Submission

By

THE NEW ZEALAND INITIATIVE

to

The Ministry of Health

on the Government Bill

COVID-19 Public Health Response Amendment Bill (No 2)

11 October 2021

Prepared by:
Dr Eric Crampton
Chief Economist
The New Zealand Initiative
PO Box 10147
Wellington 6143
eric.crampton@nzinitiative.org.nz

INTRODUCTION AND SUMMARY

0.1 This submission on the Government Bill *COVID-19 Public Health Response Amendment Bill (No 2)* [The Bill] is made by The New Zealand Initiative, a think tank supported primarily by chief executives of major New Zealand businesses. The purpose of the organisation is to research to contribute to developing sound public policies in New Zealand to help create a competitive, open and dynamic economy and a free, prosperous, fair, and cohesive society.

0.2 The Initiative has followed Covid policy closely since early 2020. We have published several reports and briefing notes on Covid policy; that work has included discussion of Covid testing and policy related to it.

0.3 The Bill includes provision, at the proposed Section 11(1)(d), for the Government to take substantial control of Covid testing companies and labs. It allows the Government to set quality standards, to require that test results be reported, to manage supplies of materials used by testing labs, and to provide differently for different classes of testing laboratories. The Bill also allows, at the proposed Section 11(1)(e), the Government to requisition testing consumables, and to requisition tests. It provides, at proposed Section 11A, compensation for requisitioned materials and tests at a market rate, with disputes to be determined by the District Court.

0.4 Our submission is restricted to matters covered in proposed Section 11 and proposed Section 11A.

0.5 We urge the Government to substantially reconsider its approach. We expect that these sections are motivated by a laudable desire to strengthen testing capabilities and improve testing capacity. The proposed measures risk working against those ends.

0.6 The International Organization for Standardization already provides the appropriate quality standard for medical laboratories at ISO 15189. Regulatory moves by New Zealand to supplant or undermine ISO standards would risk making New Zealand tests less reliable. Procurement for Covid testing is best handled through normal commercial negotiation rather than through requisitioning. Deemed market rate compensation risks being substantially short of the losses that requisitioning could impose. And acquiring tests through requisition undermines incentives to provide testing capacity.

0.7 If the Government will not abandon provisions in proposed Sections 11 and 11A, we urge regular internationally credible review of standards adopted in place of ISO 15189, to ensure they have not denigrated test reliability. We also urge that companies subject to requisition orders be provided not only compensation at a market rate, but also compensation for costs affected companies endure consequent to those orders. Requisitioning of tests and materials could easily force test providers to breach existing contracts. Indemnification is appropriate.

0.8 We also view it as strongly contrary to procedural fairness that a prominent testing laboratory was only informed about the existence of this legislation less than a week before the closing date on submissions. In the limit, the Bill provides the Minister or Director-General of Health the authority to impose new standards on labs; to requisition the lab's necessary supplies and potentially render them unable to fulfil critical private contracts while compensating only at the market rate for the requisitioned supplies; and, to requisition lab testing capacity at a market price while again ignoring the consequence for existing contracted clients.

0.9 Promises to compensate any affected laboratory at either the market rate for requisitioned consumables, or for requisitioned tests do not begin to compensate the affected laboratories for the harm these measures will impose *even if they are never invoked*. The measures

substantially denigrate private labs' ability to credibly promise surety of continued test supply to contracted clients at the exact time when those tests will be most valuable to those clients. These measures must be withdrawn. Failing that, compensation should be substantially strengthened.

0.10 To put it even more clearly: the proposed measures here intended to improve the security of supply of testing material, and of tests, for the public health response will threaten security of supply. We are more likely to encounter shortages of consumables and of testing capacity because of the measures here proposed.

0.11 Finally, while we can understand a potential motivation for backstop requisitioning capability, the conditions under which it might be justifiable also introduce severe risk for anyone who might consider investing in capacity upgrades in other critical areas.

Proposal 1: Setting quality standards.

