

OPINION

‘Marching-In’ on Remdesivir: Wrong, Pointless and Bad for Patients

BY PETER KOLCHINSKY

August 14, 2020 at 5:00 am ET

A coalition of state attorneys general [has asked for the Department of Health and Human Services](#) to let other companies manufacture and sell Gilead’s COVID-19 treatment remdesivir, in order to expand supply and reduce the drug’s cost.

These AGs misunderstand the drug’s manufacturing process, ignore the economics behind its development, and demonstrate ignorance of the disease itself. They are willfully blind to the value that remdesivir provides to individual patients and to the U.S. health care system more broadly. And in asking for this “march-in” right, the AGs are also attempting to apply a law, [1980’s Bayh-Dole Act](#), that in fact isn’t applicable to the remdesivir situation.

Gilead’s antiviral has been [shown in clinical trials](#) to benefit hospitalized COVID-19 patients and [received an emergency use authorization](#) from the Food and Drug Administration in May 2020. The AGs in the letter, led by California Democrat Xavier Becerra and Louisiana Republican Jeff Landry, say that Gilead is “unable to assure a supply of remdesivir sufficient to alleviate the health and safety needs of the country amid this pandemic,” and that its remdesivir supply is “dangerously limited.”

Let’s start with how many patients will need it. In their letter to HHS, the attorneys general point out that Gilead has said it will make 2 million courses of remdesivir treatment by the end of 2020, and make a reasonable estimate that 85 percent, or 1.7 million courses, would be used to treat U.S. patients. They then note Gilead would be unable to supply enough remdesivir to treat all of the 4.6 million cases of COVID-19 in the United States at the time of the letter.

Of course, many of those U.S. COVID-19 cases occurred months ago, before remdesivir’s EUA. Even if they were all active cases today, the vast majority of people who contract COVID-19 aren’t hospitalized. And while [remdesivir is only indicated for hospitalized patients](#), it is not actually appropriate for all hospitalized patients (National Institutes of Health guidelines prioritize low-flow oxygen patients). Thus only a small fraction of the 4.6 million U.S. COVID-19 patients would benefit from remdesivir, as it’s currently used.

It’s true that Gilead isn’t yet making enough remdesivir to treat that fraction of patients. But the company [ramped up manufacturing months ago](#) and will have enough to meet global demand, including all relevant U.S. patients, by October. So would allowing another manufacturer to jump in at this stage help boost supply between now and then? Not even close.

Manufacturing remdesivir isn’t trivial. If the HHS secretary granted march-in rights today, and lined up a capable manufacturer tomorrow, that supply would still not be available until well into 2021. Gilead has also been able to [improve its manufacturing processes and condense its manufacturing timeline](#) to as short as six months. A manufacturer starting from scratch would likely need almost a year to amass an adequate supply. This isn’t even hypothetical: Gilead has [already granted free licenses](#) to generic drugmakers in Asia and Africa to make enough



The AGs also assert that remdesivir is too expensive. They point to a [study](#) suggesting that the drug could be made at a cost-per-treatment of less than a dollar a day. But that study has been [dismissed](#) and [discredited](#) by health economists as flawed and inaccurate for flouting intellectual property rights, minimizing the cost of R&D, and ignoring the savings remdesivir generates by enabling people to leave the hospital sooner.

The AGs also advance a false narrative that the federal government, and not Gilead, has paid for the lion's share of remdesivir's development. Indeed, [the government provided about \\$76 million](#) in total direct support to some of Gilead's academic collaborators for their research on antivirals across several disease areas. Of that, government grants totaling about \$19 million were specifically earmarked toward coronavirus research.

But this amounts to less than 2 percent of [Gilead's expected total investment in remdesivir in 2020](#) alone. Every bit helps, to be sure, but Gilead itself has taken on the vast majority of the risk of getting remdesivir to patients. (Meanwhile, insurance companies are [raking in record profits](#) on the backs of U.S. citizens and patients, and not risking a thing.)

