LEGAL INQUIRY

IF THERE ARE PRODUCT DEFECTS IN MEDICAL PRODUCTS USED FOR THE COVID-19 PANDEMIC, WHAT DO YOU DO?

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What is a Product?

A good distributed commercially that is (1) tangible personal property, (2) the result of a fabrication or production process, and (3) passed through the distribution channel before the consumption of the good. *Black's Law Dictionary*

Type of Products

Face Masks

Gloves

Scrubs

Test Swabs

Ventilators

Defects

Design

Manufacturing

Warnings

PRODUCT LIABILITY:

DEFECTS CAUSING DEATH OR INJURY

As a result of the thousands of injuries and/or deaths related to Covid-19, families are losing spouses, parents, children, companions, and incomes. They are also experiencing significant pain and suffering. I was recently asked what legal recourse may be available when a loved one dies, or is injured, as the result of Covid-19 and it is suspected that the cause of death or injury is related to either (a) the failure of a ventilator or (b) the failure of a piece of the personal protective equipment (PPE).

Two legal theories come to mind: strict liability; and/or a negligence cause of action against multiple entities including, but not limited to manufacturers, suppliers, distributors or sellers of PPEs. As we know, millions of masks and ventilators have been recently manufactured and distributed across the nation to medical facilities. These products are intended to assist the end users with the care of persons who have been diagnosed with Covid-19 or other illnesses. When the loved one, after

Restatement (Second) 402A

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

(a) the seller is engaged in the business of selling such a product, and

(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although

(a) the seller has exercised all possible care in the preparation and sale of the product, and
(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

hospitalization, dies or suffers an injury, we are left wondering what happened inside of the hospital room that may have contributed to or caused the person's injury or death. Lately, the general response to families' inquiries is the standard statement: "complications with pre-existing illnesses" resulting into death or a prolonged fight with the illness.

What if there is more to the story? Based upon the country's history of dealing with the manufacture of products, even medical equipment, we know that there are margins of error during the manufacturing phase. These margins widen when products are rushed through production on compressed timelines and steps are shaved to meet deadlines. Based upon years of litigating product defect cases, I have learned that in a time of urgent need, the most important step that is generally eliminated by companies is quality control. The manufacturer's purpose for implementing a quality control procedure, during the manufacturing process, is to ensure that a product is safe to use by the consuming public **before** that product is placed into the stream of commerce.

Due to the alarming and immediate need for masks, gloves, test swabs, and ventilators, the consuming public has observed many companies (some with no history of manufacturing medical

devices and supplies) answering the government's call for assistance. Consequently, there is also a significant reduction in the amount of time needed for the production of such equipment and devices. The legal community knows that if the t's are not crossed and the i's are not dotted, lives can be impacted. Why would that be different during a pandemic? The tough questions must be asked now and the answers should be evaluated to determine what legal claims need to be considered and who may be the responsible parties for the injuries to and death of loved ones.

Product Defects: Strict Liability and/or Negligence

There are three types of product defects that could possibly exist and cause the death or injury to a person who used a defective product (i.e. mask or protective suit) or was serviced by someone using a defective product (ventilator, test swab, or medication): (1) manufacturing defect; (2) design defect or (3) a warning defect. For example, in the event an investigation reveals that a mask failed to prevent the transmission of the virus and caused a person to contract the virus due to the presence of perforations or loose straps, those conditions are deviations from the normal design of masks and may be deemed manufacturing defects. The manufacturing defects could be actionable as a claim of strict liability pursuant to the Restatement (Second) 401a (generally adopted by the states) or a claim of negligence against all persons who are responsible for placing that mask into the stream of commerce. Those persons may include the manufacturer, the distributor, the seller, and the end user (i.e. hospital and the doctor). Be alert and conscientious to the following fact: to pursue either legal theory, the prosecuting litigant must understand that it has the burden to prove a crucial legal element to succeed in a claim against a responsible party, **causation**. What caused the injury or death? What caused the product's defect? Did the product's defect cause the death or injury?

To answer these inquiries, it is important to ask the tough questions now. The appropriate representative for the loved one (if not the loved one) should ask for medical notes from the chart associated with the loved one's care, the list of names of persons who cared for the loved one, the list of medications and medical procedures used to treat the loved one while hospitalized. If the loved one is transported by ambulance to a medical facility, remember to obtain the name of the company that transported the loved one to the facility. For the medical transport company, ask the same questions and obtain the same lists and documents. It is imperative to assemble as much information and data as possible in order to understand what occurred in the hospital room or at the time of the injury (i.e. contraction of the virus) The above list is not exclusive or an exhaustive list of evidence needed to pursue a claim.

Once the pertinent information has been assembled and preserved, it can be evaluated by legal counsel to determine if there is a viable product liability cause of action. For more information, please feel free to contact **Karen D. Fultz, Esquire, Sheehe & Associates, P.A., Florida.**