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Via First Class Mail and Email
jimpicciche@ascensionhealth.org

Joseph R. Impicciche, JD, MHA
President and Chief Executive Officer
Ascension
4600 Edmundson Road
St. Louis, MO 63134

Re: Misuse of Remdesivir to Treat COVID-19 in Ascension's Hospitals

Dear Mr. Impicciche:

Our firm represents Dr. Naomi Wolf of Daily Clout, Health Freedom Defense Fund and concerned citizens who regularly use Ascension's health care services, including its hospitals in Santa Rosa Beach, Florida. We are sending you and your leadership team this letter in response to the continued use of the anti-viral drug remdesivir to treat COVID-19 patients, including children, in Ascension's hospitals.

Remdesivir is an antiviral drug that the Food and Drug Administration hastily approved for emergency use during the first year of the pandemic to deter doctors from treating COVID patients with ivermectin and hydroxychloroquine, cheap alternatives that have been proven to help treat similar diseases before. Subsequent studies have shown remdesivir to be a failure in treating most COVID patients. For example, a large study conducted by the World Health Organization in 2020 showed that remdesivir did not reduce mortality or the duration of illness in COVID-19 patients. The drug has also been associated with renal and liver toxicity by the National Institutes of Health, and the WHO's Collaborating Center for International Drug Monitoring found at least 7,480 adverse reactions to remdesivir in less than two years, including 945 cardiac disorders and 560 deaths. As a result, the WHO said remdesivir should *not* be used to treat COVID patients.

Top American health officials said otherwise, but their recommendation was based on a small, flawed study that predated the WHO's study. Furthermore, doctors on the ground have also reported minimal benefits from remdesivir. For example, Dr. Ken Lyn-Kew, a doctor at

National Jewish Health in Denver, said: "The data show it really doesn't work very well in hospitalized patients."

Despite this evidence, American health officials have not reconsidered their decision to recommend remdesivir, nor have they reconsidered their decision to grant emergency use approval for the drug's use on COVID patients. That is not proper. The courts closely monitor administrative decision-making, especially at the federal level. ""Not only must an agency's decreed result be within the scope of its lawful authority, but the process by which it reaches that result must be logical and rational." *Allentown Mack Sales & Serv., Inc. v. NLRB*, 522 U.S. 359, 374 (1998). This focus on the government's decision-making process means that a plaintiff in an administrative law case can show the government acted arbitrarily because it "ignored … evidence altogether or provided reasons for its decisions that were contrary to the evidence presented." *Innova Sols., Inc. v. Baran*, 338 F. Supp. 3d 1009, 1024 (N.D. Cal. 2018) (discussing cases).

Our clients are preparing a case against the FDA and other regulators to challenge the government's continued recommendation of remdesivir and to rescind its emergency use authorization. We expect that case to be filed in the next sixty days and we expect it to succeed, especially given the international opposition to using remdesivir in COVID patients. Indeed, the only reason hospitals appear to be using remdesivir in COVID patients is financial: they receive a twenty percent bonus on Medicare payments when they use the drug on a COVID-positive patient. That is obviously improper. It also violates the doctrine of informed consent, the principle that patients have a say in their medical care and that health care providers must educate them about both the potential risks and rewards of treatment, especially unproven therapeutics like remdesivir.

Thus, Ascension should not wait for the FDA litigation to be resolved. Ascension's medical providers are required by law to inform their patients of the risks and benefits of any medical intervention and patients are legally entitled to proper and accurate informed consent about all medical interventions being offered to them so that they may make voluntary informed decisions. Ascension also has the ethical responsibility to provide patients with this information. Anything less than that constitutes a knowing and reckless breach of the doctors' professional duty to get their patients' informed consent and could be actionable under various state laws—laws that are not preempted by the federal PREP Act. *See, e.g., Estate of Maglioli v.Andover Subacute Rehab. Ctr. I*, 478 F. Supp. 3d 518, 529 (D. N.J. 2020) (holding that PREP Act does not "more broadly displace state-law causes of action for, *e.g.*, malpractice or substandard care" that are grounded in defendant's failure to do something).

In your roles as CEO, and as legal counsel to Ascension, you have both an official duty and the personal responsibility to avoid harming Ascension's patients. Thus, we urge Ascension to lead by example. Step outside the FDA/CDC/NIH echo chamber. Look at the studies. Listen to the international community and the doctors on the ground. Follow the doctrine of informed

consent and stop using a drug that has failed to provide any meaningful benefit for hospitalized COVID patients and which appears to be doing more harm than good.

Our clients are happy to discuss these issues with you further. In the meantime, please accept this letter as putting Ascension on notice of the limited benefits and the serious risks of remdesivir. All rights and remedies are expressly reserved.

Sincerely,

Scott J. Street

cc. Christine Kocot McCoy, JD (ckocot@ascensionhealth.org)