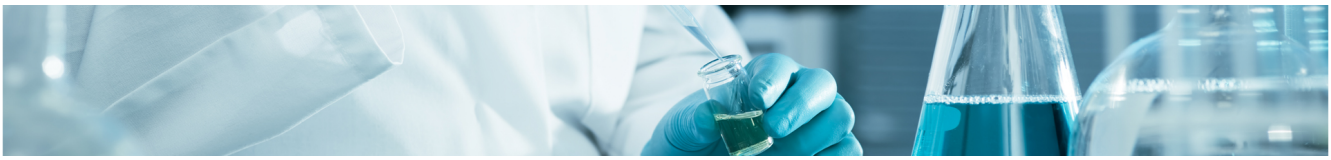

Send Back That Shoddy Product - Contract Remedies Illustrated After Purchase of Junky Medical Supplies (COVID-19)

May 14, 2020

By Noel Courage and Jennie Yum

COVID-19 has brought about a global scramble for medical devices, such as personal protective equipment ("**PPE**") and diagnostic test kits. Inadequate supply from existing vendors has forced governments and hospitals to urgently source medical devices from new suppliers and distributors with very little time to properly vet them. The result: some good product, but also reports of low quality, underperforming, or even contaminated product. This article looks at possible avenues of contract recourse for buyers that receive substandard goods. The article focuses on medical devices, but the recourse is applicable to many other types of products.

To meet the heightened demand for N95 masks, for example, the Food & Drug Administration ("**FDA**") in early April began to allow imports from manufacturers whose masks had been tested by a suitable independent laboratory but had not been tested by US authorities. Subsequent testing by the National Institute for Occupational Safety and Health ("**NOISH**"), the regulatory body responsible for testing and rating masks and other PPE in the US, found that a significant percentage of imported masks allowed more particles to pass through than permitted by US safety standards. In response, the FDA pulled approval for N-95 style masks for more than 60 manufacturers. Many purchasers were left with a supply of dangerous masks, unsuitable for healthcare workers exposed to COVID-19. The FDA has discretion to require sellers to recall unsafe medical devices, allowing buyers to send them back to sellers for a full refund.

Closer to home, there have been similar reports of faulty medical devices. New Brunswick and Ontario have each reported receiving shipments of contaminated, and therefore unusable, testing kits and nasal swabs intended for COVID-19 screening. Meanwhile the City of Toronto had to recall $200,000 worth of surgical masks that had been distributed to workers in long-term care homes when the masks were found to be prone to tearing and ripping while in use. As discussed below, these situations appear to have been resolved between the parties by reference to their contracts. This article will not look at regulatory authority involvement in recalling unsafe medical products (unsafe medical devices should be reported to Health Canada, even if the contract issues are resolved between the parties).

Generally, sellers must provide goods that meet the quality standards set out in the sales agreement, or else may be liable for breach of contract. There are also implied warranties of quality in many sales contracts pursuant to provincial sale of goods legislation[1], unless specifically excluded by the contract terms. Despite these remedies being available, in the case of substandard goods, renegotiation of the contract may be the best outcome if the goods are usable at some level, even though not removing the sting and inconvenience of receiving inferior goods.

In one recent case, the Canadian government received a large order of substandard N95 masks. Instead of rejecting the shipment outright, the Canadian government negotiated a price reduction and intends to deploy the masks to a lower risk healthcare setting. In the other examples above, New Brunswick sent back the shoddy product and is expecting a replacement shipment of testing kits. Toronto will receive a refund from the supplier for the faulty masks and is also considering further legal action. The masks were already in use by city staff at long-term care locations with confirmed cases of COVID-19 at the time of the recall, exposing the staff to danger. The city and mask manufacturer may also be exposed to potential liability if staff are harmed as a result of the poor quality mask.

There are typically specific provisions in a sales contract relating to fulfillment (performance) of the contract and product quality. The specifics of these provisions will govern the type of recourse available. These are discussed in more detail below.

Conditions, Intermediate Terms and Warranties

Conditions regarding product quality specifications must be carefully worded as they are important to being able to reject the goods and demand proper replacement goods. For example, the description "N95 masks" is less meaningful from a quality perspective than "NIOSH-certified N-95 masks." Only independently tested N-95 masks have NOISH certification. "N-95 style masks" are a different type of mask that may also filter out tiny particles but are not certified. Another example of specificity is to describe a quality brand name for the masks (e.g., 3M) and the materials that the buyer requires the masks to be made. Samples may be requested for viewing.

Contractual terms relating to the nature of the goods can be drafted in such a way that they are either conditions, intermediate terms, or warranties. Importantly, the legal recourse available to contracting parties differs for breaches of each of these types of terms. Terms relating to quality of the goods should be drafted as conditions. A *condition* is critical to the contract such that if there is a breach of a condition, the buyer can terminate the contract and claim damages, even for minor breaches.

If the contractual terms relating to the quality of the goods are considered less than a condition of the contract, such as an *intermediate term* or a *warranty*, then the buyer may not be able to terminate for minor breaches. For intermediate terms, a sufficiently serious breach may still justify contract termination, but if the breach does not substantially deprive the buyer of what was bargained for (i.e., is not considered "serious" in the legal sense) then it may not justify termination. Alternatively, a breach of a warranty about the nature of goods will typically only permit the buyer to sue for damages, but not to terminate the contract. Despite these general principles, the contract can be written to specify that breach of an intermediate term or warranty does give the right to terminate.

Refusal to Perform Essential Elements of Contract

If a seller performs some aspects of a contract but refuses to perform other, essential aspects of a contract, there may be an *anticipatory breach*. This differs from a complete failure to perform (or ghosting), described in our earlier article, wherein the seller simply fails to deliver at all.

If the unperformed aspects of the contract deprive the buyer of substantially the whole benefit of the contract, then that may be considered an *anticipatory repudiation* of the contract. The buyer may reject the repudiation, and if the seller does not perform, then hold the seller liable for damages and/or potentially claim for *specific performance* (i.e., performance of the contractual duty). This will obviously not be practical on an international, time sensitive contract for goods. Alternatively, the buyer can accept the repudiation, terminate the contract and claim for damages. This option is also not practical when the goods are required as soon as possible, as in the case of PPE, but damages can at least provide some potential recourse for losses incurred by setting up a new contract with a different seller that will be fulfilled.

Due Diligence, Contract Terms

As always, basic contractual due diligence cannot be neglected. In the case of PPE, due diligence can help buyers to identify sellers that are not properly authorized to produce PPE, as well as fraudulent sellers. See our earlier article for more details on due diligence.

The COVID-19 crisis has exposed weaknesses in the medical device supply chain. This article focuses on quality, but the risks for buyers contracting with new suppliers that have not thoroughly been vetted include other issues such as generally poor performance under the contract, late performance, and payment issues (e.g., demands for additional money). The consequences of each and options for legal recourse need to be discussed on a contract-by-contract basis with a lawyer.

---

[1] Note that the remedies under sale of goods legislation may vary depending on the parties to a sale, for example business to business sale versus retail business to consumer.

professional advice. To obtain such advice, please contact a Bereskin & Parr LLP professional. We will be pleased to help you.