Truth in Testimony Disclosure Form

In accordance with Rule XI, clause 2(g)(5)*, of the *Rules of the House of Representatives*, witnesses are asked to disclose the following information. Please complete this form electronically by filling in the provided blanks.

Committee: Judiciary (U.S. House of Representatives)

Subcommittee: Crime, Terrorism, and Homeland Security

Hearing Date: Jan 28, 2020

Hearing Subject:

Fentanyl Analogs: Perspectives on Classwide Scheduling

Witness Name: [redacted]

Position/Title: Professor of Neurobiology (in Psychiatry)

Witness Type: ○ Governmental ⊗ Non-governmental

Are you representing yourself or an organization? ○ Self ⊗ Organization

If you are representing an organization, please list what entity or entities you are representing:

College on Problems of Drug Dependence, Public Policy Officer

If you are a non-governmental witness, please list any federal grants or contracts (including subgrants or subcontracts) related to the hearing's subject matter that you or the organization(s) you represent at this hearing received in the current calendar year and previous two calendar years. Include the source and amount of each grant or contract. *If necessary, attach additional sheet(s) to provide more information.*

Please see attached

If you are a non-governmental witness, please list any contracts or payments originating with a foreign government and related to the hearing's subject matter that you or the organization(s) you represent at this hearing received in the current year and previous two calendar years. Include the amount and country of origin of each contract or payment. *If necessary, attach additional sheet(s) to provide more information.*

World Health Organization - Expert Committee on Drug Dependence
- Switzerland

2019 $4,000
2018 $4,000
2017 $8,000 (+ $2,364 travel expenses)

Ongoing Research Support:

FDA: BAA-17-000123 (Comer) **$1,996,614** **08/15/2017 thru 05/30/20**
U.S. Food and Drug Administration
The proposed study will examine the reinforcing effects of oxymorphone and other mu opioid agonists using two different drug self-administration procedures.
Role: Principal Investigator (PI)

R01 DA035207-02 (Comer) **$2,676,383** **09/15/2014 thru 08/31/2020 (NCE)**
NIDA
Risks and Benefits of Overdose Education and Naloxone Prescribing to Heroin Users
This study assessed the impact of NYSDOH overdose education programs on opioid overdose in New York City along with way to improve the medical intervention among heroin users who witness an overdose event.
Role: PI

U54 DA037842-03 (Levin) **$14,367,844** **09/01/2014 thru 06/30/20**
NIDA
Shared Pharmacotherapeutic Strategies for Cannabinoid and Opioid Use Disorders
Project 3: Laboratory: Pharmacotherapies for Opioid Use Disorder (PI: Comer)
The goal of Project 3 is to examine medications that may have utility in treating OUD, using our laboratory model and our decision algorithm to logically evaluate candidate medications to be tested in clinical settings.
Role: PI of Project 3

U01 DA038876-01A1 (Pentel/Pravetoni) **$3,878,411** **09/01/15 thru 07/31/20**
NIDA (via Minneapolis Medical Res Found)
Vaccines for Prescription Opioid and Heroin Abuse
Role: Co-Investigator; PD/PI on the consortium to Columbia University from MMRF

R01 DA039169 (Comer) **$618,634** **06/15/2017 thru 05/31/2022**
NIDA
Medication Development for Opioid and Alcohol Abuse: Laboratory Studies in Humans.
This series of clinical laboratory investigations aims to assess the ability of gabapentin to reduce the abuse potential of opioid and alcohol when given alone and in combination in controlled clinical laboratory settings.
Role: PI

1UG3 DA047709-01 (Bellinger) **$5,658,273** **09/15/2018 thru 08/31/2020**
NIDA
An ultra-long-acting oral treatment for opioid use disorder
The goal of the proposed program is the preclinical development and clinical proof of concept of an oral once-weekly therapy for opioid use disorder incorporating buprenorphine and naloxone into a Lyndra dosage form. Successful completion of this grant would yield clinical data demonstrating a novel MAT with improved pharmacokinetics, a patient- and provider- preferred route of administration, and an optimal dosing interval for patient adherence with the potential for cost-effective directly observed therapy.
Role: Sub-award PI on consortium to Lyndra, Inc.,

