Dr June Raine, CEO, MHRA,
cc Professor Lim, Chairman, JCVI
Sajid Javid MP, Secretary of State for Health & Social Care
Commission on Human Medicines
Paediatric Medicines Expert Advisory Group

14th November 2021

Dear Dr Raine,

Re safety of COVID-19 vaccines in children

We are a group of doctors and scientists who wrote to you on 17th May, then again on 6th June and most recently to the JCVI on 19th August regarding our major concerns over the safety and indeed the necessity for COVID-19 vaccines for children. Our specific questions remain unanswered, despite increasing evidence of vaccine adverse events in this age group both abroad and in the UK. Your promise made Nov 20th 2020, *"There is absolutely no chance that we will compromise on standards of safety or effectiveness"* seems to have been abandoned.

Our combined clinical and scientific experience leaves us deeply concerned about safety for teenagers receiving the vaccines at the present time and in particular, the lack of timely analysis and publication of adverse events occurring in 12-17-year-olds. Following the FDA and CDC authorisation of the Pfizer vaccine for 5-11-year-olds, we are also concerned that emergency use authorisation will be granted here before the outcomes in 12-17s have been fully assessed, and despite an open acknowledgement from Pfizer that '*the number of participants in the current clinical development program is too small to detect any potential risks of myocarditis associated with vaccination. Long-term safety of COVID-19 vaccine in participants 5 to <12 years of age will be studied in 5 post-authorization safety studies, including a 5-year follow-up study to evaluate long term sequelae of post-vaccination myocarditis/pericarditis'.*

We have the following urgent questions.

Given the demonstrated excess in deaths in young men aged 15-19 since May 2021, can you provide a breakdown by vaccination status, providing interval in days between vaccination if any and death?

Given an estimated 76% of school children have already been infected with Sars-CoV-2, plus the clear superiority of natural over vaccine-induced immunity, how can these children benefit?

Given the poor N-antibody response when natural infection follows vaccination, can you be sure that non-immune children won't be forced into a programme of recurrent booster shots as seen in adults?

Have you seen any data which can predict the quantity of spike protein produced by individuals following a specified dose of mRNA and have you any biodistribution data for humans?

What follow-up data have you seen from the American group reporting late gadolinium enhancement on cardiac MRI scans?

What other potential long term side effects have been considered?

What is the NNTV (number needed to vaccinate) to prevent one death or hospital admission?

Given that children are not seriously impacted by COVID-19, and there has never been an emergency situation regarding children's health relating to SARS-CoV-2 infection, how have you defined 'Emergency' for the purposes of these authorisations? What ethical considerations have been considered?

Yours sincerely,

Dr Rosamond Jones, MD, FRCPCH, retired consultant paediatrician
Professor Keith Willison, PhD, Professor of Chemical Biology, Imperial, London
Professor David Livermore, BSc, PhD, Professor of Medical Microbiology, University of East Anglia
Professor Anthony J Brookes, Department of Genetics & Genome Biology, University of Leicester
Professor Richard Ennos, MA, PhD. Honorary Professorial Fellow, University of Edinburgh
Professor Angus Dalgleish, MD, FRCP, FRACP, FRCPath, FMed Sci, Professor of Oncology, St Georges Hospital, London

Professor John Fairclough FRCS FFSEM retired Honorary Consultant Surgeon

Lord Moonie, MBChB, MRCPsych, MFCM, MSc, House of Lords, former parliamentary under-secretary of state 2001-2003, former consultant in Public Health Medicine

Dr John Flack, BPharm, PhD. Retired Director of Safety Evaluation, Beecham Pharmaceuticals 1980-1989 and Senior Vice-president for Drug Discovery 1990-92 SmithKline Beecham

Dr Alan Mordue, MBChB, FFPH. Retired Consultant in Public Health Medicine & Epidemiology

Dr Roland Salmon, MB BS, MRCGP, FFPH, Former Director, Communicable Disease Surveillance Centre Wales

Dr Gerry Quinn, PhD. Postdoctoral researcher in microbiology and immunology

Dr Geoffrey Maidment, MD, FRCP, retired consultant physician

Mr Malcolm Loudon, MBChB, MD, FRCSEd, FRCS(Gen Surg), MIHM,VR, Consultant Surgeon

Dr Branko Latinkic, BSc, PhD, Reader in Biosciences

Dr Helen Westwood MBChB MRCGP DCH DRCOG, General Practitioner

Katherine MacGilchrist, BSc (Hons), MSc, CEO/Systematic Review Director, Epidemica Ltd.

Mr James Royle, MBChB, FRCS, MMedEd, Colorectal surgeon

Dr Livia Tossici-Bolt, PhD, NHS Clinical Scientist

Dr Elizabeth Evans MA(Cantab), MBBS, DRCOG, Retired Doctor

Dr Mark A Bell, MBChB, MRCP(UK), FRCEM, Consultant in Emergency Medicine

Mr Ian F Comaish, MA, BM BCh, FRCOphth, FRANZCO, Consultant ophthalmologist

Dr Scott Mitchell, MBChB, MRCS, Associate Specialist in Emergency Medicine

Dr Andrew Isaac, MB BCh, Physician, retired

Dr Theresa Lawrie, MBBCh, PhD, Director, Evidence-Based Medicine Consultancy Ltd, Bath

Dr Emma Brierly, MRCGP, General Practitioner

Dr Rohaan Seth, Bsc (hons), MBChB (hons), MRCGP, Retired General Practitioner

Dr Franziska Meuschel, MD, ND, PhD, LFHom, BSEM, Nutritional, Environmental and Integrated Medicine

Dr Kulvinder Singh Manik MBChB, MRCGP, MA(Cantab), LLM, Gray's Inn

Dr Peter Chan, BM, MRCS, MRCGP, NLP, General Practitioner, Functional medicine practitioner

Dr Marco Chiesa, MD, FRCPsych, Consultant Psychiatrist & Visiting Professor, UCL

Dr Alan Black, MBBS, MSc, DipPharmMed, retired pharmaceutical physician

Dr Noel Thomas, MA, MBChB, DCH, DObsRCOG, DTM&H, MFHom, retired doctor

Dr Michael D Bell, MBChB, MRCGP, retired General Practitioner

Dr Sarah Myhill, MBBS, Dip NM, Retired GP, Independent Naturopathic Physician

Margaret Moss, MA (Cantab), CBiol, MRSB, Director, The Nutrition and Allergy Clinic, Cheshire

Dr David Morris, MBChB, MRCP(UK), General Practitioner

Dr Greta Mushet, MBChB, MRCPsych, retired Consultant Psychiatrist in Psychotherapy

Dr Jenny Goodman, MA, MB ChB, Ecological Medicine

Dr Charles Forsyth, MBBS, BSEM, Independent Medical Practitioner

Dr Fiona Martindale, MbChB, MRCGP, GP in out of hours

Dr Christina Peers, MBBS, DRCOG, DFSRH, FFSRH, Menopause Specialist

Dr Chris Newton, PhD, Biochemist working in immuno-metabolism

Dr Stefanie Williams, Dermatologist

Dr David Bramble, MBChB, MRCPsych, MD, Consultant Psychiatrist

Dr Damien Downing, MBBS, MRSB, private physician

Mr Anthony Hinton, MBChB, FRCS, Consultant ENT surgeon, London

and others .....