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RISKS AND REMEDIES FOR CLAIMS ARISING FROM INACCURATE DIAGNOSTIC TESTS

BY ELIZABETH J. STREELMAN, NATHALIE SMYTH, ANITA GORNEY, DAN BRETTLER, AND MICHELE FIELDS

Last year, the World Health Organization called on all countries to ramp up their testing programs with a view to slowing the advance of the COVID-19 pandemic. Pharmaceutical and diagnostic companies rushed to develop diagnostic tests, some of which are alleged to be inaccurate and unreliable.

In this article, Kennedys Law and Conner Strong & Buckelew examine the liability and insurance risks of putting 'fast-tracked' diagnostic products on the market and how companies may be able to limit their related exposures.

CLAIMS THAT MAY ARISE FROM INACCURATE DIAGNOSTIC TESTS

PRODUCT LIABILITY CLAIMS

Claims arising from the sale, distribution and end-consumer use of inefficacious diagnostic kits in the US could arise in a number of ways against multiple players in the distribution chain:

- **Strict liability** of the producer for defects in the design or manufacture of a test, or for failure to warn a patient of potential inaccuracies in the result;
- **Negligence** of the manufacturer or supplier for breach of their duty of care to provide the recipient with an accurate test; and/or
- **Breach of implied or express warranty** by the producer, particularly where tests are marketed as 100% accurate.

While it is more common to see claims for false negative tests, claims may also arise from false positive results, which could cause emotional distress and financial hardship both to the end consumer and to people with whom they have had contact. Indeed, attorneys in Canada have been retained to bring a class action on behalf of nursing home residents, who received eight false positive COVID-19 test results. The plaintiffs (which also comprise nursing home staff, their close friends and family) allege that the false positive results caused them emotional harm and loss of earnings.[1]

SHAREHOLDER LITIGATION

Actions may also be brought by shareholders of pharmaceutical companies arising out of false and misleading statements made about the accuracy of diagnostics tests.[2]

Indeed, in June 2020, an action was issued by shareholders of one of the first diagnostics companies to receive approval for the manufacture and distribution of COVID-19 diagnostic tests in the US and EU.[3]

[1] https://www.biospace.com/article/releases/miskin-law-bringing-class-action-over-false-positive-covid-19-test-results/

[2] In violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934

[3] Gelt Trading, Ltd. v. Co-Diagnostics, Inc., No. 20-cv-00368 (District of Utah)

According to the shareholder's lawsuit, the COVID-19 test was stated publicly to be "100% effective" in detecting the virus. When the FDA later announced that no diagnostic test was 100% accurate, the company's stock price fell, resulting in huge shareholder losses. Proceedings were issued on the basis that the company had violated federal securities laws[4] pertaining to, among other things, deceptive practices in securities trading. While the parties await the outcome of the lawsuit, it is unlikely that the liability immunity afforded by recent public health crisis legislation (discussed in further detail below) will be available to companies, which are alleged to have violated such laws.

POTENTIAL DEFENSES

There are a number of grounds on which manufacturers and players in the chain of distribution of Covid-19 and other diagnostic tests may be able to protect or defend themselves insofar as possible against the risks of such litigation.

IMMUNITY

In 2005, in preparation for the possibility of a massive public health crisis, the U.S. government crafted the Public Readiness and Emergency Preparedness (PREP) Act, which authorizes the Department of Health and Human Services (HHS) to issue a PREP Act Declaration that:

- provides immunity from liability for, among other things, any loss caused by the administration or use of 'countermeasures' (including treatment and diagnosis products) to diseases constituting a risk of a future public health emergency;
- suspends multi-year testing requirements; and
- approves emergency use of desperately needed novel drugs, including vaccines.

Liability immunity under PREP extends to manufacturers, distributors, program planners[5] and qualified persons[6] for claims arising from personal injury, business disruption, or property damage.

In March 2020, the Coronavirus Aid, Relief and Economic Security (CARES) Act extended the protections provided in the PREP Act to manufacturers of any drug, biological product, medical device or vaccine used to treat, diagnose, cure, prevent or mitigate COVID-19 or a virus mutating therefrom.

The protection is, however, not absolute as the FDA can revoke emergency use authorization when appropriate, particularly if it has concerns about the accuracy or efficacy of any such products or devices.