1UG3 DA047711-01 (Comer/Pravetoni) **$3,788,472** **09/15/2018 thru 08/31/2020**
NIDA
Phase 1a/1b Clinical Trials of Multivalent Opioid Vaccine Components
The proposed Phase 1a/1b studies are designed to evaluate a novel treatment strategy for OUD. Specifically, the safety, immunogenicity and preliminary efficacy of a vaccine (OXY-KLH) targeted against oxycodone (Study 1) and a vaccine (M-KLH) targeted against heroin/morphine (Study 2) will be evaluated in participants diagnosed with OUD.
Role: Contact PI

1UG3 DA047711-01 (Vanover/Comer) **$3,249,130** **01/01/2019 thru 12/31/2020**
NIDA
Development of ITI-333, a μ-opioid Receptor Partial Agonist and 5HT2A and D1
Receptor Antagonist, for the Treatment of Opioid Use Disorders
Intra-Cellular Therapies, Inc. ("ITI"), has a biotechnology platform that has enabled discovery of innovative pharmaceutical therapies for CNS disorders based on intracellular signaling. In this project, we propose to develop a novel, small molecule, ITI-333, as a safe, brain-penetrant drug targeting molecular pathways in the

brain implicated in the development of OUD. Here, we present a clinical development plan designed to advance ITI-333 through human clinical evaluation as a medication for the treatment of opioid withdrawal and relapse and as an aid for the treatment of co-morbid symptoms of depression and anxiety in individuals withdrawing from opioids.
Role: Multi PI

1UG3 DA047720-01 (Bisaga) **$3,713,497** **09/15/18 thru 8/31/2020**
NIDA
Evaluation of safety and phatmacokinetics of naltrexone implant
This project will test the safety and duration of effective blood levels of an innovative subcutaneous implanted formulation of the opioid receptor blocker naltrexone.
Role: Co-I on consortium to Columbia University

Recently Completed Research Support:

R21 DA040225-01 (Jones) **$202,500** **08/01/2016 thru 07/31/2019**
NIDA
Using Pharmacogenetics to Better Evaluate Naltrexone for Treating Stumulant Abuse
he proposed study will compare the ability of NTX to alter the abuse potential of IN M-AMPH in individuals differentiated on the basis of the *OPRM1* A118G SNP.
Role: Co-Investigator

False Statements Certification

Knowingly providing material false information to this committee/subcommittee, or knowingly concealing material information from this committee/subcommittee, is a crime (18 U.S.C. § 1001). This form will be made part of the hearing record.

[redacted]

Witness signature

01-23-2020

Date

Please attach, when applicable, the following documents to this disclosure. Check the box(es) to acknowledge that you have done so.

☒ Written statement of proposed testimony

☒ Curriculum vitae or biography

*Rule XI, clause 2(g)(5), of the U.S. House of Representatives provides:

(5)(A) Each committee shall, to the greatest extent practicable, require witnesses who appear before it to submit in advance written statements of proposed testimony and to limit their initial presentations to the committee to brief summaries thereof.

(B) In the case of a witness appearing in a nongovernmental capacity, a written statement of proposed testimony shall include a curriculum vitae and a disclosure of any Federal grants or contracts, or contracts or payments originating with a foreign government, received during the current calendar year or either of the two previous calendar years by the witness or by an entity represented by the witness and related to the subject matter of the hearing.

(C) The disclosure referred to in subdivision (B) shall include—

(i) the amount and source of each Federal grant (or subgrant thereof) or contract (or subcontract thereof) related to the subject matter of the hearing; and

(ii) the amount and country of origin of any payment or contract related to the subject matter of the hearing originating with a foreign government.

(D) Such statements, with appropriate redactions to protect the privacy or security of the witness, shall be made publicly available in electronic form not later than one day after the witness appears.