Opioid Awareness

FDA Commissioner **Scott Gottlieb**, M.D., believes that in order to alleviate the opioid crisis, we need to start listening to those personally impacted.

Learn why making a dent in the opioid epidemic means considering long-term solutions.

Discover why opioid addiction — like any other — can't be cured, but with careful administration and planning, can be treated.

FIND SUPPORT

As we form a deeper understanding of opioid abuse, so too do we develop resources to help those struggling with addiction. To help yourself or someone you know:

CALL
SAMHSA's National Helpline
1-800-662-HELP (4357)
TTY: 1-800-487-4889

Parent Helpline
1-855-DRUGFREE

VISIT
Partnership for Drug Free Kids
www.drugfree.org

SAMHSA's Prescription Drug Misuse and Abuse Website
www.samhsa.gov/prescription-drug-misuse-abuse

SAMHSA's Behavioral Health Treatment Services Locator
www.samhsa.gov/find-help

American Society of Addiction Medicine
www.asam.org

Protecting Americans from the Public Health Crisis of Our Time

The Centers for Disease Control and Prevention is dedicated to combating the American opioid crisis through education, scientific research and assistance.

The opioid overdose epidemic is the public health crisis of our time — and it's having a tragic impact on families and communties across our country. In 2016, approximately 115 Americans died every day from overdoses involving prescription opioids, illegal opioids like heroin and illicitly-manufactured fentanyl and its analogues. While we don't have final data for 2017 yet, early data show that the number could be as high as 134 overdose deaths per day. Families affected by this tragic crisis experience unimaginable loss and pain.

The health impacts of opioid misuse go beyond overdose and addiction. The epidemic also brings an increase in hepatitis and HIV infections, and newborns suffering from drug withdrawal. We didn't get into this crisis overnight — and we won't get out of it overnight — but stopping the epidemic is a priority of centers for disease control and prevention (CDC).

The CDC provides research, education and direct assistance to those on the front lines. We fund states to collect data through various systems, from medical examiners and coroners to emergency departments and prescription drug monitoring programs. This information helps the public health community better understand the causes of the epidemic, who is most at risk and how best to prevent both misuse and overdoses. We are also working to improve the quality and timeliness of data needed to quickly respond to emerging issues and target prevention in the hardest-hit communities.

Opposing opioids

The U.S. Department of Health and Human Services and the current administration are serious about this public health emergency, and congressional leaders have provided much-needed additional resources. Recent funding for the CDC will strengthen opioid emergency response work and support state, local, tribal and territorial public health agencies.

The CDC is also dedicated to educating the American public. Last year, we launched the Rx Awareness campaign, detailing the dangers and risks of prescription opioids in order to empower people to make safe choices. We support health care providers and health systems with guidance, data and tools to safely manage patient needs and reduce prescribing risks.

Dr. Robert R. Redfield
Director, Centers for Disease Control and Prevention

"We must support the families of those fighting addiction, **and recognize that stigma is the enemy."**

This fast-moving opioid overdose epidemic can affect your family no matter your age, sex, race or where you live. Responding to a crisis of this magnitude means we must all work together. That's why the CDC is working closely with health systems and health departments, law enforcement, first responders and community-based prevention and treatment organizations. Opioid dependency is a complex condition with biological, social, psychological and environmental drivers, and the medical piece of the solution has too long been neglected. For those struggling, don't lose hope — help for long-term recovery is available. To win, we must support the families of those fighting addiction, and recognize that stigma is the enemy of public health.

It's going to be a tough fight — but through the power of science, the power of medicine, the power of public health and faith in the future, we can end this epidemic and save lives. ■

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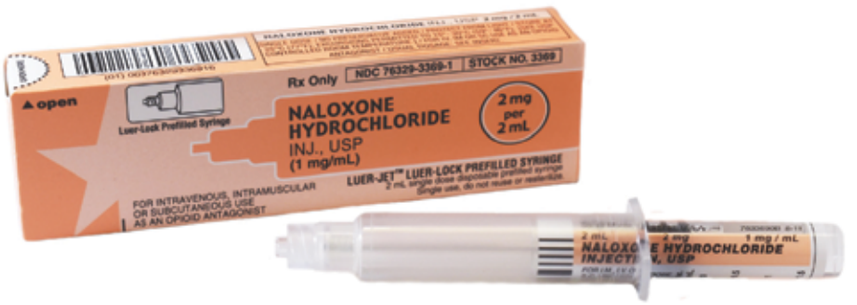
Generic Naloxone HCl Injection, USP 2mg/2mL in a needleless Luer-Jet™ prefilled syringe.

Syringe tip is compatible with luer activated system.

For intravenous, intramuscular and subcutaneous administration.

For more information, please contact Amphastar customer service at 1-800-423-4136



INDICATIONS AND USAGE

Naloxone hydrochloride injection is indicated for the complete or partial reversal of opioid depression, including respiratory depression, induced by natural and synthetic opioids including, propoxyphene, methadone and certain mixed agonist-antagonist analgesics: nalbuphine, pentazocine and butorphanol and cyclazocine. Naloxone hydrochloride is also indicated for the diagnosis of suspected or known acute opioid overdosage.

CONTRAINDICATIONS

Naloxone hydrochloride injection is contraindicated in patients known to be hypersensitive to it or to any of the other ingredients in naloxone hydrochloride.

WARNINGS

Drug Dependence

Naloxone hydrochloride should be administered cautiously to persons including newborns of mothers who are known or suspected to be physically dependent on opioids. In such cases an abrupt and complete reversal of opioid effects may precipitate an acute withdrawal syndrome.

Repeat Administration

The patient who has satisfactorily responded to naloxone hydrochloride should be kept under continued surveillance and repeated doses of naloxone hydrochloride should be administered, as necessary, since the duration of action of some opioids may exceed that of naloxone hydrochloride.

Respiratory Depression due to Other Drugs

Naloxone hydrochloride is not effective against respiratory depression due to non-opioid drugs and in the management of acute toxicity caused by levopropoxyphene.

PRECAUTIONS

In addition to naloxone hydrochloride, other resuscitative measures such as maintenance of a free airway, artificial ventilation, cardiac massage, and vasopressor agents should be available and employed when necessary to counteract acute opioid poisoning. Abrupt postoperative reversal of opioid depression may result in nausea, vomiting, sweating, tremulousness, tachycardia, increased blood pressure, seizures, ventricular tachycardia and fibrillation, pulmonary edema, and cardiac arrest which may result in death. Excessive doses of naloxone hydrochloride in postoperative patients may result in significant reversal of analgesia and may cause agitation.

Usage in Adults-Postoperative Opioid Depression

Several instances of hypotension, hypertension, ventricular tachycardia and fibrillation, pulmonary edema, and cardiac arrest have been reported in postoperative patients. Death, coma, and encephalopathy have been reported as sequelae of these events. These have occurred in patients most of whom had preexisting cardiovascular disorders or received other drugs which may have similar adverse cardiovascular effects. Although a direct cause and effect relationship has not been established, naloxone hydrochloride should be used with caution in patients with preexisting cardiac disease or patients who have received medications with potential adverse cardiovascular effects, such as hypotension, ventricular tachycardia or fibrillation, and pulmonary edema.

Drug Interactions

Large doses of naloxone are required to antagonize buprenorphine since the latter has a long duration of action due to its slow rate of binding and subsequent slow dissociation from the opioid receptor.

Use in Pregnancy

Teratogenic Effects: Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. **Non-teratogenic Effects:** Risk-benefit must be considered before naloxone hydrochloride is administered to a pregnant woman who is known or suspected to be opioid-dependent since maternal dependence may often be accompanied by fetal dependence. Naloxone crosses the placenta, and may precipitate withdrawal in the fetus as well as in the mother. Patients with mild to moderate hypertension who receive naloxone during labor should be carefully monitored as severe hypertension may occur.

