

FOR IMMEDIATE RELEASE

Thursday, May 14, 2020

CLAIM vs. REALITY

Rick Bright was transferred from his role as BARDA director to lead a bold new \$1 billion testing program at NIH, critical to saving lives and reopening America. Mr. Bright has not yet shown up for work, but continues to collect his \$285,010 salary, while using his taxpayer-funded medical leave to work with partisan attorneys who are politicizing the response to COVID-19. His whistleblower complaint is filled with one-sided arguments and misinformation. HHS is reviewing the complaint and strongly disagrees with the allegations and characterizations made by Rick Bright.

Chloroquine and Hydroxychloroquine

CLAIM: On April 22, 2020, Rick Bright claimed he was ousted from his role as BARDA director due to political pressure for his opposition to using hydroxychloroquine as a COVID-19 treatment.

REALITY: Under Rick Bright's leadership, BARDA identified chloroquine and hydroxychloroquine as potential COVID-19 treatments. Rick Bright was the sponsor of getting hydroxychloroquine and praised his team for acquiring the drugs

- **Rick Bright pushed for quick and serious consideration of chloroquine:**
 - Rick Bright asked his team to give serious consideration to chloroquine as a treatment for COVID-19, and considered reports of studies abroad suggesting that chloroquine showed promise as a treatment for COVID-19.
- **Rick Bright sought to secure hydroxychloroquine:**
 - Rick Bright sought to acquire a donation of hydroxychloroquine from Teva Pharmaceuticals, including some produced abroad.
- **Rick Bright celebrated chloroquine acquisitions:**
 - Rick Bright praised the members of his team for their work to acquire chloroquine on multiple occasions, and characterized those efforts as a success for HHS as a whole.
- **BARDA leadership, including Rick Bright, identified chloroquine and hydroxychloroquine as drugs in the therapeutic pipeline for COVID-19:**
 - BARDA leadership recognized that chloroquine is FDA-approved, widely used for the treatment of malaria, inexpensive to produce, and has human safety data. They also found that chloroquine and the closely related hydroxchloroquine were being tested as prophylaxis for healthcare workers

and other high-risk individuals. As a result, they considered them part of the therapeutic pipeline for COVID-19.

CLAIM: HHS pushed hydroxychloroquine as a treatment without scientific support.

REALITY: Hydroxychloroquine is FDA-approved to treat malaria, a type of lupus, and rheumatoid arthritis. BARDA identified hydroxychloroquine as one of a handful of small molecule-based antivirals in the current therapeutic pipeline for COVID-19, and recognized that early studies from abroad showed that hydroxychloroquine has promise as a treatment for COVID-19. Ultimately, Rick Bright requested, and FDA issued, an emergency use authorization (EUA) for hydroxychloroquine that provided for use of hydroxychloroquine as a treatment for COVID-19.

CLAIM: In his whistleblower complaint, Rick Bright claims that he “exhausted all avenues to alert government officials.”

REALITY: Rick Bright contradicts his own claim on page 7 of the OSC Form 14 in his whistleblower complaint, where he concedes that he did not appeal, grieve, or report his concerns under any other available procedure, including, for example, a report to the Office of Inspector General.

COVID-19 Preparedness

CLAIM: Rick Bright, virtually alone within the Administration, predicted the severity of the COVID-19 pandemic and the resources needed to address it.

REALITY: As head of BARDA, Rick Bright’s role was limited to providing support for the development of drugs, vaccines, and diagnostics. He didn’t have visibility into the enormous amount of work being done by Secretary Azar and Dr. Kadlec, much less by other components of HHS and the Administration as a whole. Rick Bright’s assumption that others were not concerned with and working on various workstreams related to COVID-19 preparedness is bizarre and false.

CLAIM: Secretary Azar and Dr. Kadlec ignored and opposed Rick Bright’s push for necessary resources to begin vaccine, drug, and diagnostic development.

REALITY: Rick Bright did not see all of the work done by Secretary Azar and Dr. Kadlec—much less the full strategic and operational picture across HHS and the Administration as a whole—because his role within HHS was more limited. Mr. Bright ran BARDA, which is a program office of ASPR. He had limited visibility into the whole-of-government response to COVID-19.

Even today, Rick Bright is still missing the bigger picture. Last month, President Trump

directed HHS to undertake Operation Warp Speed, an initiative to dramatically shorten the development time for a vaccine for COVID-19. There is a parallel initiative at the National Institutes of Health (NIH) to expand diagnostics for COVID-19. Instead of supporting the latter initiative in the new role to which Mr. Bright was transferred, Rick Bright has chosen to stay home, draw his \$285,010 taxpayer-funded salary, and politicize the response to COVID-19 for his own personal benefit.

CLAIM: Rick Bright was excluded from internal HHS meetings because he demanded urgent action.

REALITY: Meetings were streamlined to include staff division heads, which he is not, and ASPR representatives continued to attend all relevant meetings. He acknowledges this point in the email attached as Exhibit 15 to his whistleblower complaint, writing “Cool. I’ll ask Bob to see if he can get us in there. Barda isn’t at the same level as an opdiv or staffdiv so obvious group to cut if shrinking the table. But we have a significant role.”

CLAIM: HHS failed to act on remdesivir.

REALITY: HHS sought to obtain remdesivir from Gilead in February 2020. At that time, there were no clinical data on remdesivir efficacy with respect to COVID-19; clinical trials had just begun. Gilead had not priced the drug for sale, and considered donating a limited quantity of treatment courses of remdesivir to HHS. A donation was finalized on May 3, 2020. FDA has issued an emergency use authorization (EUA) for remdesivir, and HHS has announced an allocation methodology for the drug under the EUA.

