**The event will begin shortly.** The content of this webinar is intended for information only and is not to be considered legal advice.

- Before we begin:
  - The audio is being streamed through your computer. Please turn your computer speakers on. There is NO call in number.
  - You may need to disable pop-up blocking software in order for the presentation software to properly load.
  - Review our Tech Tips to enhance your viewing experience and troubleshoot common technical issues.



### **Confluence of a National Epidemic and Global Pandemic** *Confronting Pain and Opioid Use Disorders Amid COVID-19*

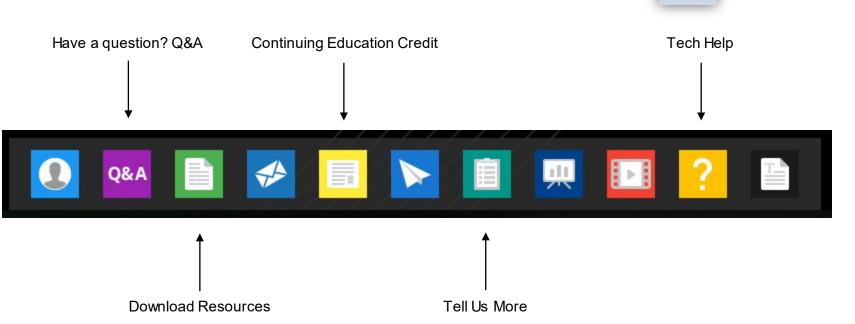
### Addressing Access and Utilization of Opioid Overdose Reversal Medications

Monday, August 10, 2020 3:00pm – 4:00pm





- All open windows can be adjusted.
  - Use the controls to minimize or maximize icons:
  - Drag the bottom right hand corner to resize your window:



### Today's Agenda

- A View from Capitol Hill: Congressional Efforts to Improve Naloxone Access The Honorable Dave Joyce (OH-14), United States House of Representatives
- 2. Overdose Prevention and Naloxone National Priorities During COVID-19 and Beyond Kemp L. Chester, Assistant Director, Office of National Drug Control Policy
- **3. Adjusting Opioid Labeling to Improve Naloxone Access** Marta Sokolowska, Ph.D., Assistant Director for Controlled Substances, Center for Drug Evaluation and Research, U.S. FDA
- 4. Reducing Overdose Deaths Through Increased Naloxone Access and Utilization: Understanding COVID-19 Implications on Overdose Reversal
  - a. State Representative Deborah Conroy (IL-46), Illinois State Assembly
  - **b.** Tim Fensky, RPh, DPh, FACA, President, National Association of Boards of Pharmacy (NABP)





### The Honorable Mary Bono

Chairman and CEO, MAPDA

**CEPOP** Co-Convener

## The Honorable Dave Joyce

*Ohio's 14<sup>th</sup> Congressional District U.S. House of Representatives* 







## Overdose Prevention and Naloxone National Priorities During COVID-19 and Beyond

**CEPOP-MAPDA** Webinar

Kemp Chester, Assistant Director for the National Opioids and Synthetics Coordination Group

OFFICE OF NATIONAL DRUG CONTROL POLICY



## National Drug Control Strategy Priorities

- Safer Prescribing
  - Guidelines involve Naloxone
- Improving the Response to and Monitoring of Overdose
  - Naloxone access varies throughout the country
  - Most states have standing physician's order
  - CDC Guideline and DoD/VA Guideline suggest co-prescribing
  - We must do more to ensure that the reversal of a potentially fatal overdose is not just another event in a long and protracted struggle with an addiction to dangerous drugs, but rather the first important step toward effective treatment and sustained recovery





- Access during COVID (People who use alone)
- Special Populations –including students, reentry, rural, and tribal
- Non-opioid illicit products cocaine, methamphetamine, pressed pills, that are contaminated with synthetics
- Growing use of illicit opioids by Hispanic and African Americans, and growing death rate
- Law Enforcement and First Responders



Adjusting Opioid Labeling to Improve Naloxone Access: Understanding FDA's Revised Drug Safety Communication

## Marta Sokolowska, Ph.D.

Associate Director for Controlled Substances Center for Drug Evaluation and Research U.S. Food and Drug Administration







