PJ O'Brien & Associates

PO Box 916 The Junction NSW 2291

January 21, 2025

US Food and Drugs Administration Services Division of Dockets Management 5630 Fishers Lane, Room 1061 Rockville, MD 20852

U.S. Department of Health and Human 200 Independence Avenue SW Washington, DC 20201

Secretary of Health and Human Services

By email: edrls@fda.hhs.gov mc001@fda.hhs.gov

OCRMail@hhs.gov

Attention: Commissioner of the U.S. Food and Drugs Administration, Dr. Robert M. Califf and Secretary of Health and Human Services

Dear Commissioner Califf and Acting Secretary Fink

Citizen Petition: FDA revoke or suspend the approvals for the modRNA Covid-19 products of Pfizer and Moderna

- 1. We **enclose** a Citizen Petition filed on behalf of former barrister Julian J Gillespie, Kevin McKernan, former Team Leader for Research and Development at the Whitehead Institute/MIT Center for Genome Research, Human Genome Project, and Chief Scientific Officer and Founder of Medicinal Genomics, Dr Jessica Rose, Mathematician, Immunologist, Computational and Biochemical and Molecular Biologist, Dr David J. Speicher, Virologist, and L. Maria Gutschi, Pharmacy Consultant, requesting that the FDA revoke or suspend the approvals for the modRNA Covid-19 vaccine products of Pfizer and Moderna, and refrain from any further approving or licensing of future modRNA Covid-19 products from those companies.
- 2. The grounds for revoking or suspending the approvals are:
 - a. The approvals have at all times been legally invalid due to the failure by the FDA to require and receive Environmental Assessments (EAs) from each company, which EAs would have disclosed to the American public in late 2020 the true characterisation of the Pfizer and Moderna Covid-19 products as

Gene Therapies requiring, prior to any possible EUA approval, a public comment period and consideration of public submissions on the Gene Therapy nature of the products, being legal requirements the FDA circumvented without legal authority; and

- b. The Covid-19 products of Pfizer and Moderna contain grossly excessive levels of synthetic DNA contamination and genetic sequences known to promote and cause cancers and genetic disease.
- 3. The petitioners look forward to your timely review of this petition. They are available to answer questions and to provide any additional relevant information.

Sincerely yours,

Katie Ashby-Koppens

PJ O'Brien & Associates

Lawyer, NSW, Australia

katie@pjob.com.au