Rick Bright’s superiors in ASPR leadership—including Dr. Kadlec—participated in the inter-agency process on remdesivir and HHS ultimately acquired remdesivir without disrupting the global supply chain for the drug. ASPR leadership (not BARDA) is currently helping manage the distribution of remdesivir.

CLAIM: On January 10, 2020, Rick Bright raised the need to obtain the genetic sequencing for COVID-19, yet Secretary Azar and Dr. Kadlec took no action.

REALITY: Many at HHS and across the Administration were already working on it. That issue became moot two days later, when China made the virus sequence public.

CLAIM: In mid-January 2020, Rick Bright sought more resources and to obtain virus samples. Dr. Kadlec and HHS leadership did not share Rick Bright’s sense of urgency.

REALITY: HHS tried to acquire virus samples for BARDA from China through the WHO and China itself. In addition, ASPR leadership independently tried to obtain virus samples for BARDA through a U.S. academic institution, the National Academy of Sciences, and China. Rick Bright was not privy to those efforts because of national security concerns. The efforts of HHS and ASPR leadership were unsuccessful due to

China's unwillingness to share virus samples.

CLAIM: Despite Rick Bright's efforts, HHS failed to act after Mike Bowen, from the mask manufacturer Prestige Ameritech, sounded the alarm about mask shortages.

REALITY: BARDA is not responsible for purchases of masks or other personal protective equipment (PPE). Prestige Ameritech nonetheless contacted Rick Bright directly and sought government support to expand its manufacturing capacity as well as expedited regulatory clearance. Rick Bright referred Mr. Bowen to the leadership of the Strategic National Stockpile (SNS)—the ASPR program that purchases PPE—and told Mr. Bowen to “[p]lease keep me looped in as appropriate.” Though Mr. Bright had no authority over the SNS, he remained involved in Prestige Ameritech's communications with the SNS, and even alleges that he sought to insert BARDA into the funding of that vendor (and no others). In his whistleblower complaint, he even states that he “emailed Dr. Johnson and Dr. Disbrow about considering providing financial support to Prestige Ameritech to reopen its defunct factories.”

Dr. Wolf from the SNS responded to Mr. Bowen in January 2020, considered the information that he provided, and informed him that the SNS would be obtaining masks through the procurement process, which included requests for information directed to potential suppliers. Since then, HHS and its inter-agency partners have procured contracts for the delivery of hundreds of millions of N95 respirators from a host of suppliers. As head of BARDA, Rick Bright was not part of the broader inter-agency effort to procure masks.

CLAIM: HHS leadership refused to heed Rick Bright's warning about the shortage of needles and syringes. On March 13, 2020, Bright raised the issue with Dr. Kadlec and was ignored.

REALITY: A number of HHS employees within the ASPR Division of Critical Infrastructure Protection had raised similar concerns well in advance of March 13, 2020. In response, and prior to March 13, Dr. Kadlec ordered the formation of a Supply Chain Task Force to address these concerns.

Once again, Rick Bright assumes, because he was not aware of initiatives outside of his scope of responsibility, that such programs did not exist. Once again, Rick Bright's assumption is false.

Contracts

CLAIM: ASPR leadership was driven by politics and not science.

REALITY: ASPR is led by Dr. Robert Kadlec, a medical doctor who has spent decades in public service, including 20 years as a career officer and physician in the United States Air

Force with five combat tours before retiring as a Colonel. His decades of experience with scientific and policy issues in the area of public health security is one of the reasons he leads ASPR, including BARDA. Dr. Kadlec considers the recommendations of his career experts and scientists, and applies his own expertise, to make decisions that provide the best protection for the American people.

CLAIM: HHS leadership awarded contracts to companies with political connections to the Administration.

REALITY: When HHS awarded contracts, it complied with the Federal Acquisition Regulation (FAR). Rick Bright's attorneys have not pointed to a HHS contract that violates a provision of the FAR. This is not surprising, as the contracts referenced in the whistleblower complaint were procured by federal contracting officers in consultation with the HHS Office of the General Counsel.

CLAIM: ASPR leadership pressured Bright to make a contract award to Aeolus.

REALITY: No contract was awarded to Aeolus.

CLAIM: ASPR leadership ignored the recommendations of scientists and awarded a lucrative contract to purchase oseltamivir, an "inferior" anti-viral for influenza, from the company Alvogen.

REALITY: Oseltamivir (a generic anti-viral) was acquired at approximately \$10 per dose, whereas baloxavir (a non-generic anti-viral) was far more expensive. ASPR could replenish more expiring anti-virals in the strategic national stockpile (SNS) with oseltamivir. The contract for oseltamivir left the SNS the flexibility to acquire other products, including baloxavir, in the future.

CLAIM: ASPR leadership overruled staff recommendations to award a lucrative contract to Partner Therapeutics over Amgen, despite a *Procurement Integrity Act* investigation.

REALITY: The contract with Partner Therapeutics was awarded lawfully through a contracting officer, in consultation with the Office of the General Counsel, pursuant to a public interest exception.

The GAO dismissed Amgen's protest of the contract award, finding that Amgen failed to submit a timely expression of interest in response to HHS's request for information, and did not demonstrate an ability to meet the agency's requirements.

CLAIM: ASPR leadership pressured BARDA staff to support additional funding for the Emory Institute for Drug Development for clinical trials for EIDD-28017.

REALITY: No additional funding for clinical trials for EIDD-28017 has been provided to the Emory Institute for Drug Development.

