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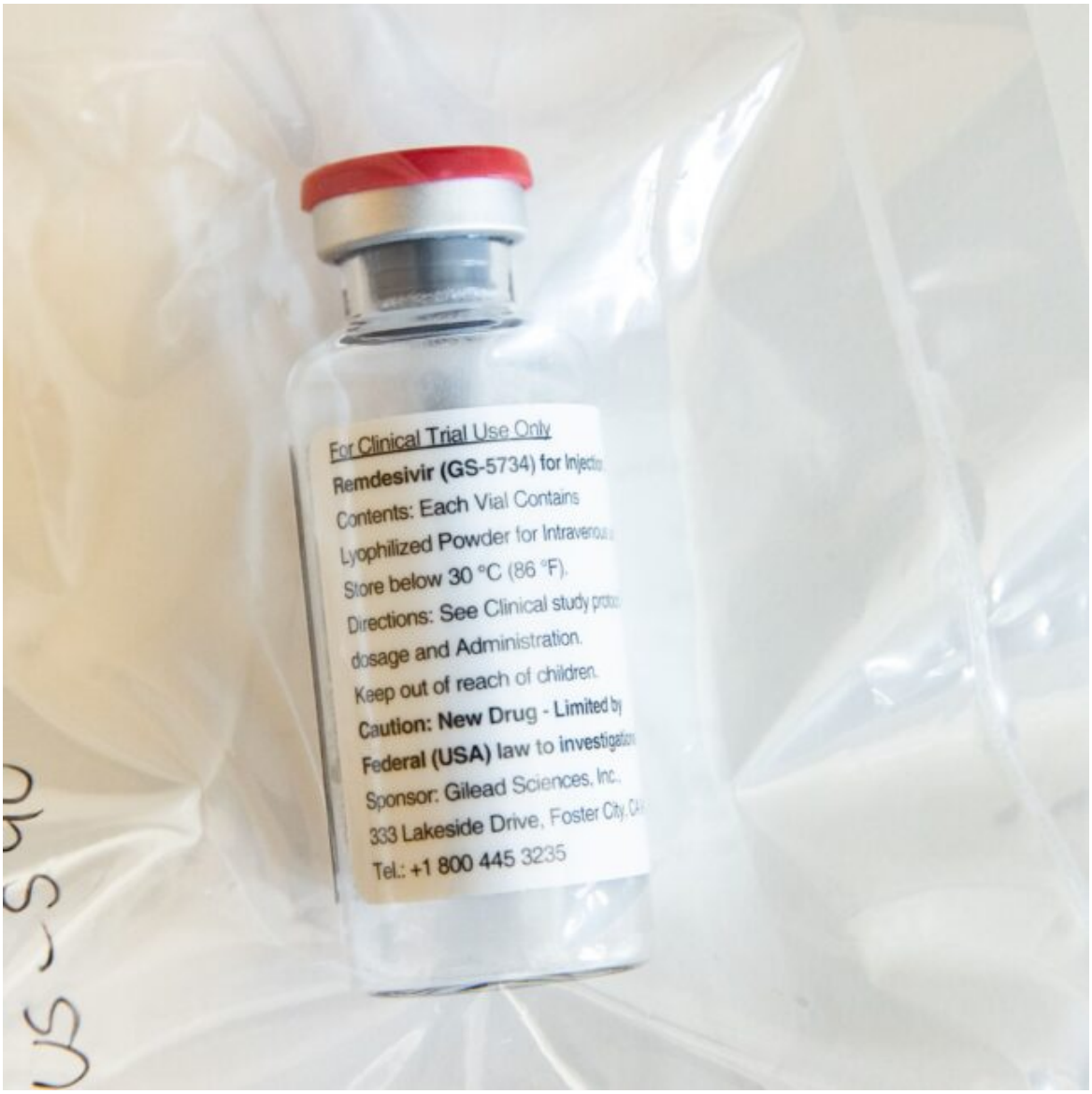
The U.S. government doesn't have patent rights to Gilead's remdesivir, despite investing millions in research

By Ed Silverman March 31, 2021



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American taxpayers may have provided $162 million toward researching

remdesivir, but the federal government does not have patent rights for the drug because the work contributed by U.S. scientists did not generate any inventive new uses, according to a government report.

Moreover, Gilead Sciences, which discovered remdesivir, had already reached collaborative research deals with various federal agencies and universities to work on its existing portfolio of patents and patent applications, including for the remdesivir compound. And this "would have left little room for the agencies to generate their own patents, the Government Accountability Office found.