Use in Labor and Delivery

It is not known if naloxone hydrochloride affects the duration of labor and/or delivery.
Nursing Mothers: It is not known whether naloxone is excreted in human milk.

Pediatric Use

Naloxone hydrochloride injection, USP may be administered intravenously, intramuscularly or subcutaneously in children and neonates to reverse the effects of opiates. The American Academy of Pediatrics, however, does not endorse subcutaneous or intramuscular administration in opiate intoxication since absorption may be erratic or delayed. Although the opiate-intoxicated child responds dramatically to naloxone hydrochloride, he/she must be carefully monitored for at least 24 hours as a relapse may occur as naloxone is metabolized.

Geriatric Use

Clinical studies of naloxone hydrochloride did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

Renal Insufficiency/Failure

The safety and effectiveness of naloxone hydrochloride in patients with renal insufficiency /failure have not been established in well-controlled clinical trials. Caution should be exercised when naloxone hydrochloride is administered to this patient population.

Liver Disease

The safety and effectiveness of naloxone hydrochloride in patients with liver disease have not been established in well-controlled clinical trials.

ADVERSE REACTIONS

Postoperative

The following adverse events have been associated with the use of naloxone hydrochloride in postoperative patients: hypotension, hypertension, ventricular tachycardia and fibrillation, dyspnea, pulmonary edema, and cardiac arrest. Death, coma, and encephalopathy have been reported as sequelae of these events. Excessive doses of naloxone hydrochloride in postoperative patients may result in significant reversal of analgesia and may cause agitation;

Opioid Depression

Abrupt reversal of opioid depression may result in nausea, vomiting, sweating, tachycardia, increased blood pressure, tremulousness, seizures, ventricular tachycardia and fibrillation, pulmonary edema, and cardiac arrest which may result in death.

Opioid Dependence

Abrupt reversal of opioid effects in persons who are physically dependent on opioids may precipitate an acute withdrawal syndrome which may include, but is not limited to, the following signs and symptoms: body aches, fever, sweating, runny nose, sneezing, piloerection, yawning, weakness, shivering or trembling, nervousness, restlessness or irritability, diarrhea, nausea or vomiting, abdominal cramps, increased blood pressure, tachycardia. In the neonate, opioid withdrawal may also include: convulsions; excessive crying; hyperactive reflexes.
Adverse events associated with the postoperative use of naloxone hydrochloride are listed by organ system and in decreasing order of frequency as follows: **Cardiac Disorders:** pulmonary edema, cardiac arrest or failure, tachycardia, ventricular fibrillation, and ventricular tachycardia. Death, coma, and encephalopathy have been reported as sequelae of these events. **Gastrointestinal Disorders:** vomiting, nausea; **Nervous System Disorders:** convulsions, paraesthesia, grand mal convulsion; **Psychiatric Disorders:** agitation, hallucination, tremulousness; **Respiratory, Thoracic and Mediastinal Disorders:** dyspnea, respiratory depression, hypoxia; **Skin and Subcutaneous Tissue Disorders:** nonspecific injection site reactions, sweating; **Vascular Disorders:** hypertension, hypotension, hot flushes or flushing.

This is a brief summary of information from the Prescribing Information (PI) and doesn't include all of the information from the full PI. See the complete PI at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=236349ef-2cb5-47ca-a3a5-99534c3a4996 or call Amphastar Pharmaceuticals customer service at 1-800-423-4136. Manufactured by: International Medication Systems, Limited, South El Monte, CA 91733,USA.

Vivitrol®
(naltrexone for extended-release injectable suspension)

TAKE ONE DAY AT A TIME, **ONE MONTH** AT A TIME.

Once-monthly, non-narcotic VIVITROL for opioid dependence.

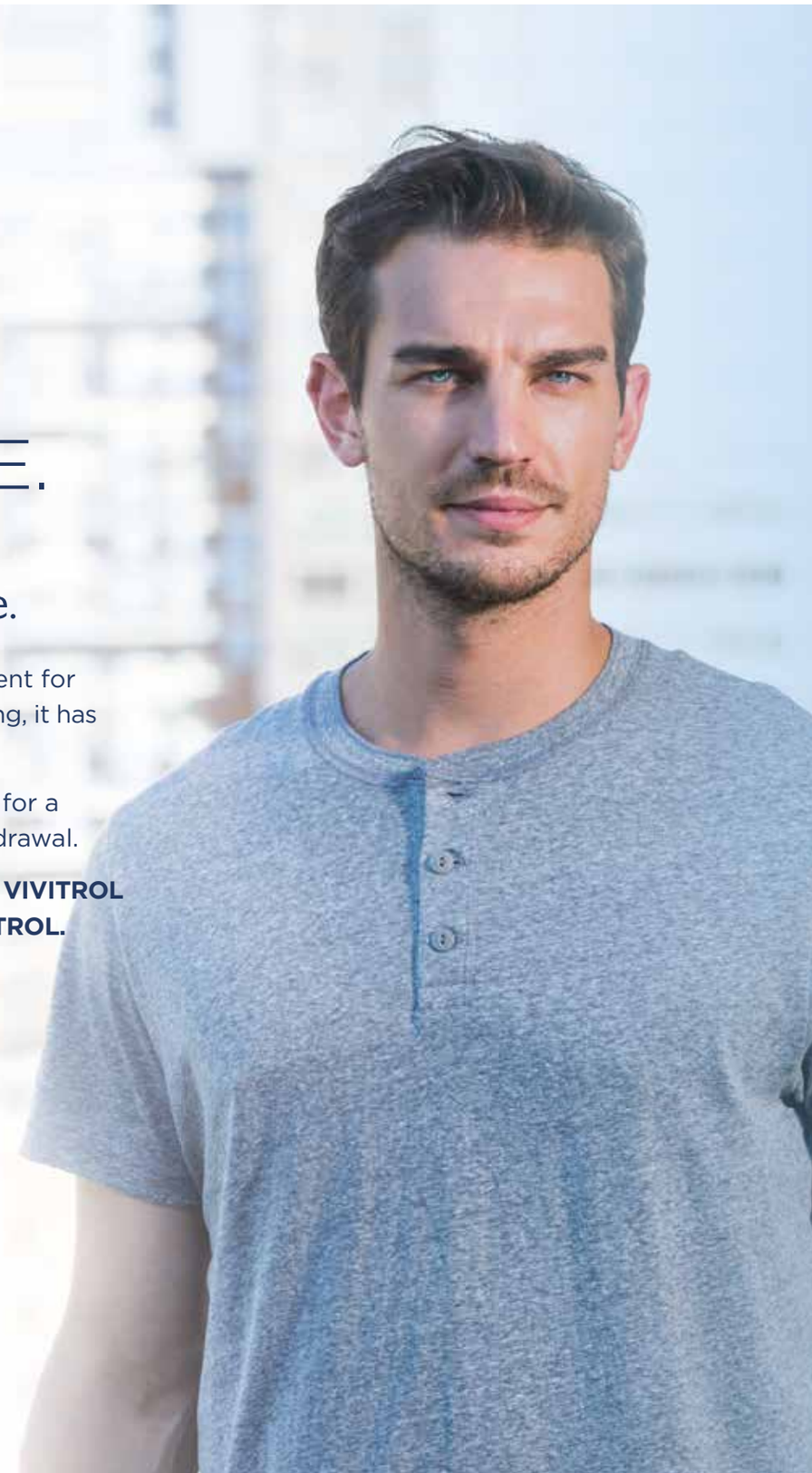
VIVITROL is a non-addictive, once-monthly treatment for opioid dependence. When combined with counseling, it has been proven to help prevent relapse after detox.

Before starting VIVITROL, you must be opioid-free for a minimum of 7-14 days to avoid sudden opioid withdrawal.

Please see Brief Summary of Important Facts about VIVITROL on facing page, including who should not take VIVITROL.

Ask your healthcare provider.

