provide little comfort to those suffering from the long-term damage caused by these conditions and to parents who may lose their child to sudden cardiac arrest. We urge the CDC not to give final approval to these vaccines at this time. We also urge the CDC to immediately pause recommendation for use of these vaccines in healthy young adults and children pending further clinical studies on these relevant populations of young adults. Moreover, to the extent the vaccines continue to be used on young adults and children, we urge the CDC to issue strong cautions for the use of these vaccines in youth who are involved in any form of athletic competition and may be placed at higher risk of sudden death due to cardiac arrest. These children should be monitored before and after vaccination to ensure they have not experienced myocarditis or pericarditis, which would limit their participation in competitive athletics for at least 6 months. All parents should be clearly and fully advised of the heightened risks of myocarditis and pericarditis in young adults and children as well the risks imposed by these conditions. Finally, the CDC should advise that EU-approved vaccines may *not* be mandated.

Very truly yours,

Jeff Landry	Steve Marshall	Austin Knudsen
Louisiana Attorney General	Alabama Attorney General	Montana Attorney General