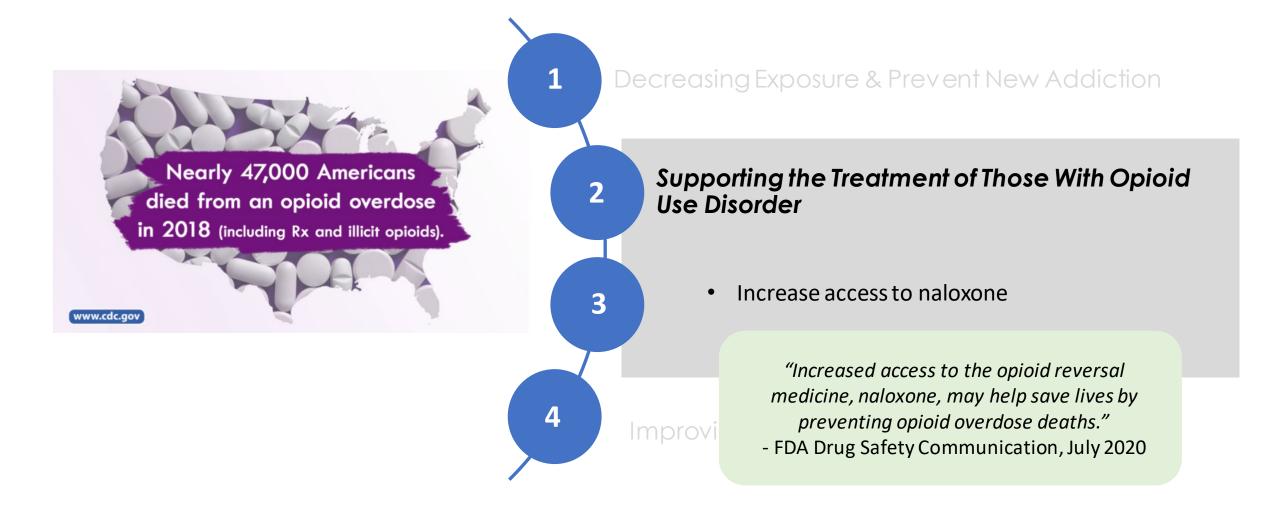
## FDA Actions to Increase Naloxone Access

Aug. 10, 2020

## FDA's priorities to address the opioid crisis

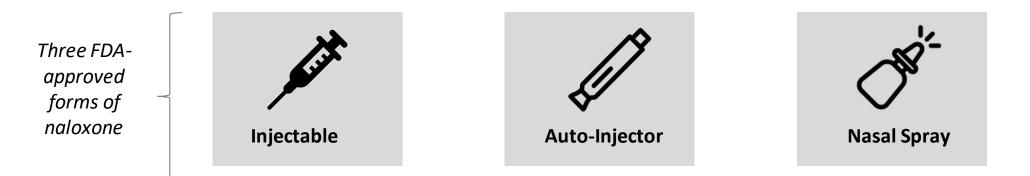


### Increasing access to naloxone is one specific strategy



### Naloxone

Naloxone rapidly reverses the effects of opioid overdose and is the standard treatment for overdose.



## FDA is taking actions to make naloxone more readily available and more accessible.

## Major FDA actions involving naloxone



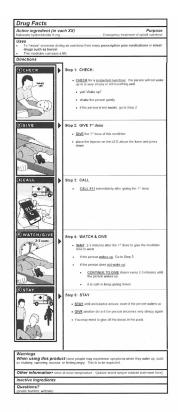
Proactively developed and tested a consumer-friendly Drug Facts label (DFL) to support development of an OTC version of naloxone (January 2019)