IT'S ABOUT **TIME.**



VIVITROL.com

BRIEF SUMMARY OF **IMPORTANT FACTS** ABOUT VIVITROL

What is the most important information I should know about VIVITROL?

VIVITROL can cause serious side effects, including:

1. Risk of opioid overdose. You can accidentally overdose in two ways.

- VIVITROL blocks the effects of opioids, such as heroin or opioid pain medicines. **Do not** try to overcome this blocking effect by taking large amounts of opioids – this can lead to serious injury, coma, or death.
- After you receive a dose of VIVITROL, its blocking effect slowly decreases and completely goes away over time. If you have used opioid street drugs or opioid-containing medicines in the past, using opioids in amounts that you used before treatment with VIVITROL can lead to overdose and death. You may also be more sensitive to the effects of **lower** amounts of opioids:
  - after you have gone through detoxification
  - when your next VIVITROL dose is due
  - if you miss a dose of VIVITROL
  - after you stop VIVITROL treatment

Tell your family and the people closest to you of this increased sensitivity to opioids and the risk of overdose.

2. Severe reactions at the site of injection. Some people on VIVITROL have had severe injection site reactions, including tissue death. Some of these reactions have required surgery. Call your healthcare provider right away if you notice any of the following at any of your injection sites:

- intense pain
- the area feels hard
- large area of swelling
- lumps
- blisters
- an open wound
- a dark scab

Tell your healthcare provider about any reaction at an injection site that concerns you, gets worse over time, or does not get better within two weeks.

3. Sudden opioid withdrawal. To avoid sudden opioid withdrawal, you must stop taking any type of opioid, including street drugs; prescription pain medicines; cough, cold, or diarrhea medicines that contain opioids; or opioid-dependence treatments, including buprenorphine or methadone, **for at least 7 to 14 days** before starting VIVITROL. If your healthcare provider decides that you don't need to complete detox first, he or she may give you VIVITROL in a medical facility that can treat sudden opioid withdrawal. **Sudden opioid withdrawal can be severe and may require hospitalization.**

4. Liver damage or hepatitis. Naltrexone, the active ingredient in VIVITROL, can cause liver damage or hepatitis. Tell your healthcare provider if you have any of these symptoms during treatment with VIVITROL:

- stomach area pain lasting more than a few days
- dark urine
- yellowing of the whites of your eyes
- tiredness

Your healthcare provider may need to stop treating you with VIVITROL if you get signs or symptoms of a serious liver problem.

What is VIVITROL?

VIVITROL is a prescription injectable medicine used to:

- treat alcohol dependence. You should stop drinking before starting VIVITROL.
- prevent relapse to opioid dependence, **after** opioid detoxification.

You must stop taking opioids before you start receiving VIVITROL. To be effective, VIVITROL must be used with other alcohol or drug recovery programs such as counseling. VIVITROL may not work for everyone. It is not known if VIVITROL is safe and effective in children.

Who should not receive VIVITROL?

Do not receive VIVITROL if you:

- are using or have a physical dependence on opioid-containing medicines or opioid street drugs, such as heroin. To test for a physical dependence on opioid-containing medicines or street drugs, your healthcare provider may give you a small injection of a medicine called naloxone. This is called a naloxone challenge test. **If you get symptoms of opioid withdrawal after the naloxone challenge test, do not start treatment with VIVITROL at that time.** Your healthcare provider may repeat the test after you have stopped using opioids to see whether it is safe to start VIVITROL.
- are having opioid withdrawal symptoms. Opioid withdrawal symptoms may happen when you have been taking opioid-containing medicines or opioid street drugs regularly and then stop. **Symptoms of opioid withdrawal may include:** anxiety, sleeplessness, yawning, fever, sweating, teary eyes, runny nose, goose bumps, shakiness, hot or cold flushes, muscle aches, muscle twitches, restlessness, nausea and vomiting, diarrhea, or stomach cramps.
- are allergic to naltrexone or any of the ingredients in VIVITROL or the liquid used to mix VIVITROL (diluent). See the medication guide for the full list of ingredients.

What should I tell my healthcare provider before receiving VIVITROL?

Before you receive VIVITROL, tell your healthcare provider if you:

- have liver problems, use or abuse street (illegal) drugs, have hemophilia or other bleeding problems, have kidney problems, or have any other medical conditions.
- are pregnant or plan to become pregnant. It is not known if VIVITROL will harm your unborn baby.
- are breastfeeding. It is not known if VIVITROL passes into your milk, and if it can harm your baby. Naltrexone, the active ingredient in VIVITROL, is the same active ingredient in tablets taken by mouth that contain naltrexone. Naltrexone from tablets passes into breast milk. Talk to your healthcare provider about whether you will breastfeed or take VIVITROL. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take any opioid-containing medicines for pain, cough or colds, or diarrhea.

If you are being treated for alcohol dependence but also use or are addicted to opioid-containing medicines or opioid street drugs, it is important that you tell your healthcare provider before starting VIVITROL to avoid having sudden opioid withdrawal symptoms when you start VIVITROL treatment.

What are other possible serious side effects of VIVITROL?

VIVITROL can cause serious side effects, including:

Depressed mood. Sometimes this leads to suicide, or suicidal thoughts, and suicidal behavior. Tell your family members and people closest to you that you are taking VIVITROL.

Pneumonia. Some people receiving VIVITROL treatment have had a type of pneumonia that is caused by an allergic reaction. If this happens to you, you may need to be treated in the hospital.

Serious allergic reactions. Serious allergic reactions can happen during or soon after an injection of VIVITROL. Tell your healthcare provider or get medical help right away if you have any of these symptoms:

- skin rash
- swelling of your face, eyes, mouth, or tongue
- trouble breathing or wheezing
- chest pain
- feeling dizzy or faint

Common side effects of VIVITROL may include:

- nausea
- sleepiness
- headache
- dizziness
- vomiting
- painful joints
- decreased appetite
- muscle cramps
- cold symptoms
- trouble sleeping
- toothache

These are not all the side effects of VIVITROL. Tell your healthcare provider if you have any side effect that bothers you or that does not go away. You are encouraged to report all side effects to the FDA.
Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

This is only a summary of the most important information about VIVITROL.

Need more information?

- Ask your healthcare provider or pharmacist.

Read the Medication Guide, which is available at vivitrol.com and by calling 1-800-848-4876, option #1.

This brief summary is based on the VIVITROL Medication Guide (Rev. July 2013).

Alkermes®

A Private Sector Solution to the Opioid Epidemic

As the opioid epidemic continues to ravage our country, the private sector is working to change the landscape of addiction treatment for the better.

In 2016, 20.1 million Americans had a substance use disorder. Two million of them were addicted to opioids — including prescription and illicit drugs. Opioid overdoses ravaged America, taking the lives of over 42,000 people in 2016 alone, marking a 25 percent increase from 2015 and making it the worst year on record.

This isn't just another statistic. It represents lost loved ones. And it's an added reminder of how addiction differs from other chronic illnesses. Even though addiction can be managed effectively with medical treatment, only 1 in 10 Americans with this disease ever receives care. And the few who do often receive substandard care or advice that is not based on research.

Incentivizing quality and access

Recognizing this gap, Shatterproof adopted a businesslike approach and brought together insurers, providers, advocates and other stakeholders to improve access to quality treatment. As a result of the work of this Task Force, 16 insurance companies representing more than 248 million individuals agreed to adopt eight National Principles of Care for the treatment of addiction.

"Addiction will be treated with **the same urgency and respect as other diseases."**

By signing on to these standards, insurers have committed to identifing, promoting and rewarding addiction treatment that is shown to improve a patient's life. Together, they will use their market influence to incentivize high-quality practices while making a strong statement: addiction will be treated with the same urgency and respect as other diseases.