Contrary to the AGs contention, there is no "market failure" for remdesivir – only the extraordinary effort of a company fighting a pandemic.

Invoking Bayh-Dole will not result in more remdesivir available to Americans in the next year. But attempting to invoke it reveals just how misguided these particular AGs are about right vs. wrong in medicine, health insurance, and the needs of patients.

And while expressing concern for the uninsured, not once did these AGs call for insurance reforms to lower out-of-pocket costs for remdesivir, or for expanding insurance to all families. The reality is that uninsured families in America would not be able to afford the costs of hospitalization for COVID-19 even if remdesivir were free and came with \$1,000 attached to it. That's the real injustice.

Peter Kolchinsky, a biotechnology investor and scientist, is managing partner at RA Capital Management LP, and author of "The Great American Drug Deal." He is not affiliated with Gilead in any way, and RA Capital Management does not currently have a position in Gilead.

Morning Consult welcomes op-ed submissions on policy, politics and business strategy in our coverage areas. Updated submission guidelines can be found [here](#).



General Disclaimers

The information contained herein (the "Materials") is provided for informational and discussion purposes only and contains statements of opinion and belief. The Materials are not, and may not be relied on in any manner as, legal, tax, or investment advice. The Materials do not constitute an offer to sell, a solicitation to buy, or a recommendation for any security, nor do they constitute an offer to provide investment advisory or other services by RA Capital Management, L.P. and its affiliates and/or any investment products it advises (collectively, "RA Capital" or the "Firm"). Each recipient should make its own investigations and evaluations of RA Capital, and any investment products it advises, and should consult its own attorney, business adviser, and tax adviser as to legal, business, tax, and related matters thereto. The information contained in the Materials is not intended to be, and should not be viewed as, "investment advice" within the meaning of 29 C.F.R. §2510.3-21 or otherwise.

Any views expressed herein, unless otherwise indicated, are those of RA Capital as of the date indicated, are based on information available to RA Capital as of such date, and are subject to change, without notice, based on market and other conditions. No representation is made or assurance given that such views are correct and such views may have become unreliable for various reasons, including changes in market conditions or economic circumstances. Such views may have been formed based upon information, believed to be reliable, that was available at the time the Materials were published. Certain information contained herein concerning economic trends and/or data may be based on or derived from information provided by independent third-party sources. RA Capital believes that the sources from which such information has been obtained are reliable; however, it cannot guarantee the accuracy of such information and has not independently verified the accuracy or completeness of such information or the assumptions on which such information is based. RA Capital has no duty or obligation to update the information contained herein.

The content of the Materials neither constitutes investment advice nor offers any opinion with respect to the suitability of any security. Any references, either general or specific, to securities and/or issuers are for illustrative purposes only and are not intended to be, and should not be interpreted as, advice or recommendations to purchase, continue to hold, or sell such securities, or as an endorsement of any security or company. Certain current and prior investments may be highlighted in order to provide additional information regarding RA Capital's investment strategy, the types of investments it pursues, and current or anticipated exit strategies. In addition, due to confidentiality restrictions, the information contained herein might not reference investments in certain companies. Accounts managed by RA Capital may invest in certain companies referenced in the Materials; however, RA Capital makes no guarantees as to accuracy or completeness of views expressed in the Materials. Any strategies and companies referenced in the Materials may not be suitable for all investors.

As stated above, the Materials are not an offer or solicitation for the purchase or sale of any security, including any interest in RA Capital Healthcare Fund, L.P. (the "Master Fund") or RA Capital Healthcare International Fund Ltd. (the "Offshore Fund," and, collectively with the Master Fund, the "Fund"), and should not be construed as such. Such an offer will only be made by means of a confidential Private Placement Memorandum (the "PPM") to be furnished to qualified investors upon request. The information contained herein is qualified in its entirety by reference to the PPM, which contains additional information about the investment objective, terms, and conditions of an investment in the Fund, and also contains certain disclosures that are important to consider when making an investment decision regarding the Fund. In the case of any inconsistency between any information contained herein or in the Materials and the PPM, the terms of the PPM shall control.

