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January 17, 2014

Mitch Zeller J.D.
Director Center for Tobacco Products
Food and Drug Administration
Document Control Center, Room 020J
9200 Corporate Boulevard
Rockville, MD 20850

RE: Requiring ITP/IND for E-cigarettes research

Dear Mitch,

I understand that the FDA is considering requiring an ITP/IND prior to allowing federally-funded research on electronic cigarettes. While such a request might make sense for e-cigarettes for which a therapeutic indication is being sought, it is a terrible idea for e-cigarette research more broadly. My concerns are as follows:

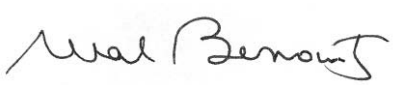
1. The use of e-cigarettes in the U.S. population is increasing exponentially over time. Physicians and other health care providers and policy makers are seeking information on which to base advice for patients or the general public regarding use of e-cigarettes. Any delays in generating any new research data would be highly detrimental to this process.
2. Relatively few data are available on e-cigarettes by which to determine the risks vs. benefits of e-cigarette use in populations. Clinical and policy decisions should be made on the basis of data.
3. More than four hundred e-cigarette products are currently on the market. These have widely differing designs, including variable liquid composition, different chamber size, different batteries, different nicotine and constituent delivery, and different particulate size and distribution. It would be impossible to obtain the necessary data on manufacturing and safety of constituents for the various products to obtain an ITP/IND in a timely manner, if at all.
4. NIDA could develop a prototype e-cigarette for research, but this prototype would take considerable time to develop and would be limited to one or a few design characteristics. These limitations would result in a great delay in gaining information on e-cigarette pharmacology and safety and would

have limited application to many products on the market now and in the future.

5. There are critical unanswered questions related to use patterns, nicotine delivery, addiction liability and safety that can be studied in people using their chosen e-cigarette products. Such research is not necessarily part of a research program to gain approval for therapeutic use.
6. Requiring an ITP/IND or NIDA e-cigarette prototype will paralyze much of the research that has been funded (or submitted for possible funding) and which is critical to inform public health.

In summary, data on the addiction liability and safety of various e-cigarette products are desperately needed to inform public health decisions. Requiring an ITP/IND for e-cigarettes would delay needed research and would be detrimental to public health. I strongly urge the FDA not to require an ITP/IND for e-cigarette research, other than that intended to support application for a therapeutic indication.

Sincerely,



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