STATE OF THE ART

In product liability litigation, a 'state of the art' defense is available to a manufacturer who can prove that a product incorporates the best technology and scientific knowledge available at the time the product was manufactured. Evidence of the level of technology and lack of other advanced technology on the market at that time are key to this defense.

[4] Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder.

[5] Individuals and entities involved in planning, administering, or supervising programs for distribution.

[6] Persons authorized to prescribe, administer, or dispense covered countermeasures.

Given that there is still so much unknown about the novel coronavirus and its various mutations, this defense could be particularly useful to defendant manufacturers in COVID-19 litigation who can show that their testing products were developed with the best technology and scientific knowledge available at the time, against the background of urgency with which such products were required.

ACCURACY IN ADVERTISING

In an effort to avoid a potential claim from being brought, producers of diagnostic tests should, at the outset, take great care with the preparation of their statements as to the efficacy and accuracy of the product, not only in order to avoid the potential for shareholder actions and other claims based on reliance of such statements, but also to maintain the integrity of the product and the company.

COMPARISON WITH LAWSUITS ARISING FROM THE HIV EPIDEMIC IN THE 1980S

Comparisons can be drawn from the emergency response to the COVID-19 pandemic and the HIV epidemic in the 1980s where HIV blood screening tests were developed expediently in the face of the national health crisis.

At the time, several blood-screening tests failed to detect HIV in blood supplies later used for transfusions. As a result, patients infected with the virus filed litigation. While the consequences of these failures were tragic, the New Jersey Supreme Court found in favor of the test manufacturer on the grounds that the claim was pre-empted by the FDA's unique regulation of the HIV screening tests, and that the tests had been developed expediently in the face of a national crisis.[7] In reaching its decision, the court took into account that the FDA had:

- actively directed the manufacturer concerning the design format of the tests;
- determined the appropriate cut-off[8];
- dictated the exact wording of the test package inserts;
- directed the manufacturer not to instruct blood banks to retest samples below the cut-off; and
- actively monitored both the 'first generation' tests' field performance, and the development of the 'second generation' tests.

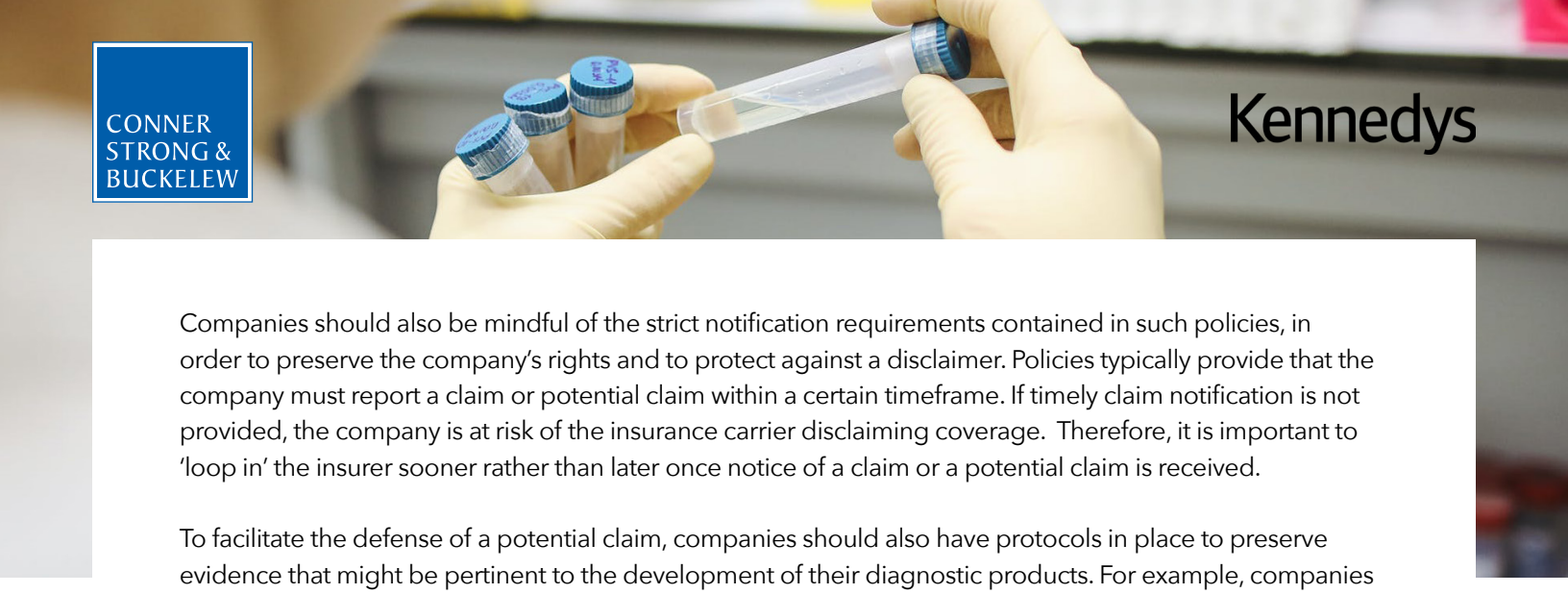
Should any similar claims be brought against manufacturers of Covid-19 tests, for example where a patient did not seek early medical intervention and consequently died or suffered severe illness as a result of a false negative Covid test, it will be necessary to carefully consider whether and to what extent this case law, the PREP and CARES Acts, and any intervention by the FDA and similar authorities, may be relevant in the defense of such claims.