1.0 In proposed Section 11(1)(d)(i), the Minister or Director-General is provided authority to issue Public Health Orders setting quality control measures and minimum standards in relation to laboratories that undertake COVID-19 testing. The Ministry of Health provides further detail in its *Fact Sheet 5: Regulating COVID-19 laboratory testing and managing testing supplies and capacity*, and in a Regulatory Impact Statement.

1.1 The Regulatory Impact Statement raises potential issues with the quality of testing, noting that the Act provides no explicit power to manage laboratories and the test methodologies used. It also notes that the Act does not provide provision to impose differential regulation on private and public laboratories.

1.2 Neither the Fact Sheet nor the RIS specify any problems in quality control in labs currently. Nor do they acknowledge that the International Organization for Standardization already provides an appropriate quality standard for medical laboratories at ISO 15189.

1.3 Government can ensure quality of testing in several ways. In the first instance, it can ensure that any testing for which it has contracted is undertaken in labs meeting the appropriate ISO 15189 classification. It can ensure that all providers of contracted tests release their validation data for examination, including examination by international experts. If necessary, it can refuse to contract with suppliers that are unable to meet quality standards.

1.4 The ISO 15189 standard includes provisions for initial quality certification and ongoing evaluation and audit. If those standards are inadequate, the Government should make clear exactly what the perceived failure is. The standard affects medical laboratories in general, not just Covid testing. If there is a failure in the standard in ensuring quality control, that failure will be systematic across all kinds of medical laboratory testing, across all countries using the ISO standard. The New Zealand Government could provide a substantial service to the international community in improving laboratory standards if it has identified an actual remediable inadequacy in the ISO standard. However, nothing in the RIS or the Fact Sheet identifies any potential problem in that standard.

1.5 There is substantial risk that any new standard imposed by the Director-General of Health or the Ministry of Health will worsen outcomes where a reliable international accreditation standard already applies. There is also risk that standards will be weakened, rather than strengthened, potentially to the advantage of one potential test provider over others.

1.6 Until and unless the Minister or the Director-General can detail inadequacies in the relevant ISO standard, this section should be removed. Alternatively, it could be replaced with a requirement that any lab providing testing services to the Government must meet ISO 15189 accreditation.

1.7 We have heard reports that the Ministry of Health has pressured IANZ to reduce the applicable standard, to allow saliva testing that does not meet ISO 15189 requirements. This increases our concerns that discretion in standard-setting, rather than holding to international ISO standards, will not improve the reliability of testing.

Proposal 2: Requiring the reporting of test results

2.0 At proposed Section 11(1)(d)(ii), the Minister or Director-General is provided authority to issue Public Health Orders requiring COVID-19 test results to be reported to the Director-General's public health national testing repository. The Ministry of Health provides further minor detail in the Regulatory Impact Statement

2.1 Where the proposed requirement applies only to testing labs, rather than to providers of point-of-care Rapid Antigen Tests, integrating test results into the Repository makes sense, so long as laboratories providing those results are provided access to the relevant systems.

2.2 We understand that, from January 2021, Rako Science repeatedly requested to be able to report into that system, with its requests rebuffed by the Ministry until very recently.

2.3 The proposed requirement must come with a commensurate obligation that the Ministry provides access to the relevant systems in a timely fashion, lest the requirement be used to frustrate the entry of potential test providers to the benefit of existing test providers.

Proposal 3: Managing the supply of testing consumables

3.0 At proposed Section 11(1)(d)(iii), the Minister or Director-General is provided authority to issue Public Health Orders managing the supply of testing consumables (such as reagents and swabs) used by laboratories. At proposed Section 11(1)(e)(i), the Minister or Director-General is enabled to require that a Covid testing lab deliver or use, in accordance with directions given under the order, Covid testing consumables that the Minister considers necessary for purposes of the public health response.