Modeling health care solutions

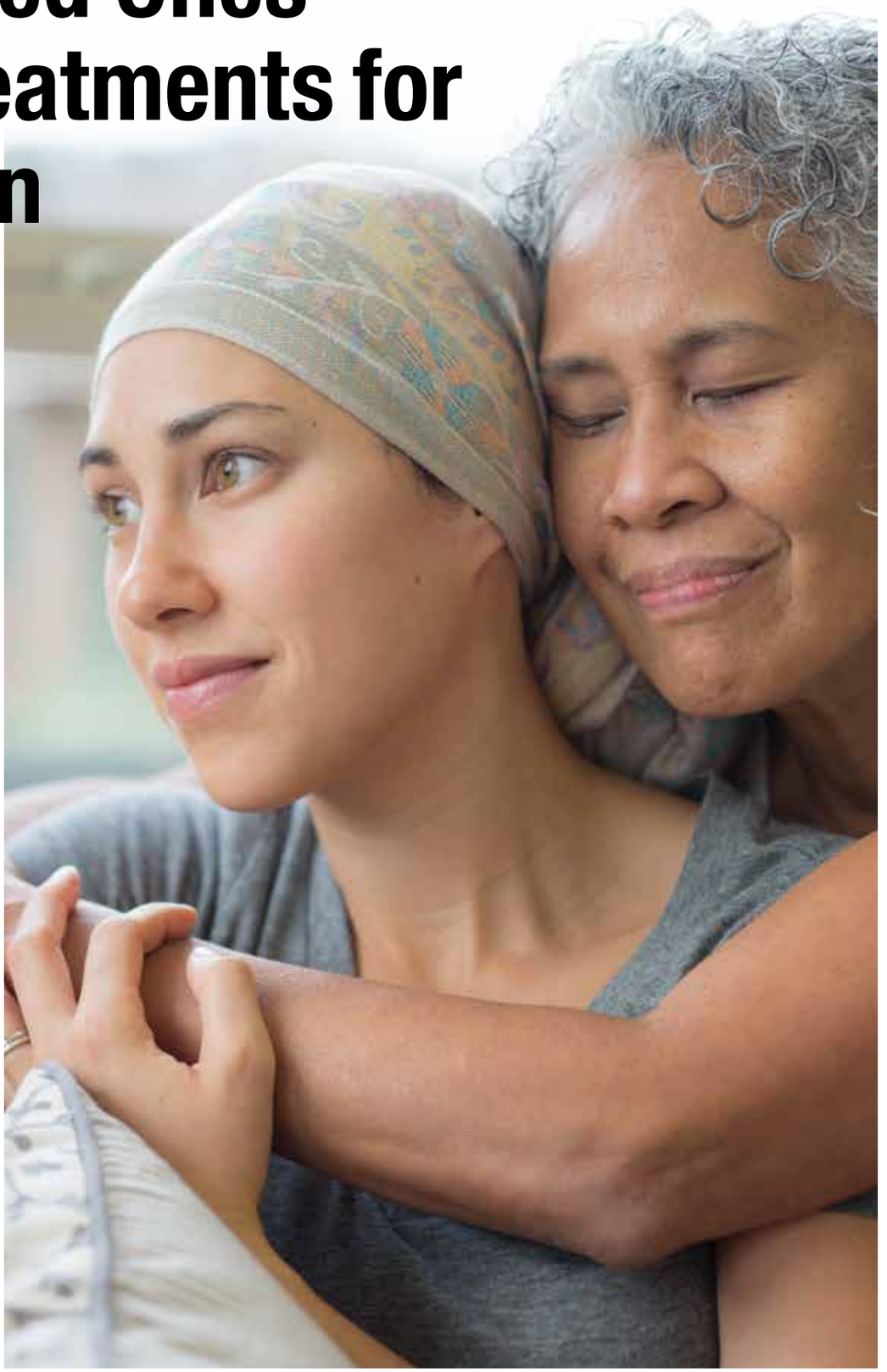
Shatterproof is also working to bring transparency and credibility to the system of addiction treatment. Recognizing that family members and friends often don't know where to direct a person in crisis for the best type of treatment, we are adapting strategies from other health care sectors. This will help consumers locate care, help insurers decide which providers to include in their networks and help programs identify any areas for improvement.

Addiction is not a moral failing or a character flaw, and it is necessary that we take steps as a society to reverse the long-ingrained stigma associated with this disease. Improving access to treatment that saves lives is the only way to prevent more tragedy. Shatterproof is changing the landscape of addiction treatment in the United States by removing barriers and moving toward proven medical treatment. ■

Gary Mendell, Founder and CEO, Shatterproof

Recovering Loved Ones With Proven Treatments for Opioid Addiction

Eliminating opioid issues won't happen unless we first eliminate the stigma surrounding addiction and increase access to proper medication.



Addiction is a chronic disease — like diabetes and asthma — and, just like other chronic diseases, it requires treatment by medical professionals. Addiction can't be cured — but it can be successfully treated.

While best managed with a combination of medical interventions, psychosocial supports and lifestyle changes, evidence clearly shows us that U.S. Food and Drug Administration-approved medications should be a central component of treating opioid addiction. While some argue that patients should stop using medication for opioid addiction treatment, we must remember the goal of treating chronic diseases: to put symptoms into remission. Furthermore, it is unrealistic to expect perfect adherence to a treatment plan for any chronic disease. If patients misuse drugs or alcohol while trying to abstain, it doesn't mean that they are failing in their treatment, or that they are a failure. It means that they are managing their disease one day at a time.

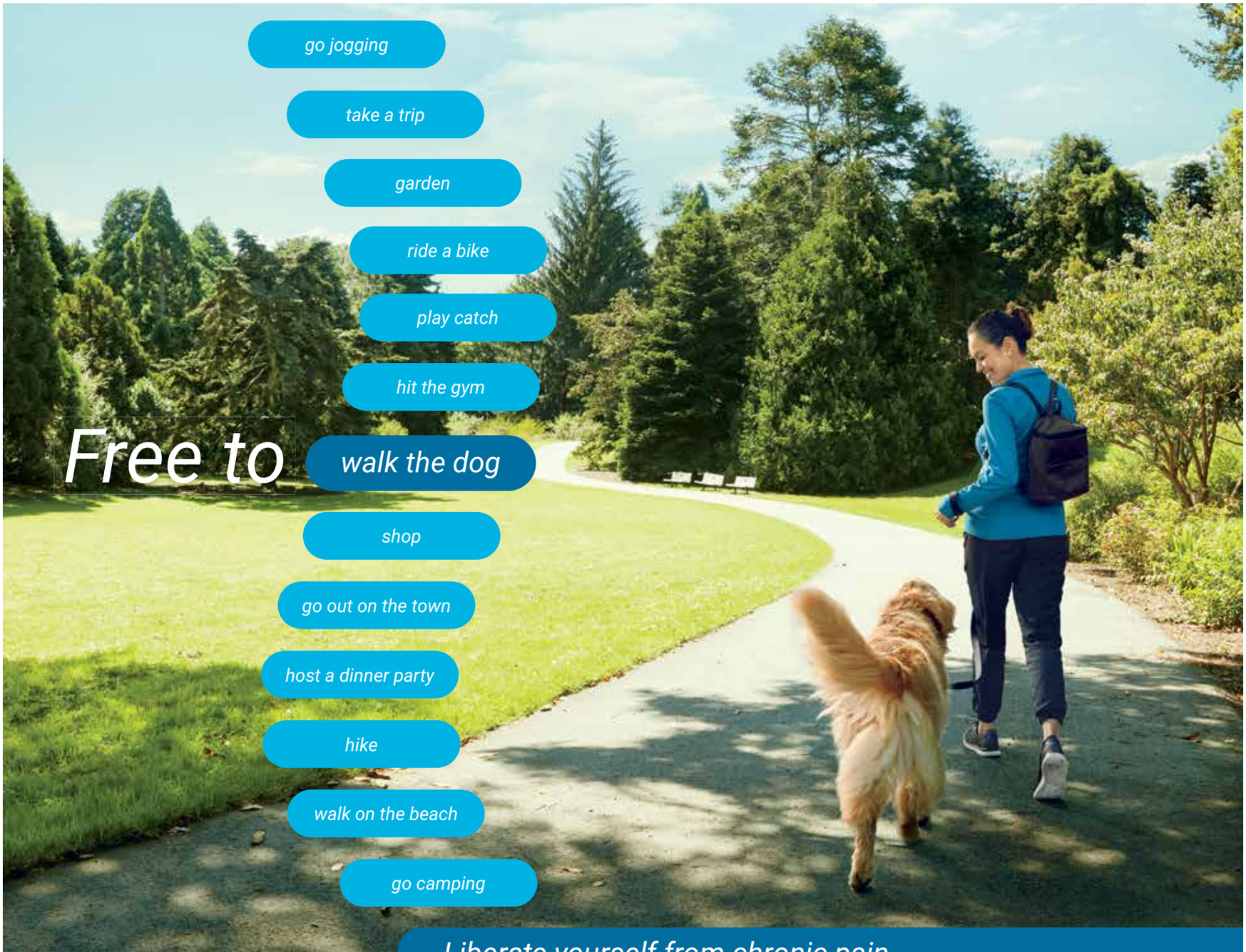
Addiction medicine is an extremely rewarding specialty. Much of what we do as doctors is done to postpone death. However, when I treat addiction, I can truly save a life. People addicted to opioids can and do get their lives back. When people receive appropriate treatment, dramatic improvement is often seen within weeks. My patients tell me that their families are talking to them again, that they can see their kids again, that they have an apartment, that they've gotten a job.

