

Researchers develop new tool to prevent heroin deaths

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A new, lifesaving product aimed at reducing the death toll from heroin abuse—developed by a professor at the University of Kentucky College of Pharmacy—is in its final round of clinical trials and has received Fast Track designation by the Food and Drug Administration.

The product, a nasal spray application of the anti-opioid drug naloxone, was developed by Daniel Wermeling, UK professor of pharmacy practice and science, through his startup company AntiOp Inc.

Naloxone is the standard treatment for suspected [opioid overdose](#), already in use by emergency rooms and emergency medical technicians across the country. Opioids are the class of pain-killing drugs that are related to morphine, including prescription drugs such as hydrocodone and oxycodone, as well as illegal drugs such as heroin.

Currently, naloxone is administered by injection. The [nasal spray](#) eliminates the need for needles, with a ready-to-use, single-use delivery device inserted into the nose of an overdose victim. The product delivers a consistent dose, absorbed across the nasal membranes even if the patient is not breathing.

"The goal is to make the medication available to patients at high risk of opioid overdose, and to caregivers, including family members, who may lack specialized medical training," Wermeling said. "The treatment could be given in anticipation of EMS arrival, advancing the continuum of care and ultimately saving lives."

Nationwide, deaths from opioid overdose are on the rise, according to data from the Centers for Disease Control and Prevention. Kentucky, long troubled by widespread abuse of prescription opioids, has seen a dramatic rise in deaths from heroin overdose in recent years. In autopsies from 2013, the state medical examiner attributed 230 deaths to heroin overdose, an increase of more than 60 percent from the previous year.

UK President Eli Capilouto congratulated Wermeling on his success with AntiOp, saying that it reflects the core values of the university.

"Too many Kentucky families have experienced the tragedy of seeing a loved one's life cut short by a drug overdose," Capilouto said. "The epidemic of opioid abuse in our state presents an enormous and urgent challenge, not only for health care providers and law enforcement, but also for us here at the University of Kentucky. Dr. Wermeling's project is putting a powerful new tool into the hands of those on the front line of the fight against heroin, both here in Kentucky and beyond. This type of innovation embodies the three main components of the university's mission—education, research and, above all, service."

UK College of Pharmacy Dean Timothy S. Tracy said Wermeling's work also provides an illustration of "bench-to-bedside" research in action.

"Dr. Wermeling's project is a great example of how UK College of Pharmacy faculty are working each and every day to create healthier Kentucky communities," Tracy said. "Dr. Wermeling and his collaborative team of research colleagues saw a problem facing families in Kentucky and across the nation and developed an innovative solution. That type of translational approach is important to our college, this university, and, of course, the future of our Commonwealth."

Wermeling's research was supported by a three-year, \$3 million grant

from the National Institutes of Health through the National Institute on Drug Abuse with additional funding from the Kentucky Science and Technology Corporation. In May, AntiOp partnered with Reckitt Benckiser Pharmaceuticals to accelerate production and worldwide marketing of intranasal naloxone.

The Fast Track program of the FDA is designed to expedite the development and review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. Fast Track-designated drugs ordinarily qualify for priority review, thereby expediting the FDA review process.

"As an educator, pharmacist, researcher and entrepreneur, being able to work on this naloxone project has been a dream come true," Wermeling said. "I often tell my students and colleagues that this project has allowed me to use all of the skills I have learned over the years. It has been the ultimate problem-solving project, requiring me to utilize my pharmacological skills, my drug delivery knowledge, my business and marketing skills—all at the same time.

"At the end of the day, however, this project has always been about people. It has always been about utilizing the knowledge and skills that we have to improve patient care."

Provided by University of Kentucky

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