3.1 The Ministry of Health provides further detail in its *Fact Sheet 5: Regulating COVID-19 laboratory testing and managing testing supplies and capacity*, where it notes that the Minister would have the ability to reprioritise supplies for the public health response. The Regulatory Impact Statement notes concerns about potential competition over access to laboratory consumables, which are in short supply globally, and that managing the supply of testing consumables is a response to that concern.

3.2 Every part of this proposed rule is misconceived.

3.3 First, the Government has not established that laboratories are holding inadequate reserves of consumables.

3.4 If the Government does not trust that laboratories are maintaining adequate reserves of consumables, in the first instance, it should look to its own contracting arrangements to ensure that they provide appropriate incentives to maintain surge capacity. Two obvious ways are available.

3.4.1 The Government could pay a higher price for every test while applying penalties for inability to deliver during periods of surge demand. This would provide laboratories with an incentive to maintain larger stockpiles of consumables.

3.4.2 Alternatively, and preferably, the Government could set a payment schedule that includes higher prices for tests undertaken during periods in which testing is greatly in excess of normal demand so that laboratories would find it worthwhile to bear the capital cost of maintaining far higher stockpiles of consumables that might be in short supply.

3.5 Both reasonable ways of ensuring adequate supplies of consumables provide laboratories with incentive to maintain and manage those supplies. The Government's proposal instead would sharply penalise any laboratory that had maintained an adequate supply of consumables and, in doing so, would provide every laboratory with a strong incentive to run down their own reserves.

3.5.1 Maintaining large reserves of consumables as guard against the shortages that can happen during large Covid outbreaks is costly. That cost can only be recouped by the labs undertaking that cost if they can provide a lot of testing during such an outbreak.

3.5.2 If the Government instead requisitions those supplies at a "market price", it effectively promises to expropriate those laboratories that have maintained adequate supplies to the benefit of those that did not. Any laboratory expecting to be so-expropriated would be failing its duty to its shareholders if it maintained reserves of consumables that would risk being expropriated by the Government.

3.5.3 Consequently, the Government here *very strongly risks* creating the shortage that the measure seeks to remedy. This is true regardless of any signalled intent from the Government, noted in *Fact Sheet 5*, that it wishes not to invoke these measures. The situation in which these measures would be invoked is the same situation that provides incentives for companies to maintain contingency reserves of consumables in the first place.

3.6 If the Government wishes that larger stockpiles be maintained, and if the Government does not wish to do this by contracting with laboratories in the ways described in 3.4.1 or 3.4.2, the Government could instead decide to establish its own stockpile of consumables, to be released to testing laboratories during any period of increased demand for tests. This measure would also reduce laboratories' incentive to maintain their own stockpiles. But it is less risky than threatening to expropriate stockpiles from laboratories.

3.7 If the Government is determined to maintain requisitioning provisions, we strongly urge it to establish a reserve of consumables to help mitigate the shortage it is very likely to otherwise cause.

3.8 If the Government is determined to maintain requisitioning provisions, it should also indemnify any testing providers whose materials have been requisitioned, while also immediately compensating private providers whose labs risk being expropriated.

3.8.1 Private labs whose materials have been effectively taken from them by the Government will be unable to fulfil contracts for private testing that they have undertaken with third-party customers. Those third parties may be substantially harmed. Some will have based their own Covid risk-management plans on the availability of accurate testing during a substantial outbreak. If, for example, Huntly power station, or a large chicken processing plant, or a private hospital providing elective surgery, is no longer able to access regular reliable tests for its staff, because the Government has requisitioned all of the necessary testing materials from their contracted private provider, substantial losses will occur. All of these require indemnification of the test provider.

3.8.2 Currently, private test providers can provide clients with some certainty about their ability to deliver testing by maintaining appropriate stockpiles. If a private client wishes to guarantee testing availability over a suitable period, it need only contract with the private provider to maintain sufficient supplies over time horizons limited only by the potential expiration of materials. The Government, through this rule, will make all such contracts less valuable to private clients because there is nothing any test supplier can do to guard against the risk of having all of its materials expropriated by the Government precisely when a client finds testing to be most important. As a consequence, both private testing companies and their clients are harmed by this measure the instant it is legislated, even if it is never used. Compensation seems appropriate. Withdrawing the proposed measure is even more appropriate.