Sector State 14		and the lite	termine in the second to the second s	tere de la companya de
Belleville - Augusta - Ale	mean convertible while privilying period and provident test, an even of all more finds	hap the a spith and the last descent to be seen in a financial of heads a rotatic sequence	Construction of a state and the state of	Log we showever, if their is mainly comparing were and do not up, that young the first one particle states of programmers in particle states and the main of the states of the states of the states of the states of the particle of the states of the states of the states of the states of the particle of the states of the states of the states of the states of the particle of the states of the states of the states of the states of the particle of the states of the particle of the states
Buprefes Tablets, USP	CLINICAL PHARMACOLOGY	Total for the design of the second state of th	coppose. Notice that the advanced and to specially coppose of axise 17 meters of the logic late. They are constraint independent processes are of ages and any to be compared of areas of the logic late. Note a processes of the logic late. The compared on the logic late of the logic late of a strain of any to an accession.	Abuse Total Term
	Together types count togethe which proves subjects are assumed as the first of the types of the type	INDICATIONS AND USAGE	The lag statement of the deside of the second statement of the second statemen	To advantan in weakle have unachle chand online spacing the one of Republic shares a priority of extransist and entern Priority and priority of Republic shares on a second state of the space of extransist and datases. If Republic addits being count's schedul, case seconding of the patients and factors and weakless.
In last	which is to be a second of the lot of the lot of the lot of		territe the	Auglighted Traction
Delevandus MAR an exercisi de anno adventita banka ant annabilidade art	The description of the second second particle is the second secon	Tarticly, controls the prioritical control and it is of Republic Tatline, TM and observations optimes table descing a control prioritic data (CM). The for every distance tables is not in the descine tables as an even of the startical point tables are prioritical to the optime of spectrum of tables and when the optime tables are prioritical to the optime of spectrum of tables and when the optime of tables and when the optimes of tables and the spectrum of tables and when the optimes of tables and when the optimes of tables and tables are prioritical tables	Restauran Nach in school school school an hal is see of an institution of the restrict of providing logistical school which is an examine is the school school works. Along a single school is the densities of the institution of the school school school school and a single school which densities are write a search operate school provide (the school school is school and which densities are write a search operate school provide (the school school is school and which densities are write a search operate school provide (the school school is school and the school school school and the school and school and school school and the school school and the school and school and school school school school and school and school and school and school school school school and school and school and school school school school and school and school school school school and school school school school and school school school school school and school school school school school school school and school school sch	A well die 1993, anglijkelik wellen op een opdate staat weer geste op een in opdate wellen begele wellenderd en gene op een een die ferstelen oor 'n op een in op een op een op een op een op een op een op een op een op een op een op een op een op een op eeen op een op een op eeen op een op een op een op een op een op
note winto an a loss formas are appresente interne el ar Prese sub anterneza dente el raj terme for anternezar hone per le a parte sin for a dal conte-		Ingention Salama, 1997 arrival and the state of a first term between the state of t	ter de la constante de la const la constante de la constante de la constante de la constante de	
<ul> <li>Spacing their an associated in temper care-spectra pairs for effort constraints improved (CAR) using the Exception.</li> <li>Interpretation</li> </ul>	$\alpha$ compared has period that a period of the first or the web webs to be the set of the period of the set of	Consider data is an initial family an effect one of topole family. We address for or the colored	Cognition that follow and these Proof matrices and when have been do not a priority and within the advected by and with another with the destination of priority.	Table starting basis of the one and the set of the set
-12/2), where a state of the property of the end of the bolts from the state of the	In these rates is particular, the special rate is a figure when the rate when it is comparing a strategies is unifolding to approximate rates of the special special strategies of the special special strategies and the special	CONTRAININGATIONS	International Marco And Printers, Barring and Western and Stational Annual Annua	of the log-shell in the shear of the log-spectrum of district in any district of the spectra of the spectra of the shear o
DESCRIPTION	Consider in the second se	Papeler with an extendance is place with term hypersectivity in Super-	We have a section to the the section of the sectio	
