



## US HEALTHCARE REFORM: BIOTECH DATA EXCLUSIVITY AND BIOGENERICS

When the US House of Representatives passed the landmark healthcare reform earlier this month the legislation provided the biotechnology industry with a 12 year period of exclusivity for data relating to new biologics and provided the US Food and Drug Administration (FDA) with the flexibility to create a pathway to enable the approval of biogenerics (or biosimilars).

The data exclusivity period is the time during which information provided to the FDA by the originator of a biologic in an application for approval of the biologic is protected. This period of data exclusivity is separate and distinct from other forms of intellectual property protection, such as patents. Assuming that a biologic is approved, the new 12 year period of data exclusivity provides biotechnology companies with the possibility of extending the protection of the biologic beyond the lifetime of a patent.

The legislation also includes a provision that effectively allows competitor companies to use the originating biotechnology companies' safety and efficacy data to register biogenerics after the 12 year data exclusivity period.

It has been argued that in providing both the data exclusivity period and competitor companies with the ability to use the data after the 12 year period, the legislation aims to offer a balance between affording access to biologics to patients and creating the incentives necessary to attract the massive investment required for the discovery and development of biologics. It will be interesting to see over time whether the legislation does indeed provide the balance sought.

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