"Addiction can't be cured — **but it can be successfully treated.**"

Change for the better

We will not find our way out of this epidemic, however, with outdated treatment methods and a system that gives too few people access to evidence-based care. We must end the discrimination and stigma surrounding this disease. Patients need access to evidence-based care and a better understanding of all medically-appropriate options available to them. This is what we would expect with any other medical condition. If we truly want to end our nation's opioid overdose epidemic, then we must stop doing what we know does not work and focus on what we know does. It's time to get our friends and families back. ■

Kelly J. Clark, M.D., President, American Society of Addiction Medicine



Liberate yourself from chronic pain.

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HF10® is a medical device option that is proven to provide long-term relief from chronic back and leg pain.

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Learn more at HF10.com/relief

Rx Only: Patient experiences with the Senza spinal cord stimulation (SCS) system vary by individual, including the amount of pain relief. The occurrence of adverse effects associated with SCS implant surgery or use also varies by patient. **Brief Summary:** A summary of important information follows. Please see https://www.hf10.com/resources/safety-information for complete information. Please consult your doctor to fully understand Senza benefits and risks. **Indications for Use:** The Senza spinal cord stimulation system is an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain. **Contraindications:** These include patients not fit for surgery. **Warnings/Precautions:** There are warnings or precautions against or regarding: Senza use in patients who are or may become pregnant; patients undergoing diathermy or with other active implanted devices, or those undergoing CT scans, ultrasound or other procedures, among others. **Adverse Effects:** Senza is implanted surgically, so surgical complications are possible, such as infection, pain, bleeding and, very rarely, paralysis or death. After Senza placement, potential side effects include allergy or infection, loss of pain relief, pain or uncomfortable stimulation, burns or device or component malfunction resulting in corrective surgery, lead replacement or device removal. HF10 claims are supported by Kapural L, et al. Comparison of 10-kHz high-frequency and traditional low-frequency spinal cord stimulation for the treatment of chronic back and leg pain. Neurosurgery. 2016 Nov;79(5):667-677. 2018253 Rev. A

A Game-Changing Option for Managing Chronic Pain Without Drugs

HF10® spinal cord stimulation offers a path back to the people they used to be.

SPONSORED

HF10™

PHOTO: NEHEMIAH STARK

Beth George can remember the day her life changed vividly. "My chronic pain started with an uninsured motorist, driving in a turn-only lane, taking the front end of my car off and tearing a disc in my back," she says. "That was in 2002, right after my 32nd birthday."

That began a dark journey into chronic pain. "The life of somebody who lives with chronic pain is just taking it from one thing to the next," she says. "My journey included pain medication, chiropractic treatments, acupuncture. I had an inversion table set up in my bedroom. I did physical therapy, water therapy, occupational therapy. I had radiofrequency ablation done where they burn off the nerve endings to give you some relief. I had countless injections. I had a spinal fusion."

But the pain persisted. "Come 2015, my leg pain came back, my back pain was out of control. I remember the doctor coming into the room, and I just burst out crying. I was not even 45 and looking at him and saying, 'Is this the rest of my life? Where do I go from here?' Do I go on permanent disability and live the rest of my life on pain medications? That was a very low point for me."

That was when Beth learned about a new treatment for chronic pain that offered some hope: An advanced form of spinal cord stimulation (SCS) called HF10® from the medical device company Nevro®.

Altering pain signals

"Spinal cord stimulators deliver mild electrical pulses to the nerves in the spinal cord, which alters the transmission of the pain signals to the brain, thus relieving pain." explains Ashwini Sharan, M.D., professor and program director of neurosurgery at Thomas Jefferson University. "A small device is implanted under the skin, which is connected to thin flexible wires that deliver the stimulation to the spinal cord. The system is then customized for each patient to optimize pain relief. This process often results in significant pain relief and improved quality of life for many patients."

HF10 improves on existing SCS technology. "Before HF10," Sharan says, "we would generally teach patients that SCS is mostly good for leg pain. However, with HF10, chronic back pain and chronic leg pain are both responsive. In addition, patients don't feel the buzzing or tingling called 'paresthesia' experienced with traditional SCS devices."

Dr. Sharan has performed over 150 HF10 implants since the FDA approved the treatment in 2015, and describes the results as 'remarkable'. "We have so many patients who had not achieved good results with their revision spinal surgeries, but after HF10, they can exercise and increase their activity again. Additionally, we have many patients who are not on medications anymore."

Long-term relief

For Beth George, HF10 has been "transformative." "I had become 'Beth with the Bad Back.' That's how everybody knew me. I was out of options." Today, everything is different. "There is nothing that I want to do that I can't do. I can walk without pain. I can sit without pain — I can actually sit through a movie."

Unlike pain medications or other therapies, HF10 provides long-term relief. "I'm over two-and-a-half years out now, and I have 95 percent drug-free pain relief — so far beyond what I thought was possible," Beth says, noting that this isn't a 'one-size-fits-all' therapy. "It can be customized for each individual — they're all about the patient experience. I still consider myself blessed every day."

When asked for her advice to others dealing with chronic pain, Beth is passionate. "Don't give up. Don't assume that pills are your answer — they're not. There are options."