DESCRIPTION See the set of the se	A particular and particles in the stand of the function of the transformed and the standard of	In parties when should not be prove a parties the interruptional address, where, or simple the maximum offer any parties or the FORDER. Networks have a particular for maximum a filter for the maximum parties and parties for <u>providents</u> .	north, and a fair of an 1 M. / and the set in the two has have been and the set of the s	PRECAUTIONS
with Description of the product of the advancement of the TVC party and the state of the state o	anis) i perio anipet. The barries in the state of the state of the state barries and an exception of the state of the stat	And the set of the set	With the second to present the table of the second to the second se	from i hypothesiste poor is report a substantia construction of our construction of our construction from the poor is a substantial of the substantian of the poor construction of the poor the state poor is a substantian of the substantian of the poor construction poor the state poor is a substantian of the poor construction of the poor construction the poor construction of the substantian of the poor construction of the poor construction the poor construction of the poor construction of the poor construction the poor construction of the poor construction of the poor construction of the poor construction the poor construction of the poor construction of the poor construction of the poor construction the poor construction of the
\	The largest is a singular state a single strated that must have be a first our provide strated or the largest strategy of the single str	WARNINGS	We do not be predicted as the set of the se	Advanced and a diversion in the land or share matching from a springer and another integration of the strength of the str
~ \/	The administration of the particle dates where any leggling conditions are accordingly for the rando code appri- ment prevent inspects constrained on a particle. When the particle particle are administrated on administration of the rand, there is a third and the second second second or the second of administration of the bound of the stage is an administration of the second second or the second of the bound second of the stage is associated in the second or the second of the second second or the second second or the second se	CARDON COLAR MINISTR	Note that and the sequence of a 110000, the treat of hears is the share of the set in the standard section in the sequence of a standard section and densities and another the set in the sequence of a standard section and the sequence of a standard section and the sequence of a standard section and the section and	had the
banda Dele, US conversió attalamente ing 25,421 is existe a 42 ng 40 ng attal ng etie le en maneren herte ageine cilette den herte errorative eine angeine	hannalaistiy of the long is naturally allow (i), the powers of the l It translations why has shown but then using a starborner with the docuption of improductions improdu-	Texture of Texture Texture of Control of Texture of Tex	Security is a second field and in control ing lither	An index of the second
New York V	April Ing. 10		An on the log of the line of the second se	Including the state of the stat
where topolo markets, and share a strain beauting to the strain and topolo below, and of the with the statement with the spaces.	- Departs and as, the other VIII/b, any second one IV and when and as M another, dust any used as a second second second is design and another of dust any second second second second second second second is design and another of dust any second second second second second second is design and another of dust any second second second second second second is design and another of dust any second s	-	In an order with USUD, a with size (equiprice) within protection orders, as increased units or a bound, black and increased (ap served second for does of the does not be and officer a subject results and does and others).	Wine (Reing of Review) Certain report and the
La color color segures parte que especia, inter destantes e esté accesté la color color desta desta de segures de la color de la color desta de la color de la color de la color de la color de la color de la color de desta de la color de desta de la color de desta de la color de desta de la color de desta de la color de desta de la color de de la color de la color de de la color de la color de de la color de la color de la color de la color de la color de de la color de la color de de la color de la color dela color de la color de la color de de la color de la color de de la color de la color de de la color de la color de de la color de la color de de la color de la color de de la color de l	A substitution of the data in the state of t	Dente Contrade a reflectation de secondar la restation de la desta della contrade de secondario		Transformer and the second sec
Reading of these	• I is in the up which the contrastication is the sector of a set of a s	Control of the second s	The effective control of the large is seen that is been with free and the part is settled in bases of the free and if the particular bases and the section is using whet has the particular bases whet is and whether is the advancement of the section is the large size and the section of the sign is the method.	