3.9 More generally, the Government should *not* set expectations that companies that exercise diligence and prudence in maintaining reserves against periods of high demand will risk losing their inventories commandeered for their troubles. If a pharmacy purchased a large stockpile of N95 masks, it would earn a return on that risk and capital cost by selling those masks at a higher price during an outbreak. If the Government promised to requisition supplies from a company doing that, taking its masks for the public health response and compensating the company only at a deemed "market price", the result would not be cheap masks for the Government in a crisis. Instead, the result would be that private firms would cease maintaining such reserves, and shortages in a crisis would be greatly exacerbated.

Proposal 4: Providing differently for different classes of testing laboratories

4.0 At proposed Section 11(1)(d)(iv), the Minister or Director-General is provided authority to provide differently for different classes of testing laboratories, for example, based on whether they are funded publicly or privately, in any issued Public Health Orders.

4.1 The intent of this proposal is difficult to discern, as is the problem it intends to solve. The Regulatory Impact Statement notes only that it is currently not possible to impose differential regulation on private and public laboratories, particularly with respect to supply of consumables, should there be a significant outbreak. However, a rule requiring that all consumables be directed according to the edict of the Director-General of Health would apply equally to private and public laboratories while presumably having the effect of directing resources away from private labs.

4.2 The measure may also have the effect of allowing the Government to avoid referring to the contracted price paid to the Government's existing contracted testing providers in determining the 'market price' paid to fully private labs outside of the Government's network, potentially to the detriment of the private provider.

4.3 Absent better justification for or explanation of what is intended here, and its necessity, this section should be withdrawn. The Government can come to whatever difference in treatment it wishes through normal commercial negotiations for contracted supply.

Proposal 5: Requisitioning testing capacity

5.0 At proposed Section 11(1)(e)(ii), the Minister or Director-General is provided authority to issue Public Health Orders requiring that testing laboratories undertake COVID-19 testing solely for the purposes of the public health response to COVID-19 while subject to the order, whether or not the laboratory is contracted by the Crown for that purpose. At proposed Section 11A(3), the legislation would compensate the private lab for the provision of requisitioned tests "at the market rate for those services."

5.1 All of the problems detailed concerning the requisitioning of consumables apply equally strongly here. The measure discourages maintaining adequate consumables supply for serving private clients during any substantial outbreak because of the risk that all contracted capacity will be requisitioned.

5.2 Every reasonable outcome the government wishes to achieve through this measure is better achieved through normal contracting arrangements with private providers for the provision of extra capacity.

5.3 The only plausible justification for this measure is the avoidance of undue bargaining power if only a single supplier can credibly scale up capacity during a period when much greater testing

is required. In that case, the Government may fear that a sole potential supplier would command extortionate rates for providing testing services. But that justification fails.

5.3.1 First, the Ministry of Health held an RFP process for saliva-based PCR testing and decided that a sole supplier could meet all of the Ministry's needs. No additional capacity from other providers was considered necessary.

5.3.2 Second, according to Rako Science, Rako was repeatedly told not to reserve any testing capacity for the public health response. Rako offered the Ministry several opportunities to increase capacity, from adopting a different University of Illinois protocol that would increase Rako's capacity eight-fold, to licensing its technologies to publicly-owned labs at a peppercorn rental.

5.3.3 Third, the Government has seen so little need to engage private suppliers in the public health response that, according to BusinessDesk[1], the Ministry of Health directed Rako Science to not provide any testing in Porirua in March during the Wellington outbreak.

5.4 If the Ministry now considers Rako Science to be the only potential provider of a large increase in testing capacity that would constitute a substantial shift in the Ministry's view of Rako. The Ministry's position has otherwise been incredibly hostile toward Rako's testing system. Shifting from denigrating Rako's platform, to considering it so vital to the public health response that requisitioning could be in order, seems incoherent.