The report, which was requested by Congress, is designed to settle a contentious debate over the extent to which the federal government should benefit from its years-long contribution into researching uses for the Covid-19 treatment. Now known as Veklury, the medicine was the first Covid-19 treatment authorized by regulators for emergency use and generated $2.8 billion in sales last year.

As a result, remdesivir has become a symbol of concern over taxpayer-funded research that leads to big-selling medicines which may be unaffordable for some patients, even as drug makers hold patent rights and keep the profits.

The issue has been gaining steam for years, but become prominence amid national angst over the high cost of medicines.

Although the subsequent emergence of several vaccines may eventually mitigate remdesivir sales, for the short term at least, the drug is expected to generate substantial profits for Gilead. For this reason, different academics and consumer advocacy groups have argued that research performed by U.S. scientists should have given the government patent rights and, therefore, a share in the profits.

Over the past year, they analyzed existing Gilead patents, the chemical structure of the remdesivir compound, published research, and the work conducted by scientists at different federal agencies. A key contention they made is that scientists at the Centers for Disease Control and Prevention should have been listed as co-inventors on one or more patents covering the drug.

Under that scenario, the federal government would have some ownership rights. The suggestions were based, in part, on contributions to remdesivir research on Ebola, which was described in several published studies that were co-authored by scientists at the CDC and the U.S. Army Medical Research Institute of Infectious Diseases.

But after speaking with government officials and scientists, as well as researchers at universities that worked with Gilead on the compound, the GAO disagreed.

For instance, the GAO was told by the principal investigators at the National Institutes of Health, who were working on coronavirus research projects, that they did not consider filing invention disclosures because their work did not involve modifying remdesivir or its parent compounds. The principal investigators stated they viewed such modifications as the threshold for filing such disclosures.

The GAO noted that NIH scientists did not submit invention disclosures from their remdesivir research, and invention disclosures were unlikely to be filed, because Gilead had already determined remdesivir was useful in treating coronaviruses before NIH began its research. NIH officials told the GAO that, given these circumstances, NIH did not conduct a so-called inventorship analysis.

In addition, NIH and Defense Department officials maintained Gilead's prior remdesivir research and patent portfolio "left few opportunities for federally supported scientists to make new patentable discoveries," the GAO wrote. NIH officials also said Gilead began patenting methods of using remdesivir to treat coronaviruses in 2015, before NIH scientists began their own coronavirus research in 2016.

Meanwhile, Gilead maintained it did not rely on any federal contributions in conducting its own research that led to the invention of remdesivir and invested $786 million in R&D from 2000 through 2020, according to the GAO report. The drug maker also contended its own scientists made "substantial contributions to the research performed in the collaborations with federally funded scientists."

In a statement, the drug maker wrote that the company "welcomes" the findings, because "the GAO further acknowledged Gilead's significant investment in Veklury, which exceeded $1 billion in 2020 alone and far outweighed any limited contributions by federal agencies."

But academics contend the GAO got it wrong and punted on a central question – whether the CDC does, in fact, have some ownership rights to Gilead patents on remdesivir. And they pointed to portions of the GAO report where the CDC officials admitted that they did not consider the question in the belief the government was unlikely to obtain any rights.

For instance, the GAO wrote that CDC scientists did not filed invention disclosures for their remdesivir work that began in 2014. Instead, they were focused on determining if remdesivir had the potential to become an effective treatment for the Ebola outbreaks in Africa, "without immediate consideration of the intellectual property implications."

The GAO then cited CDC officials, who explained that, as of March 2021, it was unlikely that the CDC "would conduct an inventorship analysis or pursue intellectual property rights given Gilead's background intellectual property and the limited potential for CDC to license any such rights."

The conclusion would appear to contradict a statement made last year by Michael Lo, a CDC scientist, whose team collaborated with the U.S. AMRIID and later tested remdesivir itself as an Ebola treatment. He noted that, "if CDC had not tested the parent [compound] against Ebola in April of 2014, I'm not sure any of the following work would have happened."

For this reason, Christopher Morten, the deputy director of the Technology Law and Policy Clinic at the New York University School of Law and one of the academics who studied remdesivir patents, argued that the central question remains unresolved. In his view, the issue is whether the CDC – not the NIH or DOD – have a claim to co-ownership or co-inventor ship. He wrote us this note:

"CDC didn't answer and apparently won't answer the key question: Did a CDC

scientist, Michael Lo, co-invent Gilead's compound patents on remdesivir, because he contributed the claimed method of treating Ebola with remdesivir? If Lo did co-invent the patents, CDC would, under the default rules of patent law, have a claim to co-ownership. But CDC appears uninterested in pursuing its legal rights."

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