



**Testimony**

of

**Hillary Kunins, MD  
Assistant Commissioner**

and

**Anne Siegler, DrPH  
Director, Initiatives and Evaluation**

**Bureau of Alcohol and Drug Use Prevention, Care and Treatment  
Division of Mental Hygiene  
New York City Department of Health and Mental Hygiene**

before the

**Food and Drug Administration**

on

**Exploring Naloxone Uptake and Use**

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My name is Hillary Kunins; I am the Assistant Commissioner for the Bureau of Alcohol and Drug Use Prevention, Care and Treatment at the New York City Department of Health and Mental Hygiene, and a board-certified internal medicine and addiction medicine physician. I have cared for many patients who suffered from overdoses and have lost patients to overdose. I am joined by my colleague, Dr. Anne Siegler, the Director of Initiatives and Evaluation for the Bureau of Alcohol and Drug Use, Prevention, Care and Treatment. On behalf of Commissioner Bassett, we appreciate the opportunity to testify regarding New York City's experience with naloxone, particularly with community-based opioid overdose prevention programs, the results of two evaluations of these programs, and about federal policy recommendations based on our experience, including over the counter designation, and approving the intranasal delivery of naloxone as an on-label use.

Like other jurisdictions, New York City is facing a serious public health problem due to opioid overdose, a category that includes heroin and opioid analgesics. Opioid overdoses have claimed the lives of more than 7,000 New Yorkers over the last decade. The rates of overdose deaths involving opioid analgesics increased over 250 percent between 2000 and 2013; this is equivalent to one New York City resident dying every other day from a prescription painkiller overdose. Emergency department visits related to prescription painkillers nearly tripled from 2004 to 2011. Heroin-involved overdose deaths are also rising in New York City, doubling between 2010 and 2013; this is similar to trends elsewhere in the United States.

Since 2009, the New York City Health Department has provided free overdose rescue kits containing two intranasal naloxone doses to community-based programs, such as syringe exchange programs, drug treatment programs and homeless shelters, as well as to friends and family members visiting detainees at Rikers Island, New York City's largest jail. We are able to do this because of the 2006 New York State Opioid Overdose Prevention Act, which allows for dispensing of naloxone to trained laypeople. The law was amended last year to allow for dispensing of naloxone under standing orders, enabling community-based programs to dispense naloxone without requiring the presence of a prescriber. The legislation also authorized pharmacists to dispense naloxone under a standing order.

The New York State policy context has facilitated naloxone distribution to some of the individuals most at-risk for overdose. New York City community-based programs, such as syringe exchange programs and drug treatment programs have been instrumental in providing individuals most likely to witness overdose with overdose prevention training and naloxone kits. To date, the Health Department has dispensed over 32,000 naloxone kits. This number has been increasing each year, with 4,000 kits distributed in 2011 and more than 10,000 last year. With support from community partners, we have been able to target this distribution to some of the city's hardest hit neighborhoods, and we continue to use epidemiologic data to drive distribution.

In addition to distributing naloxone through community organizations and treatment programs, the New York City Health Department is providing overdose response training and distributing naloxone

to visitors at Rikers Island. Approximately 100 to 200 individuals are trained monthly, and 11 reversals have been reported since the pilot began last spring. Additionally, because we know that overdose is a leading cause of mortality among shelter residents, over 700 security staff in city shelters are now trained in overdose response and carry naloxone; since the program began in 2010, 79 reversals have been reported.

Because we know that community-based reversals are underreported, we undertook a prospective one-year evaluation of our naloxone program to assess the frequency of its use. In addition, to assess population level effects on overdose mortality, we compared neighborhoods with greater naloxone access to neighborhoods without access over time. My colleague, Dr. Anne Siegler, will now share these findings with the panel.

My name is Anne Siegler, and I am the Director of Initiatives and Evaluation in the Bureau of Alcohol and Drug Use Prevention, Care and Treatment at the New York City Department of Health and Mental Hygiene. I would like to share our key findings showing that high-risk community responders observe overdoses with considerable frequency, and are able to respond effectively with naloxone. We followed nearly 400 individuals who had received naloxone training at syringe exchange programs or methadone treatment programs beginning in June 2013. Study participants witnessed a total of 338 overdoses over the course of one year; in only five events, the study participant reported the victim did not survive. In nearly three-quarters (74 percent) of these overdoses, naloxone was administered. This represents 22 naloxone administrations for every 100 individuals trained. Study participants reported observing few adverse events, the most common being symptoms typical of opioid withdrawal, such as anger (22 percent) and vomiting (11 percent). Finally, we found that in nearly all (95 percent) responses, participants were able to assemble and administer naloxone easily.

In our neighborhood-level study of heroin-related overdose mortality, which will be published soon, we found a dose-response relationship between naloxone dispensing and overdose mortality. Neighborhoods that had dispensed the most naloxone saw greater decreases in overdose mortality rates (3.1 per 1,000 residents) over time, compared to neighborhoods that had not dispensed any naloxone (0.8 per 1,000 residents), after controlling for other neighborhood characteristics.

Through this work, we have identified a number of challenges, as well as policy opportunities that could facilitate naloxone prescribing and dispensing across settings. Our qualitative research shows that younger users obtain sterile syringes through the New York State-authorized pharmacy program, rather than through syringe exchange programs. Ensuring that these individuals at high risk of overdose are able to access affordable naloxone while they are at their local pharmacy fills an existing gap in access, in New York City and nationwide. By making naloxone an over-the-counter medication, anyone at risk of overdose or concerned about a family member or friend will be able to obtain this lifesaving medication easily. Over-the-counter designation would enable pharmacy-based naloxone access without necessitating state-specific standing order laws. Over-the-counter availability of naloxone will

also allow its purchase and distribution in a variety of other community-based-settings, without the need for a prescription or standing order.

In addition, making intranasal use of naloxone on-label will facilitate increased access, offering an alternative option for individuals who may be uncomfortable administering the injection-based intramuscular formulation. During our one-year evaluation of syringe exchange and methadone program participants, a majority (73 percent) had expressed preference for the intranasal spray over the intramuscular syringe (not Evzio). There were no significant differences, however, between intranasal and the intramuscular formulations in frequency of use, effectiveness, adverse events, or trouble assembling or administering naloxone.

Naloxone affordability continues to be a challenge. Both public and commercial insurance coverage of naloxone is sparse, so that many people, even with insurance, cannot fill a naloxone prescription without significant out-of-pocket costs. Without insurance, two doses of the intramuscular naloxone purchased at a large chain pharmacy can cost around 40 dollars, which may be a prohibitive expense for individuals at risk of opioid overdose. The same is true for the recently-approved auto-injector, Evzio. A single dose of Evzio can cost upwards of 500 dollars. Commercial insurance plans may cover Evzio; however, coverage is often limited to the patient at risk of opioid overdose, and does not extend to a concerned family member or friend who may be likely to witness an overdose.

Our experience in New York City has shown us that overdose prevention training and use of naloxone is an effective response to opioid overdoses. Most often, individuals experiencing overdose will be with others who are in a position to assist. Giving them better access to naloxone will save lives.

Thank you for the opportunity to testify. Dr. Kunins and I would be happy to answer any questions that you may have.