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AUTM Statement on the Proposed Use of "March-In" Rights for Remdesivir

In 1980, Congress passed the Bayh-Dole Act — the signature legislation that launched the technology transfer system that has yielded thousands of new companies, millions of jobs, and more than $1 trillion in economic impact to the United States.

During the current coronavirus pandemic, researchers and drug developers are looking at new approaches to treating the disease, including the use of previously patented compounds. One of those pharmaceuticals is remdesivir, a drug created by Gilead.

The Bayh-Dole Act contains a fail-safe mechanism known as "march-in" rights to allow the federal government to step in and grant additional licenses under certain specific scenarios. Some have mistakenly suggested that these march-in rights should be used to gain control of remdesivir's patents in light of reports that the manufacturer cannot make enough of the drug for current needs. However, march-in rights can only be used for drugs where the patents were derived from federally funded research. Remdesivir was not.

Those same critics also believe the price being charged by Gilead is far above the cost of production. However, as NIH and the Department of Health and Human Services have repeatedly stated, pricing is *not* part of the formula for determining the use of "march-in" rights. Indeed, Senators Bayh and Dole made that clear in a 2002 Washington Post op-ed:

"Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. This omission was intentional; the primary purpose of the act was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research."

This is important, because investors in early-stage drug discovery — who spend an average of $2.87 billion per drug as of 2016 (Tufts Center for the Study of Drug Development) — will only invest if they believe there is a chance to recoup their investment. If the government sets a precedent by incorrectly allowing march-in rights to be used for remdesivir to control pricing, it risks investor confidence in the development of future therapies. Such activity would lead to fewer investments that would lead to fewer, not more, discoveries for cures of other diseases.

Universities are working hard every day to research potential treatments or vaccines for the coronavirus and a huge number of other diseases. AUTM believes that inappropriately using the Bayh-Dole Act to restrict pricing risks deterring necessary investments in a broad range of drug and scientific research to benefit society now and into the future.