45 Poplar Road
Parkville Victoria 3052

www.csl.com
www.seqirus.com
www.cslbehring.com

25 February 2021

The Secretary
Senate Select Committee on COVID-19
Parliament House
CANBERRA ACT 2600

Dear Secretary,

Submission to the Senate Select Committee on COVID-19

Thank you for providing CSL with the opportunity to appear at the Committee's public hearing on March 2nd. In advance of our verbal evidence this submission may provide the Committee with some useful background detail on CSL's manufacturing capacity and COVID-19 vaccine supply agreements.

CSL is Australia's largest biotechnology company and a global leader in protein science and plasma-derived therapies. Headquartered in Melbourne with substantial manufacturing operations in Australia, the United States, Germany, Switzerland and the UK, CSL has over 27,000 employees in more than 32 countries. CSL operates two subsidiary businesses, CSL Behring and Seqirus. CSL Behring produces biologic therapies from human plasma and recombinant proteins for rare diseases and operates significant advanced manufacturing facilities in Broadmeadows, Victoria. Seqirus produces seasonal and pandemic influenza vaccines, Australia anti-venoms and Q-fever vaccine and operates advanced manufacturing facilities in Parkville, Victoria.

These businesses are underpinned by a large research and development effort. R&D at CSL is headquartered in Parkville, Victoria and involves more than 1300 scientists around the world. Last financial year (19-20) CSL invested $US922 million globally in R&D.

CSL is very respectful of our longstanding biosecurity partnership with the Australian government and we are conscious that we are the only company with onshore vaccine translation, commercialisation and manufacturing facilities. We engaged with the Federal Government in very early 2020 to determine how we might contribute to the Australian response to COVID-19 and we have been working with them closely and collaboratively ever since.

We began working with the University of Queensland (UQ) on development of their "molecular clamp" vaccine candidate in late January 2020 and on 7 September 2020, entered into an advance purchase agreement with the Department of Health (DoH) to develop, register and supply 51 million doses of the vaccine. While UQ undertook the early development work on the vaccine and the Phase 1 clinical study, CSL had agreed to assume responsibility for the development and commercialisation from Phase 2 onwards under a licensing arrangement with UQ and the Coalition for Epidemic Preparedness Innovations (CEPI).

Regrettably however, data began to emerge from the Phase 1 study showing the generation of antibodies directed towards fragments of the HIV protein (gp41) used to stabilise the vaccine. While there was no possibility of the vaccine causing infection, it became apparent that significant changes would need to be made to well-established HIV testing procedures in the healthcare setting to

accommodate rollout of the vaccine. For that reason, on 11 December 2020 the DoH and CSL jointly agreed to terminate the supply arrangements.

Concurrently with our work on the UQ vaccine, CSL also agreed to act as a contract manufacturer for the AstraZeneca vaccine (AZ1222) for supply to the Australian population. To facilitate this work, CSL entered into the following contracts:

(a) A contract between CSL and the Department of Health (DoH), pursuant to which DoH provided CSL with funding to, amongst other things, retool and reconfigure its manufacturing facilities to cGMP standards to meet the technical requirements of the AZD1222 process (which involves a live virus) and to hire additional staff to support formulation, filling, packing and testing of the vaccine; and

(b) A contract between CSL and AstraZeneca (AZ), pursuant to which CSL has been licensed by AZ to manufacture AZ1222, following a technology transfer of AZ's manufacturing process to CSL, for supply in Australia. Under an initial order, the parties agreed that the CSL would target the manufacture of 30 million doses of vaccine. Under a subsequent order, following the termination of the UQ vaccine project, the parties agreed that CSL would target the manufacture of an additional 20 million doses of vaccine, bringing the aggregate order to approximately 50 million doses in total.

CSL's role is focussed upon the licensed onshore manufacture of AZ's product, AZ1222. The DoH and AZ have separately entered into supply agreement relating to AZ's supply of doses of AZ1222 (manufactured offshore or onshore by CSL) to the Government. CSL is not a party to the supply agreement and is not privy to its terms.

These contracts reflect the high-risk nature of vaccine development and are entered into on the basis that at any stage during development, clinical testing and 'at-risk' manufacture the vaccine programs could fail. Thus, typically the vaccine procurement contracts adopted by governments and manufacturers globally, the largest being the US Government's $US12 billion Operation Warp Speed, tend to include milestone payments due at various development stages, thereby offering upfront financial support for vaccine development and manufacture at-risk in exchange for early supply of finished vaccines.

As you will appreciate, CSL is bound by obligations of confidence to both AZ and DoH with respect to the specific terms of its contracts and related activities, which limit CSL's ability to elaborate with any degree of specificity on these contractual arrangements. We are very proud of our efforts and contribution to Australia's exemplary response to the COVID-19 pandemic. We look forward to sharing further details of the vaccine journey with the Committee.

Yours sincerely,

Dr Beverley Menner
Executive Director, COVID Projects Lead