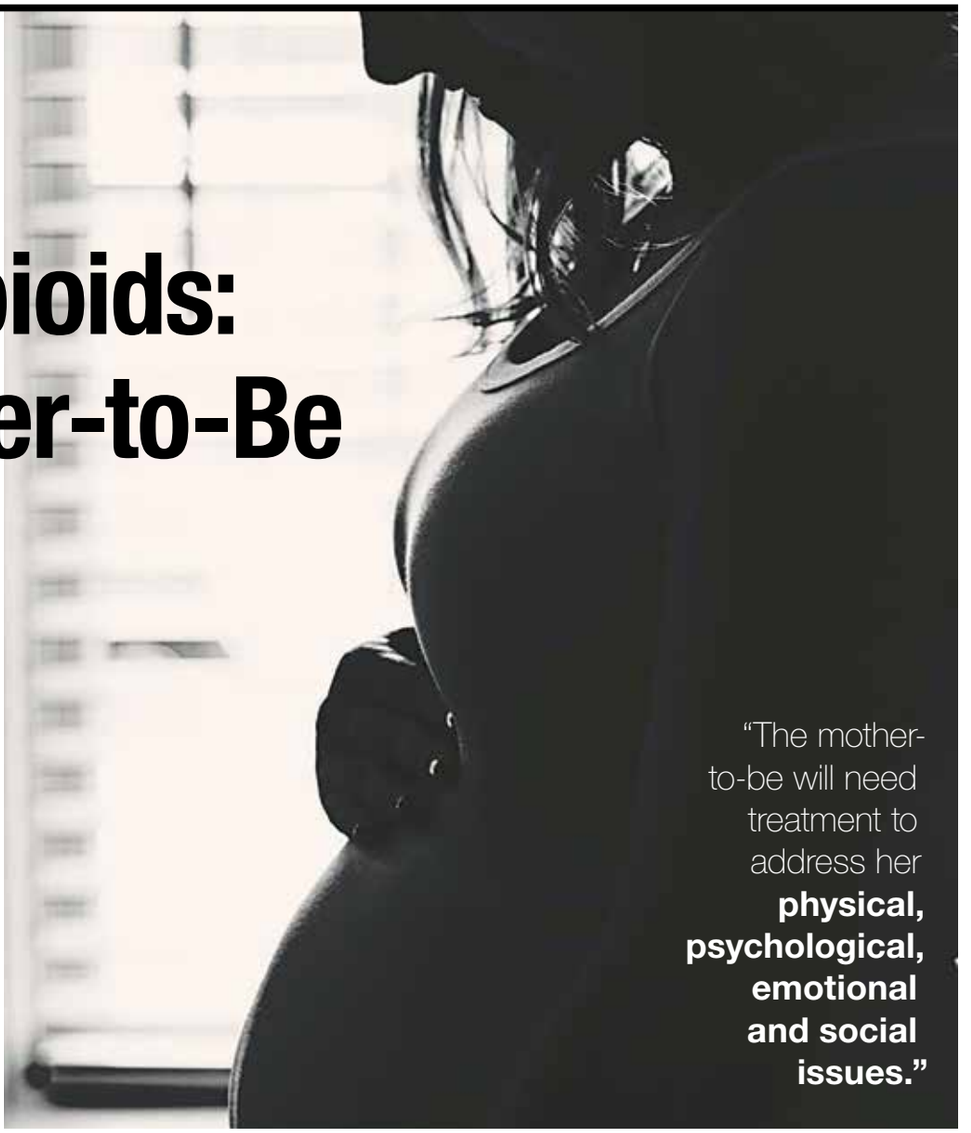
You can learn more about SCS and HF10 by visiting, www.hf10.com/relief.

HF10® spinal cord stimulation system is available by prescription only. Patient experiences vary, including the amount of pain relief and adverse effects associated with the device. Please consult your doctor to fully understand benefits and risks of HF10. HF10 is an aid in the management of chronic intractable pain of the trunk and/or limbs. HF10 should not be used in patients not fit for surgery, who are or may become pregnant, who have undergoing diathermy or with other active implanted devices, or those undergoing CT scans, ultrasound or other procedures. HF10 is implanted surgically, so surgical complications such as infection, pain, bleeding and in extremely rare cases paralysis or death are possible. Please see https://www.hf10.com/resources/safety-information for complete information. Dr. Sharan is a paid consultant of Nevro. HF10 claims are supported by the Senza Summary of Safety and Effectiveness Data (SSED). Published May 8th, 2015. ■

Jeffrey Somers

Pregnancy and Opioids: Caring for a Mother-to-Be and Her Baby

Opioid disorders tamper with pregnant mothers and their babies in terrible ways. It's past time for us to leverage available resources and lend a helping hand.



Is there a young woman in your life who is pregnant and misusing or addicted to opioids?

With comprehensive treatment and proper prenatal care, the mother-to-be can reduce the risks to both herself and the baby. She may face harsh judgment from others, but don't let this dissuade her from seeking treatment and support. As someone who cares about the mother and her baby, you have an opportunity to offer help to start her on the road to recovery and to deliver a healthy child.

Below is an excerpt from the Partnership for Drug-Free Kids' "Pregnancy & Opioids Guide: What Families Need to Know About Opioid Misuse and Treatment During Pregnancy." The Guide also includes information on supporting breastfeeding and newborn health, medication-assisted treatment, recovery care, as well as the stigma, discrimination and prejudice associated with substance use and addiction.

Get her to the doctor

"As with any pregnancy, patients need good obstetric care," explains Dr. Adam Bisaga, M.D., a research scientist at the New York State Psychiatric Institute and a professor of psychiatry at Columbia University Medical Center. "The patient should tell the obstetrician of her addiction and have someone monitoring the pregnancy. She should see them as soon as possible and get regular checkups. She and the baby will have a healthier outcome the sooner she starts to see a doctor."

What you can do:

- Encourage her to receive immediate and regular prenatal care from providers who are knowledgeable about the impact of substance use during pregnancy
- To find a helpful and supportive provider, ask around in the recovery community — or ask the provider what his or her view of addiction is to see if they're the right fit.
- Provide support by accompanying her to prenatal care appointments, if possible.
- Encourage a healthy lifestyle, good nutrition, relaxation and stress-relief techniques such as meditation and light exercise, if approved by her provider.

Get her to treatment

The mother-to-be will also need treatment to address her physical, psychological, emotional and social issues in addition to her opioid use. Nineteen states have funded treatment programs for pregnant women. The Substance Abuse and Mental Health Services Administration (SAMHSA) maintains a treatment finder, where you can search for pregnancy and post-partum programs across the country.

The mother-to-be may also need mental health treatment. An estimated 50 to 80 percent of pregnant women with an opioid use disorder also have a mental health disorder. In many — if not most — cases, trauma-informed care is needed as well. This is a treatment framework that involves understanding, recognizing and responding to the effects of all types of trauma. Trauma-informed care emphasizes physical, psychological and emotional safety and helps survivors rebuild a sense of control and empowerment.

Keep in mind that pregnant women who misuse opioids are at increased risk for pregnancy-associated complications and death. Untreated substance use disorders have been linked to high-risk behaviors, such as prostitution and crime, which can expose pregnant women to sexually transmitted diseases, violence, legal problems and incarceration. It's essential that the mother-to-be gets proper treatment for her opioid use disorder and gets good medical care for herself and her baby.

What you can do:

- Help her find trauma-informed addiction treatment. Search the SAMHSA treatment finder for pregnancy and post-partum programs across the country.
- Help her find mental health treatment, if needed, which you can also find at the SAMHSA treatment finder. It's important that her substance use and any other mental health problems are addressed simultaneously. ■

Partnership for Drug Free Kids

The Role of Drug Takebacks in Ending the Opioid Crisis

As of right now, drug takeback programs are an underutilized resource in the fight against opioids. There are myriad reasons to change that.

For Americans, opioids are a primary health concern. In fact, more than one in four (27 percent of) Americans are concerned about the government addressing the opioid epidemic — and rightfully so. Drug overdoses killed 63,632 Americans in 2016 alone, according to analysis from the Centers for Disease Control and Prevention. Their findings further showed that nearly two-thirds of these deaths involved a prescription or illicit opioid.

What needs to change

The opioid epidemic is driving the U.S. government to introduce new legislation that would fund education in addiction medicine, require the U.S. Postal Service to monitor for illicit fentanyl trafficking, aid in the research and development of non-opioid pain therapies, and more. All of these initiatives are necessary and positive steps toward the effective treatment and prevention of opioid abuse in this country, but one critical aspect that is notably absent is the accessibility of drug takeback programs.

Drug takeback programs — whether they are in the form of self-service, mail-in envelopes or pharmacy- or health care-hosted collection kiosks — are an underused component of opioid eradication. The fact is, less than 3 percent of pharmacies and other entities authorized by the Drug Enforcement Administration to collect unused prescription drugs for disposal have volunteered to do so. What's more, the vast majority (83 percent) of Americans have never given back unused prescription drugs as part of a drug takeback program. Scarier still, 42 percent of Americans claim to have 1-3 bottles of unused or unneeded prescriptions in their medicine cabinets, which is ultimately opening the potential for opioids to fall into the wrong hands through the illegal diversion, selling and illicit use of prescription medications.

