



# Advancing Treatments for Post-Traumatic Stress Disorder

**The public meeting will begin shortly**

Friday, September 6, 2024

1 – 3:30 pm Eastern Time

Funding Disclosure: This activity is one part of a multi-part Foundation project related to substance use disorder. The multi-part project is supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of an overall award of \$1,720,109 of federal funds (100% of the project). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by FDA, HHS, or the U.S. Government. For more information, please visit [FDA.gov](https://www.fda.gov).







# Welcome

**Susan C. Winckler, RPh, Esq.**

Chief Executive Officer

Reagan-Udall Foundation for the FDA

# Hybrid Meeting



## Joining online:

Microphone and video will remain off during the meeting  
Share your questions using the Zoom Q&A function



## Joining in-person:

Please write your questions on the index cards provided



This public meeting is being recorded

The slides, transcript, and video will be available at [www.ReaganUdall.org](http://www.ReaganUdall.org)

# Today's Agenda (Eastern Time)



- 1 pm** Welcome & Opening Remarks
- 1:15 pm** Federal Partner Discussion
- 1:55 pm** Stakeholder Comment\*
- 3:30 pm** Adjourn

\*For those not confirmed to issue comment today, you may submit written comment to [PTSD@reaganudall.org](mailto:PTSD@reaganudall.org) by September 21, 2024.



# Opening Remarks

## **Bernard Fischer, MD**

Deputy Director, Division of Psychiatry  
Office of New Drugs  
Center for Drug Evaluation and Research  
U.S. Food and Drug Administration

# Post-traumatic Stress Disorder (PTSD)

## The Past and Moving Forward

**Bernard A. Fischer, MD**

*Deputy Director, Division of Psychiatry*

**Office of New Drugs**

**Center for Drug Evaluation and Research**

**U.S. Food and Drug Administration**

[Bernard.Fischer@fda.hhs.gov](mailto:Bernard.Fischer@fda.hhs.gov)

# The Past

- Formally recognized by mental health in DSM-III (1980)
  - Response to Vietnam Veterans seeking care
- Known by other names:
  - Nostalgia (1700s)
  - Soldier's Heart (Civil War)
  - Shell-shock (World War I)
  - Battle Fatigue (World War II)
- Descriptions in Homer's *Iliad*, Sophocles' *Ajax*, Shakespeare's *Henry IV*



O, my good lord, why are you thus alone?

**Isolation**

For what offence have I this fortnight been

**Decreased Libido**

A banish'd woman from my Harry's bed?

Tell me, sweet lord, what is't that takes from thee

**Physical symptoms**

Thy stomach, pleasure and thy golden sleep?

Why dost thou bend thine eyes upon the earth,

**Insomnia**

And start so often when thou sit'st alone?

Why hast thou lost the fresh blood in thy cheeks;

And given my treasures and my rights of thee

To think-eyed musing and curst melancholy?

**Increased startle response**

**Depressed mood**

In thy faint slumbers I by thee have watch'd,

And heard thee murmur tales of iron wars...

And all the currents of a heady fight.

Thy spirit within thee hath been so at war,

And thus hath so bestirr'd thee in thy sleep,

**Nightmares**

That beads of sweat have stood upon thy brow

Like bubbles in a late-disturbed stream;

**Autonomic arousal**

And in thy face strange motions have appear'd,

Such as we see when men restrain their breath

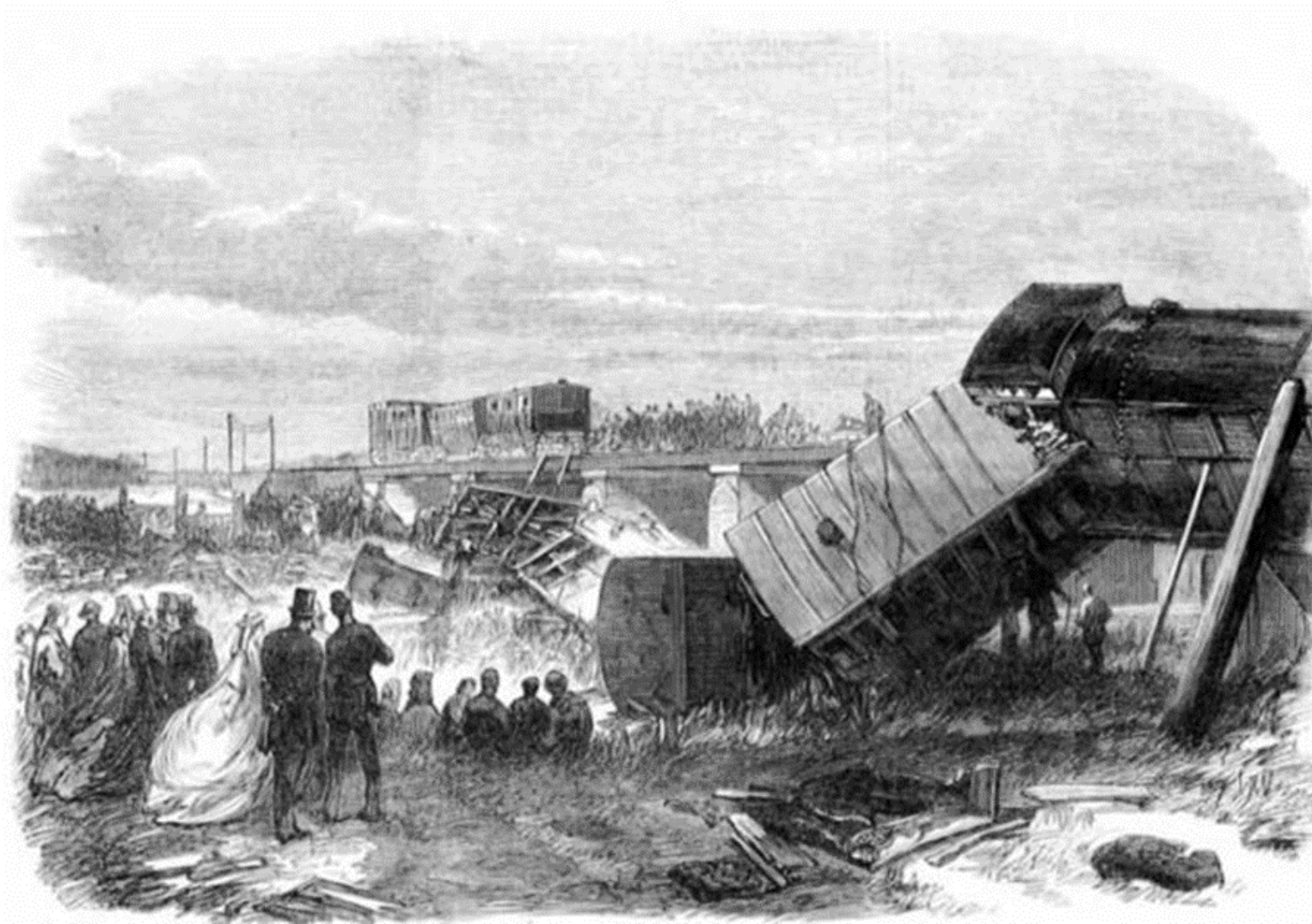
On some great sudden hest. O, what portents are these?

