

the current trends and market conditions for the Life Sciences Sector and trying to predict the future in the shadow of the Covid-19 Pandemic adds a third category to the Secretary's statement; we now must also consider the impact of the **unknown unknowns**.

Today, underwriters are contending with two types of Product Liability exposures as a consequence of Covid-19. The first is the impact of companies who are developing or manufacturing products that are intended to prevent or treat the virus. None of these products are unique to underwriters per se. What is unique is the myriad of companies who have not previously been manufacturers of life sciences products who are now diverting their manufacturing capacity to reducing the critical shortages of necessary equipment. So, underwriters who have historically depended on looking to the specific expertise and historical experience of a company in order to determine whether the risk is worth taking must now evaluate whether a company with no experience is a desirable insured. The magnitude of the problem is a function of the product being made. A low hazard product such as a plastic face shield, even when it's being made by a toy manufacturer is not likely to be a problem. The mass production of ventilators (always considered something of a high hazard product) being manufactured by an auto manufacturer is an entirely different matter.

The second exposure are products being developed to diagnose, prevent or treat the virus. Many of the companies we are seeing are both developing products as well as providing or performing some form of professional service. Those developing test kits are often analysing the test results once their products are released. Those developing vaccines or therapeutics are conducting clinical trials and have oversight responsibility for the conduct of the studies with human subjects. These are familiar exposures to Life Sciences Underwriters; however, the urgency of the work being performed, and the regulatory exceptions being made in order to quickly find safe and effective remedies is cause for increased concern.

So, what is being increased in both underwriting situations is the potential impact of the **unknown unknowns**. We have not experienced a pandemic with the potential for so much harm in over a century. We are truly in unknown territory and there are no past occurrences that can provide guidance for the future. And for liability underwriters in general, lack of past experience and guessing about the future make the current business environment daunting.

The Public Readiness and Emergency Preparedness Act (Prep Act)

In order to ensure that the developers and manufacturers of essential products during a national emergency would not be deterred from scaling up their operations over liability concerns, The Public Readiness and Emergency Preparedness Act (PREP Act) was signed into law in December of 2005. The Act authorizes the Secretary of the Department of Health and Human Services to issue a declaration that provides immunity from liability (except for wilful misconduct) for claims of loss caused by the administration or use of countermeasures to diseases, threats and conditions determined by the Secretary to constitute a public health emergency.⁴

⁴ Public Readiness and Emergency Preparedness Act

<https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx>

The Proclamation on Declaring a National Emergency for Covid-19 was issued by The President of the United States on March 13, 2020, and as such the PREP Act was put into action and applies to all “claims for loss” caused by, arising out of, relating to, or resulting from the “administration” or the “use” of a “covered countermeasure.”⁵ The list of covered countermeasures is extensive, but generally products fall into one of three categories; products that prevent, diagnose or treat Covid-19. They can be anything from face masks and gloves to ventilators, vaccines and therapeutics.

Like worker’s compensation or The National Vaccine Recovery Act, the PREP Act, seeking to avoid lengthy litigation, provides coverage on a no-fault basis.

The Prep Act and Risk Selection

Despite the broad protections offered by the PREP Act, companies developing and manufacturing covered products are still seeking product liability coverage. For those companies already operating in the Life Sciences sector, Covid-19 related products may just be a portion of the work they do, thus they require a comprehensive program for their remaining products and they expect that any products that could be covered by the Act will also be included in their coverage.

More specifically, those who are only in business to produce covered countermeasures, or those who have previously only manufactured products in non-Life Sciences industries seek coverage despite the government’s assurances. Their motivation for purchasing coverage that could be considered redundant can be summed up as ‘acting out of an abundance of caution.’ The government does not certify or approve a product as being covered under the PREP Act. A coverage determination will only be made after a claim is made. Given the broad scope of applicability, manufacturers can be reasonably assured that their products will apply, but the purchase of commercial insurance take care of the ‘just in case.’

Underwriters are certainly unaccustomed to having the kind of assurance that the Act provides. One might assume that the pricing for providing the coverage should be low and the terms should be broad. However, The Act has not yet been tested, so we have no prior circumstances to look to for predicting the outcome of a claim under the Act. There is also the possibility for an occurrence not contemplated or foreseen. We find ourselves attempting to set terms and cost in the realm of all the **unknown unknowns**.

On May 12, 2020 it was reported that a fire that broke out in an intensive care ward in a hospital in St. Petersburg in Russia that killed five people with Covid-19. The fire may have been caused by one of the ventilation machines short-circuiting, Russian news agency Tass reported Tuesday, citing a source in the emergency services.⁶ Should such an occurrence happen in the US, would the entirety of the product liability be covered under the Act? A superficial read of the legislation would point to

⁵ Public Readiness and Emergency Preparedness Act

<https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx>

⁶ Fire in Russian Hospital Kills 5 Coronavirus Patients; Ventilator Could Be To Blame

Holly Elliyatt - <https://www.cnbc.com/2020/05/12/fire-in-russian-hospital-reportedly-kills-5-coronavirus-patients.html>

there being coverage. However, given the magnitude of the damage and the no-fault basis for the coverage, would the government reimburse the manufacturer for damages beyond bodily injury, such as the mental anguish of the deceased's family, or should the injured survive, the costs of care in the event of permanent disability?