It's up to all of us — government officials, American citizens and health care leaders alike — to break the deadly cycle of drug diversion and, ultimately, end the opioid crisis by emphasizing the unequivocal value of drug takeback programs. As a leader in solutions for the safe and secure disposal of unused pharmaceuticals, Stericycle is committed to protecting people from opioid addiction. ■

Charles Alutto, CEO, Stericycle, Inc.

Tackling the Opioid Epidemic From the Inside Out

Helping those addicted to or impacted by opioids requires respecting and understanding their experiences at a personal level.

The opioid epidemic continues to have a tragic human and financial toll on individuals, families and communities throughout this country. More than 2 million Americans have an opioid use disorder (OUD), and millions more are seeking to help their loved ones get the medical and recovery support they need.

One of the ways the U.S. Food and Drug Administration (FDA) is supporting those with OUD is by using their personal experiences to inform drug development and review considerations. Our goal is to help every American who needs support to get into recovery, and to find new and better ways of treating addiction.

With that in mind, the FDA recently held a meeting to hear directly from those personally impacted by this crisis. We're extremely grateful for the invaluable perspectives shared by the more than 100 individuals with OUD and family members who participated in person, via webcast or by providing written comments. One of the strongest themes in the feedback was the impact of the unwarranted stigma and social discrimination they often experience, and the devastating impacts of OUD on their careers and relationships.

"With the right treatment and support, **recovery is possible, and individuals are able to regain control.**"

From stigma to success

OUD should be viewed similarly to any other chronic condition that is treated with medication, but overcoming the stigma surrounding it will take time and education. One thing is clear and backed by science: Despite what some may think, individuals who successfully transition into medication-assisted treatments (MAT) are not swapping one addiction for another.

With the right treatment and supports, recovery is possible, and individuals are able to regain control of their lives and end the hardships that come with opioid addiction. MAT relies on FDA-approved drugs that stabilize brain chemistry, reduce or block the euphoric effects of opioids, relieve physiological cravings and normalize body functions. Combined with counseling and other recovery supports, MAT is often the most effective therapy.

We've also heard that managing OUD is not "one-size-fits-all," and it's important to find treatment that works best for each individual. Additionally, meeting participants discussed the need for long-term treatment, difficulties adhering to and accessing treatment, as well as struggles with relapse.

We agree that offering more treatment options is critical, and we're taking steps to help facilitate the development of new treatments and new formulations of existing drugs that could have attributes that are better tailored to individuals' needs. We're also facilitating the market entry of generic versions of approved MAT drugs to help improve access. Most of all, we're committed to doing our part to tackle the stigma that can be associated with MAT. We encourage health care professionals to ensure patients are offered an adequate chance to benefit from these therapies. ■

Scott Gottlieb, M.D., Commissioner of Food and Drugs, U.S. Food and Drug Administration, U.S. Department of Health and Human Services

For Chronic Pain Sufferers, a Targeted Solution Offers Hope

PHOTO: ABE DRAPER

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For many struggling with nerve pain or spasticity, intrathecal infusion therapy offers a more effective treatment with fewer downsides.

Stacy Wilson knows something about chronic pain; she's been dealing with it her entire life. "I have cerebral palsy," she says. "When I was in my late teens I had a surgical complication and I started suffering from nerve pain — burning in my legs, spasming. We tried a lot of oral medicine, we tried nerve blocks," she says, but nothing really worked — until she was told about a new option: intrathecal therapy (IT).

IT, sometimes called the "pain pump," involves a pump being surgically implanted into the patient's body which then delivers pain medication directly into the cerebral spinal fluid (CSF). Studies have demonstrated that IT is extremely effective in pain management.

"Chronic pain is one of the most expensive chronic diseases to treat," says Chuck Bell, PharmD, president and founder of AIS Healthcare. "There is an estimated $635 billion annual expenditure treating and managing chronic pain in the United States."

"I've worked with it for over 20 years," says Stacy's doctor, Stuart Rosenblum, M.D., of the Oregon Interventional Pain Clinic. "It's targeted therapy that is at least 100 times more potent than medicine that we give orally or even intravenously with a much smaller dose."

Less pain, fewer downsides

Aside from a lower danger of addiction due to the lower dosage, IT typically offers other advantages. "Many patients have significant side effects from our commonly used medications," says Dr. Rosenblum. "We can use this micro-dosing, very low doses of medication placed directly on target, which can provide excellent pain relief or control of spasticity without serious side effects."

That's been Stacy's experience. "It has made it more manageable, and the thing I really like and I really notice is that everything I've tried in the past has made me very nauseous, so I would get relief but I would be sick to my stomach 90 percent of the time, and I have hardly any side effects from the medicine in my pump."

Sterile and safe

"Because the drug is being infused directly into the patient's cerebral spinal fluid bypassing all of the human body's natural defense mechanisms, sterility is absolutely required," explains Bell.

"I've looked widely at different suppliers in terms of who provides the best product from a safety point of view," says Rosenblum. "I selected AIS Healthcare to be the supplier of our spinal infusion pump service due to their ability to provide aseptic processing (preparing patient-specific medications from non-sterile pharmaceutical ingredients into sterile and preservative-free medications in a controlled and sterile environment) as well as their process of terminal sterilization (an additional step where the material is again sterilized while in its final container to ensure that no contamination is possible)."

"The pharmacists at AIS have over 400 years combined experience," adds Bell, "and participate in continuous training on compounding of sterile products."

The future

For Stacy, the pain pump has improved her quality of life. "I can do more social things," she says. "I can have a daily routine. I like to cook and I like to go out and about, and when I have a lot of pain I just can't do that. The pump has made it a lot easier to do it."

Both Stacy and Dr. Rosenblum view IT as an underutilized therapy. "I very often come across patients who clearly would benefit from this therapy who haven't had this therapy even brought up by their health care providers," Rosenblum says. "It's well established, it's not an investigational therapy. And I think the future possibilities for this therapy are almost boundless. When we think about some of these devastating diseases like Alzheimer's disease, multiple sclerosis or ALS, the potential medications delivered directly into the CSF can have a profound impact on these diseases. I think it's a very ripe area for research." ■

Jeffrey Somers

Access to Technology and Fighting Opioids

Neurostimulation and other innovative therapies are improving opioid addiction treatment, making things easier for patients and providers alike.

People battling chronic pain face disproportionate exposure to today's opioid epidemic partly because, for years, opioids served as the default option for managing chronic pain. While prescription opioid medication can help patients manage acute (short-term) or cancer pain, these drugs were never intended to routinely treat chronic (long-term) pain; there is a lack of evidence for such use even today. The opioid epidemic has forced a reassessment of how chronic pain is managed.

A significant opportunity lies in innovative therapies like neurostimulation — a safe, effective and proven therapy that combats pain. The therapy uses a small device implanted in the lower back to deliver electrical stimulation to the nerves along the spinal column to interrupt pain signals traveling to the brain. As companies like Abbott have pioneered new options to treat different types of chronic pain, the therapy is more effective than ever before.

Take medically-retired U.S. Army paratrooper Doug Rodd, who damaged his knees on duty. After 12 surgeries to correct his condition, Doug developed complex regional pain syndrome, a type of chronic pain.

Neurostimulation's promise

Neurostimulation therapy allowed Rodd to end his reliance on opioids and find a more effective way to manage his chronic pain. After 10 years of daily dependence on morphine, he's now completely off pain medication and back on his motorcycle — using life-changing technology to live an active life once again. While this is just one patient's story, and experiences with the therapy are unique, it speaks to neurostimulation's potential impact.

Mounting evidence corroborates Rodd's experience, demonstrating that neurostimulation can reduce or stabilize opioid use in people battling chronic pain. In one study of more than 5,000 patients, 70 percent using an Abbott neurostimulation system saw their use of opioids decline or stabilize.