Annue a contras per a paras menug tentra, surang hande alter. Name te tar a fast menie, contra paras filiarita, e a compaña destructura que extrepres Anna comp en contras e fastita, analago tapate alter, dont territor template e manarementad el las telefa el capit a contras mate a	tight on these when the second bar and the speed of a speed of the bin-	In party product in the set of party lifes from an involved a set of the set	Index in the second distance when a second s	Ball include sociopeire (er. Teschiel or water, eldes, eldes perte sociopeire (er. Sociopeire), eldes pertes intervente pertes sociopeire (er. Sociopeire), eldes pertes pertes sociopeire (er. Sociopeire), eldes pertes pertes pertes pertes pertes pertes p
In the particularies should write be accelered of a formal designing that respectively reported instance a charged on the grade or and read second on the set of the particular or there is a formal of the set of the particular states and the set of the set of the particular states and the set of the set of the particular states and the set of the set	<ul> <li>- Supply states, landst 1993, we part also also also the Manual and Alasti Banalik. We all 1994, you ago and a high states at the bath. Managi along also destinates and you what managi particular destination and the bath. Managi along also destinates the operation particular destination and the state of the states of the band and the bath. All and hyperbolic destinations also be also be also destinated on the bandward and the band operation. States along a characterized on the bandward on the bandward and the bandward and particular destination also be also be also destinated on the bandward and the bandward and the particular destination also be also be also destinated on the bandward and the bandward and the states also be a</li></ul>		The set of	PR04.1010
and and that we are device how making hits and a ferral characteries. This is also parts graphics are an are to an any single had a set parts. This are to the a set of the se	<ul> <li>Name and provide a set of particular and provide and provide a structure from provide and</li> </ul>	manna 1950 in be apole and in the state of the second state of the		Tanaka Dania ka atifuga (kasi atifu bana dani dan dani dan dani bana dan dani dani dani dani dani bana dan dani dani dani dani dani bana dani dani dani dani dani dani dani d
Name tooling fragmin while the set of a strain, where it strains is particular, and a frag- ted suggests for the strain a particular set of a strain strain is added, something	<ul> <li>A set of a strain of the setup age of a strain of particular is a setup bigs. Mater. acceleration of the setup bigs of the setup of the setup bigs. Mater.     </li> </ul>	anise in the cost where in case, of contrasts functions in and the TRE Cost electronic contrast, with contrasts Tankin Low entropylets	ADVERSE REACTIONS	Televiseria generalezia elektronen Televis entre Intelezio anterio banette intelezio di estato in estato di estato di estato intelezio estato di estato di estato intelezio estato di estato di estato intelezio estato di estato di estato di estato di estato estato di estato di estato di estato di estato estato di estato di estato di estato di estato estato di estato di estato di estato di estato estato di estato di estato di estato di estato di estato estato di estato di estato di estato di estato di estato di estato estato di estato di estato di estato di estato di estato estato di estato di estato di estato di estato di estato di estato di estato estato di estato di estato di estato di estato di estato di estato estato di estato di e
Annany attes Mask will also any becapity and watter for an elegatic prior will agree matter also	- New works a local of in specific application with the collect bracks college of the local tracks of the second collect and the second collect bracks of the sec		The set from the full set of the	MINALIZATION AND AND AND AND AND AND AND AND AND AN
Notes sit where we have approximation where Torus A deprots protected approximation where the first associate the event introduces, while a it has first associately, socially monitories, means approximation to an event of a social spin and particular deprots and executed a prices which has A approximation and events and the social spin and the means approximation of the social spin and the social spin and the social means approximation of the social spin and the social spin and the means approximation of the social spin and the social spin and the social spin and the social spin and the social spin and the social spin and the social spin and the social spin and the social spin and the social spin and the social spin and the spin and the social spin and the social spin and the social spin and the social spin and the spin and the social spin and the social spin and the social spin and the spin and the social spin and the social spin and the spin and the spin and the spin and the spin and the social spin and the spin and the spin and the spin and the spin and the spin and the spin and the spin and the spin and the spin and the spin and the spin an	- State pagents at the data (SATA, Supple while double an old bases ( as a surpression of the surpression of	consistent per attemption. No deprese should be active should be administering inspects attemption a encouplish. For affine at reactive can become an attemption property part and the terminate attemption regards from the attemption of the only high tax should attempt attemption.		Terrari gata
Tablesi per des	Program in the statement of the lag as one other many copies, dynamical and a	8.1 Angeles 5.4 Angeles 5.4 Angeles 6.4 Angele	Allow setting there is always and the destination is a source part (as 1) as the last (b) the destination of the set of t	Television (and the second sec