Some heavy business hath my lord in hand,

And I must know it, else he loves me not.

-Lady Percy

*Henry IV, Part I, Act II, Scene 3*



- Not all historical references are military
  - “Railway Spine” (Early 19<sup>th</sup> Century)

# Now

- About 4% of U.S. men and 10% of U.S. women will have PTSD in their lifetimes
- In any given year:
  - 15% Vietnam Veterans have PTSD
  - 12% Gulf War Veterans
  - 10-20% Afghanistan/Iraq Veterans
- Risk factor for suicide, housing instability, health problems/premature death

# Now

- Some symptoms exaggeration of normal response to threat
- Effective talk therapies can decrease the perceived threat
  - Can be difficult
- Approved drugs (sertraline and paroxetine)
  - Symptomatic relief
  - Don't work for everyone
- **There is an unmet need for safe and effective therapies to treat PTSD**

# Moving Forward

- New drugs
  - ClinicalTrials.gov shows 477 studies recruiting/not yet recruiting
  - Breakthrough therapy designation, priority review
- Medical devices
  - Nightware for temporary reduction of sleep disturbance related to nightmares in adults 22 years or older who suffer from nightmare disorder or have nightmares from PTSD

# Moving Forward

- Military vs. Civilian—false dichotomy?
  - “Military” can include accidents and personal assault (vs. combat)
  - Combat vs. Non-combat maybe getting closer
- Maybe single event vs. repeated trauma in context of ongoing stress
  - Single event: car accident, assault
  - Repeated trauma/ongoing stress: intimate partner violence, combat

# Moving Forward

- **Make sure trials enroll representative sample**
  - Good demographic mix (ethnicities, sexes)
  - Range of time since trauma
  - Experienced single events and repeated trauma
- Informed by knowledge of the brain/body
  - Brain circuitry in response to threat (can be studied in animals)
  - Biomarkers (risk, diagnosis, endpoints)
- Informed by studies of resilience



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# Federal Partner Discussion

## Panelists

Department of Defense

**Elyse Katz, PhD**

Office of the Assistant Secretary for Health, HHS

**Leith J. States, MD, MPH, MBA, FACPM**

Substance Abuse and Mental Health Services Administration, HHS

**Neeraj 'Jim' Gandotra, MD**

U.S. Food and Drug Administration, HHS

**Marta Sokolowska, PhD**

U.S. Department of Veterans Affairs



**Paula P. Schnurr, PhD**

**Miriam J. Smyth, PhD**

# Virtual Public Comment Process



Commenters will be called by name in alphabetical order.

- Make sure your on-screen name matches your registration name.
- We will announce the commenters in sets of three, so you know when your slot is coming up
  - The first time your name is called: **PREPARE TO SPEAK.**
  - Second time your name is called: **TURN ON YOUR CAMERA** 
  - As speaker concludes: **UNMUTE YOUR MIC** 
    - *Listen for cue from Production Team*

Commenters will have 3 minutes to speak. A countdown timer will be provided.



# Stakeholder Comments

# In-Person Public Comment Process



Commenters will be called by name in alphabetical order.

➤ We will announce the commenters in sets of three, so you know when your slot is coming up

- The first time your name **MOVE TO THE STAGE STAIRS**
- Second time your name is called: **MOVE TO THE OPEN PODIUM**
- Once you are introduced, you will **SPEAK FROM THE PODIUM.**



Commenters will have 3 minutes to speak. A countdown timer will be provided.



# Stakeholder Comments

# Advancing Treatments for Post-Traumatic Stress Disorder

**Thank you for attending!**

The meeting recording, transcript, and other materials will be available on the FDA Foundation website [reaganudall.org](https://www.reaganudall.org) next week.



REAGAN-UDALL

A thick yellow swoosh graphic that starts on the left, curves upwards and then downwards to the right, passing behind the text 'REAGAN-UDALL' and 'FOUNDATION'.

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FOR THE FDA