

Points to Consider Regarding Tobacco Industry Funding of NIDA Applicants

Introduction

The mission of the National Institute on Drug Abuse (NIDA) is to advance science on drug use and addiction and to apply that knowledge to improve individual and public health. This involves: (1) Strategically supporting and conducting basic and clinical research on drug use (including tobacco products), its consequences, and the underlying neurobiological, behavioral, and social mechanisms involved. (2) Ensuring the effective translation, implementation, and dissemination of scientific research findings to improve the prevention and treatment of substance use disorders and enhance public awareness of addiction as a brain disorder. For more than 4 decades, NIDA has been a leading Federal agency supporting research to prevent and control tobacco use and addiction. As a steward of Federal funds intended to promote the public health, NIDA must ensure the integrity of the science it supports. This includes providing guidance to any entity receiving financial support from NIDA (termed 'recipient' in this document) regarding both actual and perceived conflicts of interest that may compromise NIDA's scientific and public health mission.

Purpose

The National Advisory Council on Drug Abuse (NACDA) serves crucial roles in advising NIDA on research priorities and policy and providing a secondary level of review for applications under consideration for federal funding. The NACDA has developed this document to provide points to consider for NIDA and its recipients regarding applications from recipients that also receive support from the tobacco industry¹. For the purpose of this document, the tobacco industry is defined as companies or corporate divisions that produce, distribute, market, or sell tobacco products, along with their research and lobbying groups, and other related entities.

With the emergence of new tobacco products (e.g., vaping devices), there is a recognized need for research on their multifaceted public health impacts, including their potential to reduce harms associated with tobacco addiction as well as to promote nicotine dependence and increase tobacco use among non-smokers, especially youth. The goal of this document is to help ensure the independence of research in this area by providing additional clarification to the existing NIH regulations on managing scientific and financial conflicts of interest (COI), available at: <https://grants.nih.gov/grants/policy/policy.htm>

Rationale/Background

Integrity, transparency, and honesty in conducting research are essential to sound science and form the basis for public confidence and trust in the results of scientific research. Landmark judicial rulings against the tobacco industry found that prior tobacco industry-sponsored research

was biased in support of the interests and goals of the tobacco companies. In 2006, a federal court found that the cigarette industry engaged in willful racketeering and conspiracy to conceal the dangers of smoking from the American public by improperly suppressing and terminating scientific research and destroying research documents. This ruling was upheld in 2009 by the U.S. Court of Appeals and in 2010, the U.S. Supreme Court denied further review of the ruling¹. In the final opinion in that case, the presiding judge ruled that nine manufacturers of cigarettes and two tobacco-related trade organizations had violated the Racketeer Influenced and Corrupt Organizations Act ("RICO") by engaging in a lengthy, unlawful conspiracy to deceive the American public about the health effects of smoking and environmental tobacco smoke, the addictiveness of nicotine, the lack of health benefits from low tar and "light" cigarettes, and their manipulating the design and composition of cigarettes in order to create and sustain nicotine addiction².

Regarding more recently introduced tobacco products (e.g., electronic nicotine delivery systems), there are currently insufficient data on their potential utility as either harm reduction or tobacco cessation products. For e-cigarettes in particular, increased use by youth and young adults is a cause of serious concern. Research on these and other tobacco products should be done in a manner that is independent of outside influence and is free of any real or apparent conflict of interest. For example, tobacco companies continue to fund scientific research within academic institutions and other organizations. Researchers should also be aware of the tobacco industry's role in the development of some of the e-cigarette products. Thus, the perception that tobacco industry funding may compromise research results and their interpretation and/or serve the goals of the tobacco industry at the expense of the public's health, continues to cause concern among many stakeholders including the research community, medical and public health organizations, editors of scientific journals, policy makers, and the general public. We offer these points to consider to help ensure that the design, conduct, and reporting of research results is not compromised or does not appear to be compromised by an Investigator's or Institution's relationship with the tobacco industry.

Points To Consider

NIDA Recipients:

Even though the changing landscape of tobacco products has begun to include products that may reduce harm for some individuals, the tobacco industry nonetheless manufactures, markets, and distributes products that are addictive and, in many cases lethal. In fact, cigarette smoking remains the leading cause of preventable premature death in the US, killing approximately 480,000 people per year. Thus, it is the opinion of NACDA that the interests of the tobacco industry have been *fundamentally incompatible* with the scientific goals and public health mission of NIDA. NIDA recipients should recognize that:

- Receiving funding from the tobacco industry may compromise the perceived objectivity of their research results, which in turn could impact the overall credibility of their research findings, including its interpretation, acceptance and implementation. This includes any consulting relationships (paid or unpaid) with the tobacco industry or organizations supported—in whole or in part—by this industry;
- Acceptance of tobacco industry funds or participation in tobacco-industry supported organizations is viewed by many as contributing directly or indirectly to the industry's interests, and thus harmful to the public health; and
- Any connection between tobacco-industry supported research (or tobacco industry scientists) and NIDA could negatively impact NIDA's credibility and the public's trust in NIDA-funded research.

NIDA Considerations Regarding Research Applicants also Supported by Tobacco-Industry Funding:

- NIDA must consider whether a recipient's funding and consulting relationships, including the potential use of its name in conjunction with that of one or more tobacco companies, may impact the credibility of the research results as well as public confidence in NIDA's stewardship of its funds and its research-based recommendations; and
- When making funding decision regarding applicants who also receive tobacco-industry funding, NIDA must weigh the potential impact these funding and consulting relationships may have on public trust and confidence against the potential public good that could result from the considered application.

Conclusions

NIDA must make research funding decisions based on scientific merit and public health goals. Recipients receiving NIDA funds should consider the impact of acceptance of tobacco industry funding or consulting relationships on NIDA's credibility and reputation within the scientific community. It is in that spirit that the NACDA encourages recipients to consider in consultation with NIDA, the points set forth in this document with regard to existing or prospective sponsored research agreementsⁱⁱ with tobacco companies or their related entities.

References

¹*United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1 (D.D.C. 2006), *aff'd in relevant part and vacated in part on other grounds*, 566 F.3d 1095 (D.C. Cir. 2009) (*per curiam*), *cert. denied*, 561 U.S., 130 S. Ct. 3501 (2010). The trial court found all defendants liable for past racketeering and conspiracy violations, but did not order remedies against three of them—two dissolved industry

trade groups, and one cigarette company that the court determined had previously withdrawn from the conspiracy—on the ground that they were not reasonably likely to commit further violations. *Id.* at 903 n.75, 915-19. The court found that all other defendants were reasonably likely to commit further racketeering and conspiracy violations. *Id.* at 908-15.

²See *Phillip Morris USA*, 449 F. Supp 2d at 852-61. The court upheld the opinion that the tobacco companies repeatedly violated and continue to violate the RICO by engaging in a decades-long conspiracy to defraud consumers about the health consequences and addictiveness of cigarette smoking.

¹For the purposes of this document, tobacco industry financial support does not include funds paid to states as a result of the Master Settlement Agreement, collected as hypothecated tobacco taxes (i.e., taxes levied on tobacco products which are intended to raise funds for public health spending and discourage smoking) or won as a result of legal judgments/verdicts against the tobacco industry.

ⁱⁱSponsored research agreements are defined as agreements between recipients and commercial entities in which recipients receive funding or other compensation to support their research.