The Materials are proprietary and confidential and may include commercially sensitive information. As such, the Materials must be kept strictly confidential and may not be copied or used for an improper purpose, reproduced, republished, or posted in whole or in part, in any form, without the prior written consent of RA Capital. The recipient of the Materials must not make any communication regarding the information

contained herein, including disclosing that the Materials have been provided to such recipient, to any person other than its authorized representatives assisting in considering the information contained herein. Each recipient agrees to the foregoing and to return (or destroy upon RA Capital's instructions) the Materials promptly upon request.

Any investment strategies discussed herein are speculative and involve a high degree of risk, including loss of capital. Investments in any products described herein and the Fund's performance can be volatile, and investors should have the financial ability and be willing to accept such risks. An investor could lose all or a substantial amount of his or her investment. The Fund may be leveraged. Interests in the Fund are illiquid, as there is no secondary market for the Fund interests, and none is expected to develop. The Fund interests are subject to restrictions on transfer. Prior to investing in the Fund, investors should read the PPM and pay particular attention to the risk factors contained therein. Fees and expenses charged in connection with an investment in the Fund may be higher than the fees and expenses of other investment alternatives and may offset investment profits of the Fund. RA Capital has total trading authority over the Fund. The use of a single advisor applying generally similar trading programs could mean lack of diversification and, consequentially, higher risk. A portion of the trades executed for the Fund may take place on foreign exchanges. It should not be assumed, and no representation is made, that past investment performance is reflective of future results. Nothing herein should be deemed to be a prediction or projection of future performance. To the extent any prior or existing investments are described, RA Capital makes no representations, and it should not be assumed, that past investment selection is necessarily reflective of future investment selection, that any performance discussed herein will be achieved or that similar investment opportunities will be available in the future or, if made, will achieve similar results.

In particular, to the extent valuation information is provided for any unrealized investments, such valuations are RA Capital's estimates as of the date set forth in the Materials, and there can be no assurance that unrealized investments will be realized at such valuations. While RA Capital believes any valuations presented herein are reasonable, such valuations may be highly subjective, particularly for private investments, and are based on information provided by third parties and/or RA Capital's assumptions, any or all of which might be mistaken or incomplete. Actual realized returns will depend on, among other factors, future operating results, the value of the assets and market conditions at the time of disposition, any related transaction costs, and the timing and manner of sale. All of which may differ from the assumptions on which the valuations contained herein are based. As a result of the foregoing, actual realized returns may differ materially from the valuations contained herein.

Certain information contained in this document constitutes "forward-looking statements," which can be identified by the use of forward-looking terminology such as "may," "will," "should," "expect," "anticipate," "target," "project," "estimate," "intend," "continue," or "believe," or the negatives thereof or other variations thereon or comparable terminology. Due to various risks and uncertainties, actual events or results or the actual performance of any investment may differ from those reflected or contemplated in such forward-looking statements. Prospective investors should not rely on these forward-looking statements when making an investment decision.

None of the information contained herein has been filed with the U.S. Securities and Exchange Commission, any securities administrator under any securities laws of any U.S. or non-U.S. jurisdiction, or any other U.S. or non-U.S. governmental or self-regulatory authority. No such governmental or self-regulatory authority will pass on the merits of any offering of interests by RA Capital or the adequacy of the information contained herein. Any representation to the contrary is unlawful. The interests in the Fund have not been, and will not be, registered under the U.S. Securities Act of 1933, as amended, or qualified or registered under any applicable state, local, provincial, or other statutes, rules, or regulations. The Fund has not been, and will not be, registered as an investment company under the U.S. Investment Company Act of 1940, as amended.