Press Release

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SAFE Glen Cove Coalition: Titanium Implant to Treat Opioid Use Disorders

The Helping to End Addiction Long-term Initiative, or National Institutes of Health (NIH) HEAL Initiative is an aggressive, trans-agency effort to speed scientific solutions to stem the national opioid public health crisis. Almost every NIH Institute and Center is accelerating research to address this public health emergency from all angles.

The initiative is funding hundreds of projects nationwide. Researchers are taking a variety of approaches to tackle the opioid epidemic through understanding, managing, and treating pain and improving treatment for opioid misuse and addiction. Medication-assisted treatment for OUD is a lifesaving first-line therapy in the response to the opioid epidemic, and longer-acting medication options for patients are an unmet medical need that could increase adherence, sustain recovery, and save lives.

Researchers have posed the question- What if you take a medication today, and then forget about it for a whole year, while still receiving its health benefits? That's the kind of technology that a California biotech company is developing to treat opioid addiction. Like many diseases, opioid use disorder (OUD) can be treated successfully with medications. In the U.S., naltrexone, buprenorphine, and methadone are all approved for treating OUD and involve taking medicine every day or receiving a monthly injection. The challenge of taking these medications on a regular schedule can make adherence to treatment difficult for many people with opioid addiction. This puts patients at risk for relapse and overdose. Given the COVID pandemic addressing this issue is vital.

Delpor, a biotech company is working on a technology that would provide a longer-lasting delivery system for naltrexone. The company is developing a titanium implant that goes under the skin, where it slowly and steadily releases medication into the body for a year. Delpor's aim

is to give patients more options and make it easier for them to stay on treatment long enough to achieve long-term recovery from the disease as many people who start medication treatment for opioid use disorder don't receive treatment long enough to recover.

Naltrexone works by blocking the brain's ability to respond to opioids. People using naltrexone who take an opioid-based drug won't feel euphoria or other effects of opioids. Naltrexone is most effective when taken for six months or longer, but studies have found that only half of patients who start oral naltrexone remain in treatment six weeks later and only 15 percent are still on it after six months. Most patients who receive the injectable version do not return to their health care provider for a second shot. The company also wanted to focus on medications that people often stop taking. Naltrexone is one of a handful of drugs that the company is now studying for a possible implant.

Naltrexone is already Food and Drug Administration (FDA)—approved, which means that Delpor does not have to prove that the medication is safe. However, the company must show that the implant is safe and that it releases the medication steadily. The first set of tests, in animals, will provide data that the company will use for filing an Investigational New Drug (IND) application with the FDA within two years. If the FDA gives Delpor permission to proceed, the company will begin trials in humans to make sure that the implant performs as expected. If all goes smoothly, the implant could be submitted to the FDA for approval as soon as 2024. Once the FDA approves that application, the implant could go on the market.

That may sound like a long time, but it is remarkably fast for the process of developing a medical treatment. The funding from the NIH HEAL Initiative is helping make that timeline possible. Because only a handful of implants are on the market, private investors may be reluctant to take a chance on the research.

The NIH HEAL Initiative is funding several other projects on alternative ways of delivering FDA-approved drugs for OUD, including projects on developing a naltrexone implant that dissolves under the skin, a version of methadone that is taken once a week rather than daily, and a naltrexone injection that would last two months rather than one.

The National Institutes of Health (NIH) is the nation's medical research agency and includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. NIH is the primary federal agency conducting and supporting basic, clinical, and translational medical research, and is investigating the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit www.nih.gov.

The SAFE Glen Cove Coalition is conducting an opioid prevention awareness campaign entitled. "Keeping Glen Cove SAFE," in order to educate and update the community regarding opioid use and its consequences. To learn. more about the SAFE Glen Cove Coalition please follow us on www.facebook.com/safeglencovecoalition or visit SAFE's website to learn more about the Opioid Epidemic at www.safeglencove.org