Durbin, Senate colleagues press U.S. Army & Sanofi for affordable zika vaccine

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WASHINGTON – Amid reports that Sanofi, a French pharmaceutical company, is refusing to commit to a licensing agreement that would ensure a reasonable and affordable price for a Zika vaccine that is being developed largely with taxpayer funding, U.S. Senators Dick Durbin (D-IL), Sherrod Brown (D-OH), Bernie Sanders (I-VT), Richard Blumenthal (D-CT), Ed Markey (D-MA), and Angus King (I-ME) today pressed the U.S. Army to convene a public hearing regarding its Zika vaccine candidate licensing plans. The Senators expressed concern that the company would ultimately

charge an unreasonably high price for a vaccine that was developed with substantial federal funding.

In the letter to Robert Speer, Acting Secretary of the Army, the members wrote: **"…it is imperative that any forthcoming vaccine is accessible and affordable for all, especially given the significant taxpayer investment to date. In order to discuss these issues in an open and transparent way, we urge the Army to convene a public hearing regarding its Zika vaccine candidate licensing plans."**

In addition, the Senators sent a letter to Oliver Brandicourt, CEO of Sanofi, writing: **"Given the significant investment of taxpayer dollars and resources toward developing the Zika vaccine, we are deeply troubled by reports that Sanofi is refusing to commit to a licensing agreement that would ultimately ensure a reasonable and affordable price for the finished product. We will continue to urge the Army not to finalize any contracts with your company until such terms are met."**

The U.S. Army, in collaboration with the National Institutes of Health (NIH), has spearheaded efforts to research and develop a Zika vaccine. Last year—after conducting nearly $10 million in federally funded basic medical research, development, and pre-clinical studies at these agencies—the Army launched a process to partner with Sanofi in order to complete clinical trials, manufacture, and ultimately bring a Zika vaccine to market. Building on the millions of federal taxpayer dollars already invested, Sanofi received $43 million in funding from the Biomedical Advanced Research and Development Authority, with the potential for an additional $130 million in U.S. government funding, to conduct clinical trials and develop the Zika vaccine candidate. A successful Zika vaccine would likely be purchased by numerous U.S. government programs, including Medicaid, Children's Health Insurance Program (CHIP), and TRICARE.

Full text of today's letter to the Army is available here and below. Full text of today's letter to Sanofi is available here and below:

Dear Acting Secretary Speer:

The United States, along with much of the developing world, remains concerned about the Zika virus and possible outbreaks in the coming summer months. Congress has appropriated millions of dollars toward Zika vaccine development and we are more than eager to see a vaccine come to market in the near future. However, it is imperative that any forthcoming vaccine is accessible and affordable for all, especially given the

significant taxpayer investment to date. In order to discuss these issues in an open and transparent way, we urge the Army to convene a public hearing regarding its Zika vaccine candidate licensing plans.

Last year, more than 40,000 people in U.S. states and territories contracted the Zika virus. According to a recent Centers for Disease Control and Prevention (CDC) report, five percent of pregnant women with Zika had a baby born with a birth defect, such as microcephaly. In addition to the severe emotional trauma for families dealing with Zika-related birth defects, the lifetime financial costs to care for a child with microcephaly or other severe developmental disabilities are estimated to be as high as $10 million. With more than 70 countries around the world reporting Zika infections, Army personnel are at elevated risk for Zika exposure. Last year, the Department of Defense reported that more than 70 service members and spouses had been diagnosed with Zika.

Recognizing the threat this virus posed to families and children worldwide, the U.S. Army—in collaboration with the National Institutes of Health (NIH)—spearheaded efforts to research and develop a Zika vaccine. Last year—after conducting nearly $10 million in federally funded basic medical research, development, and pre-clinical studies at these agencies—the Army launched a process to partner with Sanofi in order to complete clinical trials, manufacture, and ultimately bring a Zika vaccine to market. Sanofi received $43 million for phase II trials, with the possibility of an additional $130 million for phase III trials.

Considering the taxpayer funds already invested in research and development of a Zika vaccine—not to mention the millions more that may be spent—we remain concerned by reports that the Army is considering an exclusive license with Sanofi, which would provide the company with monopoly rights through 2036, without any parameters to ensure reasonable pricing of the eventual product.

