

## ETHIMEDIX SUBMITS IT SMARTBOTTLE® OPIOID ADMINISTRATION TECHNOLOGY TO FDA INNOVATION CHALLENGE

### *Novel Device Designed to Deliver Controlled Drug Administration Without Risk of Theft, Abuse or Misuse*

GENEVA – October 16, 2018 – [Ethimedix](#), a medical device company developing state-of-the-art technologies for programmable, controllable drug delivery, announced that it has submitted its novel *SmartBottle*® to the [“FDA Innovation Challenge: Devices to Prevent and Treat Opioid Use Disorder.”](#) The *SmartBottle* is a non-invasive, portable, programmable and fully-secured “lockbox” device that offers a unique, new approach to controlled drug administration that eliminates the risk of abuse or misuse by the patient or healthcare provider.

“Our mission is to dramatically improve access to proper pain relief with a safe, user-friendly, tamper proof analgesic dispensing system for implementation in any and all environments,” said Leila Smith, scientific and business consultant, Ethimedix. “Our CE-marked *SmartBottle* device addresses a critical need to improve controlled access to treatment while preventing opioid use disorder, and it is a proven technology that has been effectively tested in a large European hospital group and is the culmination of years of development.”

The *SmartBottle* is an oral, drinkable controlled analgesia system designed for use both at home and in hospitals, particularly for the treatment of post-operative, chronic or palliative pain. The patient’s pain treatment is individualized by the authorized prescriber and is fully secured, traceable and trackable. With biometric authentication, the patient can take only the prescribed and programmed dose, bringing safety, comfort and autonomy to the patient while also deterring abuse or misuse. In the case of theft or tampering, the system instantly flash-neutralizes the drug, making it totally unusable and unavailable.

Ethimedix developed its *SmartBottle* technology to provide properly prescribed pain relief while addressing the growing opioid use disorder crisis. Of the 42,249 people who died from overdosing on opioids in the U.S. in 2016, 17,009 overdosed on prescription opioids.<sup>1</sup> Furthermore, the U.S. National Center for Health Statistics estimates that more than 113 people currently die per day in the U.S. from opioid related drug overdoses.

The U.S. FDA has responded to this crisis in many ways, including launching an FDA Innovation Challenge. The Challenge is a program designed to spur the development of medical devices, including diagnostic tests and digital health technologies, to help combat the opioid crisis and achieve the goal of preventing and treating opioid use disorder. Applicants selected for the Challenge will work directly with the FDA to accelerate the development of and eventual review of marketing applications for innovative products, similar to what occurs under the [Breakthrough Devices Program](#).

The *SmartBottle* has been tested and used for over 18 months at the Bicêtre Hospital, one of APHP’s 39 hospitals in Paris, where it has been readily adopted by the neurosurgery, urology and orthopedics groups. The healthcare professionals who have the opioid-filled *SmartBottle* on their carts say they have new peace of mind when they conduct patient rounds. They no longer have the risk of theft or misuse, since the tamper-proof cartridge will neutralize the opioid if anyone tries to tamper with the device, and only biometrically approved healthcare providers can dispense the pain relief medication.

Isabelle Negre, M.D., anesthesiologist with [APHP](#) and head of the Pain Centre and of the Pain Relief Commission at the Hôpitaux Universitaires Paris-Sud, said, “We have been extremely pleased with the *SmartBottle*, as it has brought a new level of safety to the hospital floor. Our healthcare providers love it because they do not have to worry about medication being diverted and misused and abused, while significantly saving time of up to one hour per shift. We have been so pleased with the technology’s performance to date that we hope to expand its use.”

The *SmartBottle* is not currently approved for use in the U.S. Ethimedix is currently seeking to partner with an approved prescription drug manufacturer to run usability trials in the U.S.

**About Ethimedix SA**

Ethimedix SA is a Swiss-based, privately owned company incorporated in 2010 with a mission to develop and provide state-of-the-art medical devices that allow programmable, controllable means of drug delivery. The company is committed to improving patient quality of life while ensuring better adherence and compliance, and preventing abuse, misuse, and diversion. For more information, visit [ethimedix.com](http://ethimedix.com).

<sup>1</sup> Mortality in the United States, 2016 NCHS Data Brief No. 293, December 2017

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