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"Right to Try" Laws Paint a New Picture on the Need for Berkley Life Sciences' Product Shortage Coverage

To many the advent of spring is a joyous time of year. Spring means new growth. Unfortunately for life science companies confronting the increased risk of product shortage litigation, growth is not always good. The recent proliferation of state "Right to Try" laws has exacerbated the risk, and crystallized the need for insurance protection to address the costs associated with this new spring legislative growth. For life science companies faced with this risk, new growth means ragweed and pollen spores. Allergy medicine is needed.

In June of 2012, Berkley Life Sciences introduced the industry's first Drug and Medical Device Product Shortage Coverage to address a new and costly litigation risk: the threat of third party lawsuits against companies because their drugs, devices, or other life science products or components are in short supply or unavailable. Companies confronting this risk quickly became aware that traditional life science insurance left them exposed and vulnerable.

Recently a number of states have enacted or are debating the passage of "Right to Try" laws granting individuals the right to access unapproved drugs and other life science products still under development. At last count 14 states have passed some form of legislation, and more than 20 are now considering it. Federal legislation has also been introduced in the form of the Andrea Sloan Compassionate Use Reform and Enhancement (CURE) Act and other expanded access legislation.

On the surface the laws look like a Monet watercolor. Expanded access for the desperately ill hoping for a miracle cure: What could be more beautiful? Below the surface of the lily pond the water is murkier. While a number of the new laws may provide some form of liability immunity for manufacturers subject to product shortage claims, some, such as the Arizona law, do not. And some immunity provisions are arguably poorly crafted or incomplete and can expose manufacturers to increased liability. Louisiana, for example, provides physicians with liability immunity but does not address manufacturers. If a user prescribed an experimental drug is denied access by the manufacturer, and the prescribing physician has immunity, around which spring flower will the bees swarm?

If a life science company provides an experimental drug not yet approved by the FDA under a state "Right to Try" law, it is far more likely that the company will need to withdraw or restrict access to the untested drug if something goes awry. Traditional insurance policies cover bodily injury as a result of taking a drug, but what happens if a user of the product sues a company for restricting access, or for injuries allegedly sustained because the user elected the experimental treatment over an FDA approved one? Even if the claimant ultimately is not successful, the company will have no coverage for the cost of defense.

Berkley Life Sciences' innovative product shortage coverage responds to a third party product shortage claim alleging injury due to the unavailability or rationing of a life science product. In addition, the coverage has a first party component: the policy covers shortage management expense, including expenses incurred to prepare and issue communications regarding the product shortages to the FDA, the public and the appropriate regulatory authorities, and shortage medical monitoring expense incurred during the product shortage in conjunction with the withdrawal or rationing of the medication.

While allergy medicine is not a cure for spring hay fever, it makes life a lot more tolerable for a life science company faced with this year's spring growth of the new "Right to Try" laws.