We have many important questions about this license and believe that U.S. taxpayers deserve answers before a final license is granted. As such, we request that the Army convene a public hearing as soon as possible on the proposed exclusive license of this vaccine to Sanofi. We would recommend that the hearing include discussion of the following topics:

- The role that federal funding has played, and will continue to play, in the research and development of the Zika vaccine, and the extent of financial investment by Sanofi;
- Why an exclusive license is preferable to a non-exclusive license in this case, how the Army makes determinations under 35 U.S.C. § 209(a) of the Bayh-Dole Act when deciding to proceed with an exclusive license, and relevant lessons from the NIH’s technology transfer experience;

- Issues regarding the pricing, affordability, and government purchasing of the resulting vaccine;
- An assessment of interest among pharmaceutical companies in partnering on a Zika vaccine; and
- Issues regarding the timing of the proposed license.

We would recommend that the hearing include a diverse witness panel, including representatives from Sanofi, the Army technology transfer division, health officials such as Dr. Rebekah Gee of the Louisiana Department of Health, public interest groups including Doctors without Borders and Knowledge Ecology International, and independent academic economists. Thank you for your consideration of this request and we look forward to your prompt reply.

Dear Mr. Brandicourt:

The U.S. Army, in collaboration with the National Institutes of Health (NIH), has spearheaded efforts to research and develop a Zika vaccine. Last year—after conducting nearly $10 million in federally funded basic medical research, development, and pre-clinical studies at these agencies—the Army launched a process to partner with Sanofi in order to complete clinical trials, manufacture, and ultimately bring a Zika vaccine to market. Building on the millions of federal taxpayer dollars already invested, Sanofi received $43 million in funding from the Biomedical Advanced Research and Development Authority, with the potential for an additional $130 million in U.S. government funding. Given the significant investment of taxpayer dollars and resources toward developing the Zika vaccine, we are deeply troubled by reports that Sanofi is refusing to commit to a licensing agreement that would ultimately ensure a reasonable and affordable price for the finished product. We will continue to urge the Army not to finalize any contracts with your company until such terms are met.

Sanofi's vaccine products are purchased by a variety of U.S. government payers—including Medicaid, CHIP, Medicare, TRICARE, and the Veterans Health Administration, as well as through our support for Gavi, the Global Fund, the United Nations Children's Fund, and the World Health Organization—totaling billions of dollars each year. With the development of a safe and effective Zika vaccine, Sanofi stands to benefit greatly from immediate market opportunities across nearly all of these sources, not to mention from countries all over the world—a financial potential that would surely be promising to competitor pharmaceutical companies. Further, approval by the U.S. Food and Drug Administration of a Zika vaccine would confer upon Sanofi a Priority Review Voucher that would be worth an additional tens of millions of dollars. Given how much taxpayer funded research has contributed to the vaccine development,

not to mention how much Sanofi stands to gain financially, we are concerned by reports that your company has refused the Army's offer of a non-exclusive license. It is worth noting that non-exclusive licenses are a fairly common practice; in fact, 95 percent of NIH agreements with industry adhere to this arrangement. Given all this, it is incomprehensible that Sanofi would still seek a monopolistic license from the Army without including a commitment to set an affordable price for this product.

While we appreciate that Sanofi has recently claimed it will limit all future drug price increases to the inflation rate for health care products, this reflects a nominal positive first step. Sanofi could simply deflect attention from price increases by launching new drugs at very high prices, thereby undermining the very practice you claim to be addressing. Our concern regarding the opportunity for future predatory pricing abuse by Sanofi is reinforced by recent lawsuits against your company for insulin pricing practices, as well as Sanofi's recent $20 million settlement with the Department of Justice for over-charging the Department of Veterans Affairs.

We believe that, in order to effectively safeguard taxpayer dollars, the Army should not enter into an exclusive licensing agreement with Sanofi unless your company commits to ultimately adopting a fair and appropriate price that ensures public access for the Zika vaccine—which, again, would not be possible without significant federal investments by American taxpayers.

Further, to assist in promoting transparency, we request that Sanofi publicly disclose the following no later than July 15, 2017:

1. Its spending on research and development into the Zika vaccine broken down by year; and
2. The amount of funding Sanofi has received from the U.S. government and U.S. government payers for all research, purchase agreements, and reimbursements for Sanofi's licensed drugs in the last five years.

As Sanofi moves forward in its pursuit of a Zika vaccine, we urge you to commit to licensing language that ultimately guarantees that people worldwide will be able to access this product at a reasonable and responsible price. We will continue to engage with the Army about this subject and welcome any thoughts you may have.