What has been seen from underwriters so far is that despite the protections provided by the PREP Act, normal underwriting considerations, hazard evaluations, terms and pricing are being quoted as they would in the absence of the Act. Risk selection is being tempered by how far afield a manufacturer may be straying from their normal pursuits. For lower hazard products such as Personal Protective Equipment (PPE) expertise is less of a concern. For more complex medical devices, and certainly for pharmaceuticals, level of expertise matters a great deal.

Although the coverage focused upon here has been Product Liability, the vicarious professional liability exposures associated with Contract Manufacturing or the conduct of human testing warrants comment. These exposures are usually covered as an addendum to a Products Liability policy for Life Sciences companies. The intention of the coverage is to cover financial losses resulting from either a mistake made while conducting work for others or any bodily injury where the cause of loss is any type of clinical advice given by way of a clinical trial protocol. If the work is being done in conjunction with a product related to Covid-19, both the PREP ACT and The Corona Virus Relief Act (CARES Act) may apply. Details about the professional liability coverage provided by the CARES Act is a subject unto itself, but for our purposes, there is a small degree of overlap in the coverage the two acts provide.

While it is still early days, there has been an emergence of Covid-19 specific coverage limitations appearing on policies. Underwriters concerns seem to be specifically focused upon any circumstances that could promote the transmission of the disease as opposed to excluding claims related to Covid-19 related products. It is more than likely additional restrictions will appear over the course of 2020, but for the present these also remain **unknown unknowns**.

Returning to the workplace – never to be the same?

Boris Johnson announced on Sunday evening that people who are unable to work from home should be “actively encouraged” to return to the workplace. This is primarily targeted at those who work in manufacturing and construction and doesn’t apply to those of us that are lucky enough to work in industries that enable remote working. It does however beg the question of what returning to the office will look like when the day does come (if that day comes at all).

The Demand for Office Space

The need for social distancing in the office in the wake of the pandemic can prompt a number of reactions from the C-suite executives calling the shots. For many this may have acted as a wakeup call and prompted the realisation that the need for head offices in central locations is no longer necessary and doesn’t serve the purpose they believed it would. For many, working from home is more efficient and suits the needs of their lifestyle better. This will certainly be a cause for concern for the property developers and REITs who have substantial money on the line. In the case of 22 Bishopsgate, London’s new tallest building that was due to open its doors this spring, it has long been speculated that it will struggle to achieve the demand for its office space, and this crisis is likely to have been detrimental towards the push for profit.

For those companies that require office space and simply can’t operate without it, the reaction may be instead to increase the amount of space they rent to allow for more space per employee. This may not be affordable for many firms in the wake of this economic disaster, but for some it may not be an option. Market traders are an example of a profession that requires ultra-fast broadband whereby a matter of milli-seconds can be the difference between profit and loss, and this can only be achieved in controlled office environments. In the interim many have been moved to disaster recovery sites, but this is not sustainable in the long run.



Lloyd’s has been looking at the different ways in which it might be possible for the underwriting room to reopen in the coming weeks/months, but this has been negatively received by the London Market Association. Their view is that if they wish to reopen the underwriting floors it is their prerogative to do so, but the market participants will simply speak with their feet and choose to stay away. It is already evident that people are becoming accustomed to working remotely with there now being 102 broking firms using electronic placing through PPL (Placing Platform Limited), with the number of users increasing by 40% between March 14th and the second week of April.

According to Lloyd’s CEO John Neal, the importance of face-to-face contact should not be underestimated, with some problems that ordinarily would only take 45 minutes to solve taking in excess of a day in the current environment.

John outlined the three options being explored for the return to the underwriting room:

1. Insurers are in the room but brokers join virtually
2. Only certain product lines to be allowed in the room at any one time
3. The introduction of a booking system for people who wish to use the building

Many employees, despite the assurance of safe, socially distanced working conditions, will be reluctant to return due to requiring public transport - where you are at much greater risk of contracting the disease. Through conversations held with colleagues throughout the market, it would seem that September 1st is the likely earliest date of return for some employees, but this to many is still seen as being too risky given the very little benefit that would be achieved.

Innovation in Insurance – no longer an oxymoron?

Convex Broker Booths

In order to adapt to the challenges of communication while working from home, Convex are trialling “Broker Booths” through their [website](#). Clicking the link to ‘Open’ broker booths should join you to a video call with Reception, who will find the Convex Underwriter you are looking for and try to connect you (should they be available). Calls are hosted by BlueJeans video conferences software which does not require any downloads.

This is great evidence of firms being proactive in their approach to making working from home as seamless as possible.

Syndicate Ki

This synergy of technology and insurance made us sit up straight in our chairs. Unsurprising that it comes with the intervention of Google.

Ki is the new standalone, fully digital, algorithmically driven, follow only syndicate from Brit. The syndicate will be accessible anytime, anywhere to act as follow capacity for a set of recognised lead markets. Ki’s algorithm will automatically evaluate and quote business and has been developed with a broker focus to ensure engagement.

As yet, we have not seen reference to etymological origins. Our early speculations surround the Japanese reference to a form of psychic energy – we like than anyway.

Just a thought...

The trend towards working from home had been gaining momentum over the previous few years, with the stigma that WFH is the same as a sneaky day off fading away. With the widespread access of high speed broadband and the massive suite of personal computing products available, there are now very few barriers to being able to work remotely. Is it possible that over the coming months/years ‘Working from Work’ will become the new ‘Working from Home’ and that ‘Working from Home’ will simply be ‘Work’?

That's all for this week

As always, if you have any questions about any of the content in this newsletter or you might have any enquires regarding the suite of services offered by the Beach team, please do not hesitate to contact any member of the team on the contacts page below. Stay safe.

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