INSURANCE CONSIDERATIONS

It is important that diagnostics companies and manufacturers have in place sufficient insurance coverage for the risks described above. While these will most likely fall within the scope of a product liability policy, coverage under E&O or D&O policies may also be relevant. For instance, companies should take great care when preparing and making representations to their shareholders and to the public to avoid any potential claims under their D&O policy.

[7] R.F. v. Abbott Laboratories, 162 N.J. 596, 745 A.2d. 1174 (2000).

[8] The cut-off value, defined by the FDA in the test's instructional pamphlet, was used by blood bank technicians to measure whether the HIV antibody was present in a donated blood sample.



Companies should also be mindful of the strict notification requirements contained in such policies, in order to preserve the company's rights and to protect against a disclaimer. Policies typically provide that the company must report a claim or potential claim within a certain timeframe. If timely claim notification is not provided, the company is at risk of the insurance carrier disclaiming coverage. Therefore, it is important to 'loop in' the insurer sooner rather than later once notice of a claim or a potential claim is received.

To facilitate the defense of a potential claim, companies should also have protocols in place to preserve evidence that might be pertinent to the development of their diagnostic products. For example, companies should ensure they preserve all electronic data, including proof of trials, testing and scientific research.

Given that each potential claim will bring its own unique issues and challenges, diagnostics companies and manufacturers should carefully consider the provisions and adequacy of their policies to ensure that they provide sufficient cover in the event of any and all risks, which may arise as a result of putting their diagnostic tests onto the market.

CONCLUSION

Many lessons can be learned from past litigation involving failed diagnostic equipment but, most importantly for manufacturers and their insurance brokers, it is critical to identify the policy that is triggered by a failed diagnostic claim and to notify the insurer(s) as soon as possible.

As we have seen, courts have historically been relatively lenient on companies who have expedited the development of their testing product in times of national emergency, particularly at the request of the government or its agencies. It is therefore hoped that, in the event that similar litigation arises, the courts will afford them the same leniency, particularly in light of the protections provided by the PREP and CARES Acts.

ELIZABETH J. STREELMAN
Partner
Defense
Kennedys, New York
Elizabeth.streelman@kennedyslaw.com
T +1-646-625-3981
M +1-516-662-9771

DANIEL S. BRETTLER
Managing Director
Life Science and Technology Co-Practice Leader
Conner Strong & Buckelew
dbrettler@connerstrong.com
973-659-6456

NATHALIE SMYTH
Senior Associate
Product Liability and Life Sciences
Kennedys, London
Nathalie.smyth@kennedyslaw.com
T +44-20-7667-9284
M +44-7710-118-164

MICHELE FIELDS, ESQ.
International Practice Leader
Senior Claim Consultant
Conner Strong & Buckelew
mfields@connerstrong.com
856-479-2138

ANITA GORNEY
Associate
Defense
Kennedys, New York
Anita.gorney@kennedyslaw.com
T +1-646-625-4003
M +1-347-327-1828