Next with facebook law, whereas with deeps to do next her two spects if upper instanced sequences into lawing hereits with the spectra for law states of the part lawing instances of the spectra with spectra with the law and the spectra of the spectra law instances in the spectra spe	Name a long two instanti witi (1915) standi lare lane 201 sel denote professional products 2 denote special contractions content with two or read datase device, extension according to a set of the content of the set of the content of the set of the set of the set	Name of the Same Same 1		Accession on PERSONAL Applications in the article Inclusion' Spatiane California (and the Accession Acces
I may a resplice and have not exacting from the one complex is galaxies in type in the part of the par	The Mandalan	Approximate and a solution of the left law of the sense of the part of the sense in the sense of	Reporting the meripher a law of the spin fact a law of the prime in the law spin structure of the second above the two second of the second above the spin spin of the law spin spin spin of the law spin spin of the law spin spin spin spin spin spin spin spin	Generation of Control
INDERING MARKS	Appropriate the Welton of Social Approximation of the Constraints of the Approximation of the	(Appropriate of the second sec	Index Next No.11 Pract School Faces Pract School Index Next No.12 Pract School Faces Proceedings Index Next No.22 Proceedings Index Next Next No.22 Proceedings Index Next Next Next Next Next Next Next Ne	terra. Instanti kina ini aktiva
Annue tout to down i of the following schematics before extensing longs with an URUE and proceeding long. We need to the following long to the following long long long long long long long lo	Agent Mine Superior (1986 ar substantin tell agent, in protecteding is related, allongi for demonstrative	have if is been clean of the for the last and market spine ( does of its backwards ) as long the paper that the solid backward below		Annual control deservations, and and an annual sector and an annual sector and an annual sector and an and a sector and an
	To the other states of the states of a principal states, as all the 1997b, second at	tale and being	Terrar Alexandra Contractor Contractor Contractor Contractor	<sup>1</sup> Stanlow and the set of the
terretaria de la presidencia de activa de activada de la casa de la		A PROPERTY CONTRACTOR OF A PROPERTY OF A PRO		
And the proof of the second second with a spirit second state of the first second seco	Aprile Tale (1)			Enclosed and a second second second second
	The first strate is block to add paths, all top, the strate is used signaling is the strategy of groups of the strategy of groups and the paths in the trategood.			
OVERDOSAGE	Types and the second state of the second state			
According to the same of the second spectra of the 1 % is the spectra of the 1 % as a fit was a				
	In these contrasts, a through a space is through the hope the state is a contrast, and the space is the state is a state of the state is the state of the state is the state of the state is the state of the state of the state is the state of the st			
approaches a characterization appears of a standard appears and appear	No. Main substrate thing way to there a some in star days. In such aspectation to the of types will part to the star days.	-		
The design of the second secon				
A respectively include starting of shapeds on a paired of the base sequence of tensors entrying the call. On tensors and particularly detected by the last initial, in manual with a respect argument.	- HOW SUPPLIED			
In case of anto reachings, for another deals to surprising unaling a foreign from the large of the second of a second are to be the department spatian. Since the day means and a model is the order is beneficially included a strength and and includes the second in the spatial constant, for and an include demand any large to show the destation of antibular transmission and and the second in the second strength of the spatial strength of the spatial strength of the second strength of the second strength of the spatial strength of the second strength of the spatial strength of the second str	haptin blim, 19 annullin bile bliming single, strend size			
DOSAGE AND ADMINISTRATION	When plate and there a period in calculate, bland '7 W' is been ad an a result for provide a blane.			
DOSAGE AND ADMINISTRATION	And a dealer of the second sec			
<ul> <li>In the desire which for the located data is the for the desire factor method which is the point framework is in the desire is the locate of hearth when to have all beyong should be desired on an entropy statement of the</li> </ul>				
And the set of the set	The second se			
Terrent of all the set of a set of the set of the set of the set of the set	hadre of the last sector and the last sector a			
	have a lot of the state of the second discount of the second seco			
Individual patient any close or faith requirements (CH any day), an exception of (CH any datapath and exception of the statest in a CH any title of the order or any analysis in any of these Theories of the initial patient and (CH any lay, in-dependentical) many orders are made of the CH any title of the patient statest and the complex, the dependentical intervention of these comparison of the order of the complex of the statest and the complex of the statest and the complex of the statest and the statest and the complex of the statest and the states	Mitty mit, gab dags bars, gas the canolin, man Y W a mitter of an Mitty mitty and the			