Physicians are taking notice of the therapy's momentum. Now it's a matter of improving patient access. Fortunately, we're seeing trends in the right direction.

Primary care physicians are building connections to interventional pain specialists who can deliver on the promise of neurostimulation. Not all pain is equal, and neither is its treatment. Ensuring that patients are seen by interventional pain specialists is critical to improving outcomes.

As access to neurostimulation increases, more patients are being offered these innovative therapies earlier in the care continuum, improving long-term outcomes and helping more people avoid unnecessary exposure to opioids for chronic pain relief.

Through collaborative partnerships and greater awareness, we can treat pain more effectively and use innovation to fight against overuse of opioids.

Keith Boettiger, Vice President, Neuromodulation, Abbott

PHOTO: COURTESY OF NATIONAL INSTITUTES OF HEALTH

A Fresh Approach to the American Opioid Problem

With millions of Americans suffering from opioid addiction, only long-term solutions will make a difference. Using recent government funding, one organization is preparing to implement them.

About 2 million Americans are addicted to opioid drugs, including prescription pain medicines, heroin and fentanyl or one of its analogues. Many millions more misuse opioids, taking opioid medications longer or in higher doses than prescribed. These statistics are staggering. And the tragic effects of the opioid crisis don't stop there, but extend to families, communities and even our entire nation.

Clearly, it takes "all hands on deck" to overcome this public health emergency, declared by the U.S. Department of Health and Human Services at the direction of President Trump last year. Among those actively engaged in this effort are researchers supported by the National Institutes of Health (NIH). To channel these efforts, NIH recently launched the Helping to End Addiction Long-term (HEAL) initiative, an agency-wide effort to speed scientific solutions to stem the opioid crisis. Using $500 million in new funding provided by Congress, HEAL will invest in a wide range of innovative projects that advance national priorities for addiction and pain research.

Access and management

America must address many urgent issues. For example, while multiple, medication-based treatments are available to treat opioid addiction, many Americans do not have access to such treatments. Even when they do, many do not stay in treatment long enough to recover fully. To tackle this problem, HEAL researchers will focus on integrating the most successful, evidence-based strategies in a number of communities hit hard by the opioid crisis. The HEALing Communities Study, a partnership between NIH and the Substance Abuse and Mental Health Services Administration, will test the impact of providing prevention, treatment and recovery support services for opioid addiction in an array of settings. These may include fire and police departments, the criminal justice system, hospital emergency departments and primary and prenatal care clinics. Once we identify what strategies are most successful, then we can deploy them nationwide to turn the tide on this crisis.

Ending addiction over the long-term will also require reducing overreliance on, and misuse of, opioid-based medications to manage pain. To do this, HEAL research will explore new methods of pain management. For example, HEAL and its partners will support efforts to understand the transition from acute to chronic pain, identify new targets for non-addictive pain treatments and speed the movement of such treatments through the development pipeline.

These are just a few of the many ways in which HEAL research will strive to overcome the opioid crisis. It's a formidable challenge, but we are confident that our nation's scientists will rise to meet it and create a future in which far fewer Americans suffer from pain or opioid addiction. ■

Francis S. Collins, M.D., Ph.D., Director, National Institutes of Health, and Nora D. Volkow, M.D., Director, National Institute on Drug Abuse


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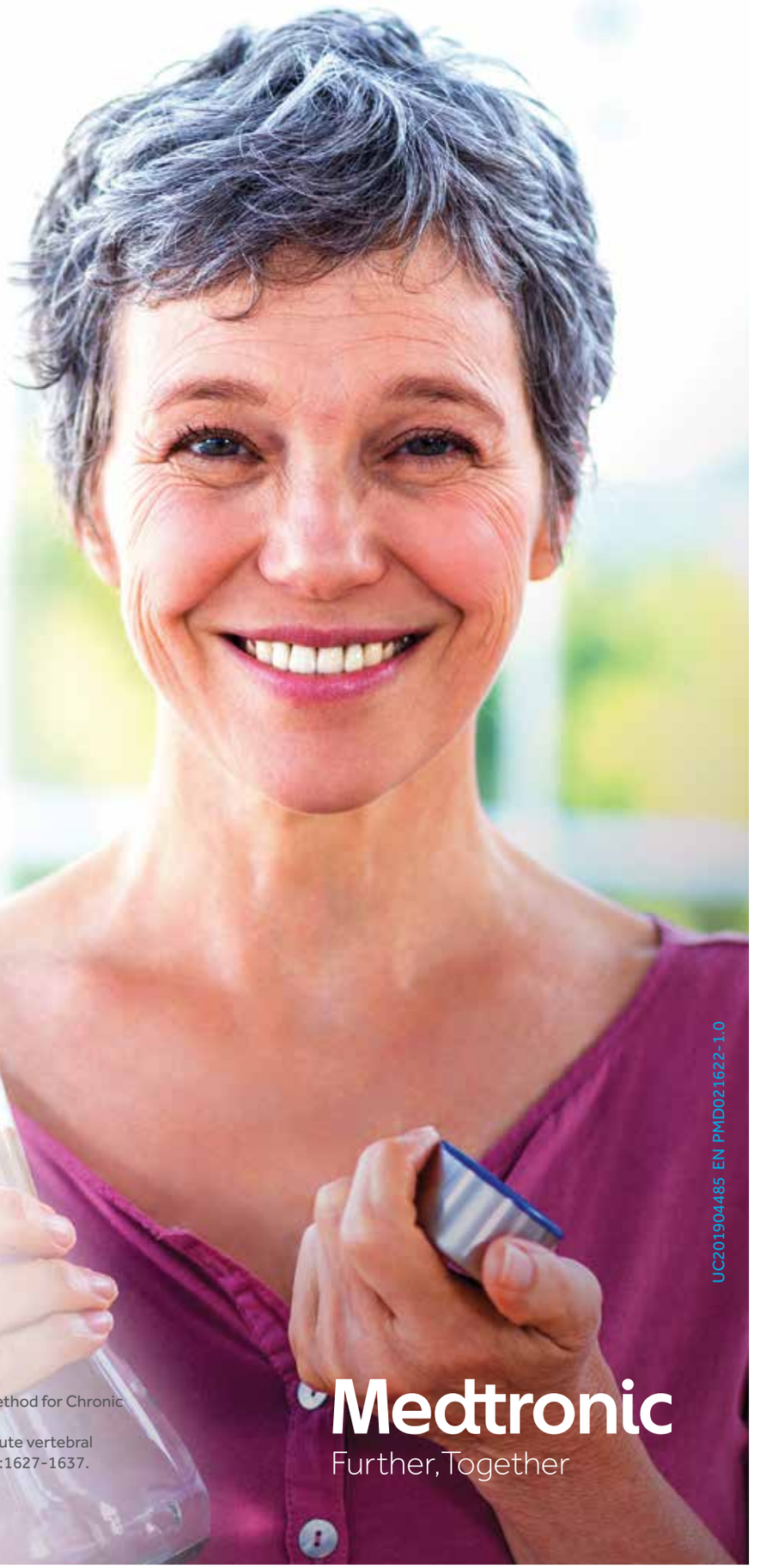
MANAGE YOUR PAIN DIFFERENTLY

Oral opioids are not the only option for treating pain or painful conditions.



We have more than a 40-year history of developing innovative medical devices that have been shown to alleviate pain for different conditions. And we've demonstrated the clinical outcomes of these products — some showing reduction in the use of prescription opioids.[1,2]

Given the current opioid epidemic and pain management crisis, our work to alleviate pain has never been more critical. That's why we leverage our capabilities and product portfolio to address the unmet needs of pain patients.

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1. Grider JS, et al. Trialing and Maintenance Dosing Using a Low-Dose Intrathecal Opioid Method for Chronic Nonmalignant Pain: A Prospective 36-Month Study. *Neuromodulation*. 2016;19(2):206-219.
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