5.5 Take, for sake of argument, that Rako Science is the only potential credible supplier of a large increase in reliable testing for the public health response. Would that justify requisitioning testing at a deemed 'market rate'? The answer must be no.

5.6 Companies sometimes make investments that only earn a return if services can be provided at a high, but still reasonable price during very high demand periods.

5.7 Consider, for example, suppliers who maintain large stocks of generators and who expect to receive a price for them, come an earthquake, that justifies holding large excess supplies in the years leading up to an earthquake.

5.8 If a company expects that taking on all of the cost of maintaining supplies for that kind of eventuality earns only Crown requisitioning at a market price, where a market price might not even be well-defined in the crisis, or where that price risks being interpreted by courts with reference to prices that prevailed during normal times, then no company will make that investment.

5.9 Rako brought innovation to New Zealand's testing capabilities when it invested in a reliable Covid test to New Zealand. Since late last year, the Ministry of Health appears to have had a hostile attitude toward Rako's test. The Director-General of Health derided saliva-based testing at 1 pm briefings, making inaccurate assertions about test reliability. And the contracting process for saliva testing saw Rako excluded.

5.10 If The Ministry now appears to want Rako's capacity as part of the public health response, after the Ministry told Rako not to scale up to provide against that need, and after the Ministry took efforts to thwart Rako through most of 2021, a return on that risky investment is necessary if the Government wishes others to invest in providing goods and services in New Zealand that

[1] Smellie, Pattrick. 2021. "Covid testing report a sharp wake-up call for Ministry of Health." *BusinessDesk* 8 October. Available at https://businessdesk.co.nz/article/opinion/covid-testing-report-a-sharp-wake-up-call-for-ministry-of-health

might otherwise be subject to future expropriation efforts. Why would anyone be willing to make costly investments in capacity useful in a tsunami, or in an earthquake, or in a future pandemic, or later in the current pandemic, if the Government's approach in these situations is to look to expropriation?

5.11 It is difficult to understate how ill-conceived the Government's regulatory approach here is. After repeatedly telling Rako that its services are not required or desired for the public health response, during periods where normal contractual negotiation was eminently possible, the Government now is legislating to give itself the right to effectively commandeer Rako's investment. The Government's approach puts Rako's existing contracts at risk, or at least substantially denigrates their value to Rako's private clients because Rako is now unable to assure continued ability to provide tests during the periods in which those tests will be most valuable to their private clients. Why would any company invest in New Zealand when the Government behaves in this way?

5.12 We strongly urge the Government to withdraw provisions at Section 11(1)(e)(ii) allowing for requisitioning of tests. It imposes costs well beyond that which might be compensated by any 'market rate' for delivered tests while strongly discouraging anyone from investing in greater capacity for delivering tests. It will have effects in other areas where companies expect the Government to resort to expropriation. And it will effectively reward the Ministry of Health for having refused to contract fairly with Rako months ago.

CONCLUSION

6.0 We urge the Government to withdraw provisions allowing the Minister of Health or Director-General of Health to compel the supply of Covid tests and testing consumables. They will have the opposite of their intended effect. Failing that, we urge the government to strengthen compensation provisions to avoid any perception it is using its Parliamentary majority to expropriate a medical supply company. The fallout of any such perception during a pandemic could be catastrophic.

6.1 We urge the Government to rely on appropriate ISO standards rather than provide the Ministry of Health the ability to set its own standards.

6.2 We further raise an issue of procedural fairness. The obvious intended target of the expropriation measures is Rako Science. Rako Science only found out about the legislation on 5 October, six days and four working days before submissions are due. One may be reminded of how, in The Hitchhikers Guide to the Galaxy, Arthur Dent only found out about the Council's proposed demolition of his home the day before it happened. The plans were kept in a locked filing cabinet in a disused basement lavatory, with broken stairs and no lights, behind a sign saying, "Beware of the Leopard". It is simply a disgrace and the antithesis of rules-based law-making.