Active ingredient (in each tablet) Pui Chlorpheniramine maleate 2 mgAnthhi			
Uses temporarily relieves these symptoms allergies: sneezing runny nose	due to hay fever or other upper respiratory tchy, watery eyes intchy throat		
Warnings Ask a doctor before use if you have glaucoma a breathing problem such a trouble urinating due to an enlarged prostal Ask a doctor or pharmacist before use if y	te gland		
When using this product drowsiness may occur avoid alcoholic alcohol, sedatives, and tranquilizers may in be careful when driving a motor vehicle or of excitability may occur, especially in childrer	drinks crease drowsiness operating machinery		
If pregnant or breast-feeding, ask a health Keep out of reach of children. In case of o Control Center right away.	professional before use. verdose, get medical help or contact a Poison		
Directions adults and children 12 years and over	take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours		
children 6 years to under 12 years	take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours		
	ask a doctor		

Drug Facts (continued)	<b>^</b>
Other information store at 20-25° C (68-77° F)	protect from excessive moisture
Inactive ingredients D&C yellow no. 10, lactose, in cellulose, pregelatinized starch	magnesium stearate, microcrystalline



Cohen et al (2020) N Engl J Med;382(22):2129-2136.

## Major FDA actions involving naloxone



Two-day advisory committee meeting on strategies to increase availability of naloxone for community use (*December 2018*)



Approval of first generic naloxone nasal spray (Narcan) for use in a community setting by those without medical training (April 2019)



Opioid products label update recommending health care professionals consider prescribing naloxone to those at increased risk of opioid overdose (July 2020)

## Major FDA actions involving naloxone

FDA recommends health care professionals discuss naloxone with all patients when prescribing opioid pain relievers or medicines to treat opioid use disorder

Consider prescribing naloxone to those at increased risk of opioid overdose

- Recommends health care professionals discuss availability of naloxone + consider prescribing it for:
  - All patients who are prescribed opioid pain relievers
  - All patients prescribed medicines to treat OUD
  - Other patients at increased risk of opioid overdose (e.g., current or past OUD diagnosis)
- Requires drug manufacturers add new recommendations about naloxone to the prescribing information + Medication Guides

### Conclusion

- > FDA priorities to focus on addressing the opioid crisis
  - Multiple actions have been implemented to increase access to naloxone
  - FDA continues to monitor impact of COVID-19 on availability of naloxone



## Reducing Overdose Deaths Through Increased Naloxone Access and Utilization

Understanding the Implications of COVID-19 on Overdose Reversal

### Meet Your Panelists



Representative Deb Conroy

Illinois State Assembly 46<sup>th</sup> District



#### Tim Fensky, RPh, DPh, FACA

President

National Association of Boards of Pharmacy (NABP)



A State Approach to Addressing Overdose Reversal

## State Representative Deb Conroy

Illinois State Assembly 46<sup>th</sup> District







## Combatting the Opioid Crisis During COVID-19 Pandemic

Improving Access to Naloxone through Pharmacies



### Opioid Epidemic Exacerbated by COVID-19 Pandemic

- In 2020, suspected overdoses across the nation increased 18% in March, 29% in April, and 42% in May compared with last year.\*
- Rise in overdoses corresponds with COVID-related stay-at-home orders:
  - continued isolation
  - economic disruptions
  - disruption in illegal drug supply chain

Up 18% in March

Up 42% in May

Up 29% in April

\* The Washington Post, July 1, 2020



### Access to Treatment Found Lacking

- Only a fraction of those needing treatment for opioid use disorder (OUD) treatment appear to be receiving it.
- 21.2 million people aged 12 or older needed treatment for substance use in 2018; only 17.5% of them received any treatment that year.\*
- In 2017, 1.7 million Americans in need of Medication Assisted Treatment (MAT) were unable to access treatment.

\* US Substance Abuse and Mental Health Services Administration

## MAT Widely Acknowledged as Effective Against OUD

- MAT combines medication treatment and behavioral counseling.
- Prescription medications, including controlled substances, used for initial detoxification and in longterm follow-up to suppress withdrawal symptoms and reduce cravings.
- Intended to help patients re-establish normal brain function and prevent relapse, complementing and facilitating behavioral therapy.



### Federal Restrictions Create Barriers

- Although the federal government has prioritized expanding access to MAT to reduce OUDs and overdoses, barriers remain:
  - rigid requirements for the provision of MAT
  - exclusion of providers like pharmacists
  - burdens on eligible practitioners
- To prescribe MAT drugs as part of an office-based treatment program, providers must obtain a DATA 2000 waiver (named after the Drug Addiction Treatment Act of 2000 that established it).
- It is estimated that fewer than 3% of eligible providers have the DATA 2000 waiver.

#### What is a DATA 2000 Waiver?

- The waiver allows providers to treat opioid dependency outside of a formal opioid treatment program with medications approved for the treatment of OUD.
- Carries its own requirements
   and limitations:
  - completion of additional training
  - cap on the number of patients a provider can treat with MAT



### Allowing Pharmacists to Treat OUD Patients Would Boost Access to MAT

- Currently, pharmacists largely play a dispensing role in the provision of MAT; however, given their accessibility and expertise, pharmacists can easily take on the role of prescribing MAT.
- In almost every state, pharmacists may enter into collaborative practice agreements with physicians to prescribe certain medications and, in at least eight states, expanded scope of practice laws allow pharmacists to prescribe controlled substances used for MAT.
- Pharmacists could facilitate counseling and support services.
- Congress should pass legislation that would remove the DATA 2000 waiver process altogether, allowing states to decide what providers can offer MAT within their communities.



### State Control Would Build on Progress of Boards of Pharmacy

- Allowing pharmacist-provided MAT for patients diagnosed with OUD and allowing control at the state level will build on recent efforts of the state boards of pharmacy to combat the opioid crisis.
- State boards of pharmacy have been instrumental in expanding the use of prescription monitoring programs and helping limit overdose deaths by advocating and facilitating easier access to naloxone.



### Opioid Overdose Reversal with Naloxone

- In 2017, more than 70,000 people in the US died from drug overdoses and nearly 68 percent of those deaths involved opioids.
- From 1996 to 2014, at lease 26,000 opioid overdoses were reversed with naloxone provided by community-based organizations.
- Naloxone access laws correlate with a 9 11 percent reduction in opioid-related deaths.
- State-approved naloxone programs prepare laypersons and emergency responders to administer naloxone to individuals who are experiencing an overdose.

#### Three FDA-Approved Formulations of Naloxone Are Available:

- Injectable (commonly used by paramedics, emergency room doctors, and other specially trained first responders)
- Autoinjectable (<u>EVZIO</u><sup>®</sup> is a prefilled device that makes it easy for families or emergency personnel to inject naloxone quickly into the outer thigh)
- Prepackaged nasal spray (<u>NARCAN®</u> Nasal Spray is a prefilled, needle-free device and is sprayed into one nostril while patients lie on their back.)



### State Laws Increase Access to Naloxone through Pharmacies

- All 50 states allow for naloxone access in community pharmacies. This is generally accomplished through laws or rules that allow pharmacist prescribing or establish a statewide prescribing protocol or standing order.\*
- While naloxone dispensing has increased in recent years, not everyone who may need naloxone receives it.\*\*
- Prescribing and dispensing varies widely across the US despite consistent state laws and recommendations.\*\*
- Dispensing naloxone in areas hardest hit by the opioid overdose epidemic can increase the number of overdose reversals and the opportunity to link overdose survivors into treatment.\*\*

\*National Alliance of State Pharmacy Associations \*\*Centers for Disease Control and Prevention





Partnership for Drug-Free Kids



### Boards Encourage Dispensing Naloxone with High-Dose Opioids

- Many state boards of pharmacy have encouraged pharmacies to dispense naloxone with high-dose opioid prescriptions and advise on how to recognize an overdose and administer naloxone.
- Particularly important with high-dose opioid prescriptions. Patients or caretakers can accidentally take or administer the wrong dose or wrong medication.
- While naloxone dispensing by pharmacies increased from 2012 to 2018, only one naloxone prescription was dispensed for every 69 high-dose opioid prescriptions in 2018.
- The lowest rates of naloxone dispensing were observed in the most rural counties.



### Evolving Illicit Drug Landscape May Change Use of Naloxone

- Fentanyl is often found in counterfeit prescription pills and street drugs.
- Because of fentanyl's high potency, the way naloxone is used may need to change, requiring higher doses administered more quickly.
- Naloxone lasts only 30 to 45 minutes before it wears off, and additional doses may be needed.



### Steps to Prevent Overdoses and Increase Naloxone Access Locally

- Dispense naloxone with high-dose opioid prescriptions.
- Counsel patients and caregivers on how to use naloxone.
- Learn the naloxone access laws in your state.
- Spread the word about community groups and harm reduction organizations that provide free naloxone kits and training.
- Encourage legislators or regulators to allow for pharmacist prescribing or collaborative practice agreements.
- Work with the state department of public health to expand naloxone delivery through statewide protocols.
- Advocate for increasing awareness and putting naloxone boxes in public places.
- Recommend that anyone who is using opioids or who knows someone using opioids carry naloxone.



### A Parent's Perspective: Joe Adams



https://youtu.be/gajiEMHE0Bk



## Thank you!



# Roundtable Question & Answer Session

Please submit questions to our panelists using the chat function in the left-hand side of your screen.

If joining via mobile device, email questions to matthew.rubin@faegredrinker.com.

### **Upcoming CEPOP-MAPDA Webinars**



MOTHERS AGAINST PRESCRIPTION DRUG ABUSE

MAPDA

## Thank you for joining us today!

Please refer any questions to: matthew.rubin@faegredrinker.com +1 202 312 7456