

September 8, 2014

Harold W. Jaffe  
Office of the Associate Director for Science  
Centers for Disease Control and Prevention  
1600 Clifton Rd  
Atlanta, GA 30333

Dear Dr Jaffe,

I would like to file a formal complaint with the Office of the Associate Director for Science, concerning the article, "Intentions to smoke cigarettes among never-smoking U.S. middle and high school electronic cigarette users, National Youth Tobacco Survey, 2011-2013" which was recently published in Nicotine and Tobacco Research and subsequently promoted by the Centers for Disease Control (CDC).

The CDC Guidance on Scientific Integrity lists one of CDC's core values as accountability and provides the following definition:

**“Accountability—As diligent stewards of public trust and public funds, we act decisively and compassionately in service to the people’s health. We ensure that our research and our services are based on sound science and meet real public needs to achieve our public health goals.” (pg 2)**

The article "Intentions to smoke cigarettes among never-smoking U.S. middle and high school electronic cigarette users, National Youth Tobacco Survey, 2011-2013" was recently published in Nicotine and Tobacco Research and subsequently promoted by the CDC. All but one of the study's authors are either CDC or FDA employees. I believe the article and subsequent communications from the CDC and the CDC authors represent clear violations of the "CDC Guidance on Scientific Integrity". I hereby formally request that you investigate this matter.

Violations:

**“As the nation’s public health agency, CDC places primary emphasis on scientific evidence for developing policies, guidelines, and recommendations. Central to this process is a commitment to transparency, honesty, and thorough consideration of the research outcomes.”**

(CDC Guidance on Scientific Integrity, pg 2)

The study and subsequent communications from CDC were not transparent or honest and did not thoroughly consider all research outcomes.

Transparency-

Rather than releasing the 2013 NYTS data to the public with an overall summary of the findings, this study and the CDC press release are the first information the public has received about the results. Not only does this limit the ability of the broader scientific community to comment on the validity of the findings, but it allows CDC to frame the results in a way that supports the “e-cigarettes are a gateway to smoking” narrative that CDC Director Frieden and CDC Office on Smoking and Health Director McAfee have been promoting.

While in reality, youth smoking and youth intention to smoke (as measured in this study) have dropped significantly as e-cigarettes have gained popularity, and a very small portion of youth that have never smoked have experimented with e-cigarettes (0.9%), this information is not being presented to the public. By releasing selected, limited findings that support CDC’s gateway narrative weeks or months before releasing the entire 2013 NYTS results, CDC appears to be intentionally creating a distorted public perception of the effects of e-cigarettes on youth smoking trends.

Honesty-

While the study authors cited precedent in other studies for doing so, defining intention to smoke as including answers of “probably not”, a combination of “probably not” and “definitely not” as well as “definitely not” or “probably not” and no answer, is dishonest. While the authors did reveal their methodology for determining intention to smoke in the study, it is not revealed in the CDC press release or comments to the media from CDC authors. Further, comparing this measure of intention to smoke from previous years with subsequent youth smoking rates clearly shows that it is not an accurate predictive measure.

However, CDC and CDC study authors treat it as such when making policy recommendations and in communication with the public.

The vast majority of members of the public would not consider defining an answer of 'probably not' as intention to smoke. If trends in youth smoking data showed that youth who answer 'probably not' to smoking intention questions are likely to go on to initiate smoking behavior, this might be warranted. However, using this definition of smoking intention when it violates the common meaning of the terms used, and is not a useful predictive measure, is dishonest.

The CDC press release states, "Among non-smoking youth who had ever used e-cigarettes, 43.9 percent said they intended to smoke conventional cigarettes within the next year." Even if the definition of smoking intention used in the study was a useful indicator, this statement would be untrue. To say a group 'showed intention to smoke' might be warranted if that were the cases. However, there is no circumstance in which it would not be dishonest to reports that youth who answered "probably not" to smoking intention questions "said they intended to smoke conventional cigarettes within the next year."

Further, CDC has violated the principle of honesty by using weighted population estimates and the term 'tripled' when communicating the number of never smoking youth that have tried e-cigarettes to the public, without also noting that this group represents less than 1% of never smoking youth. This presentation gives undue weight to the significance of the findings.

Additionally, by using the term "use" inconsistently, CDC continues to create an exaggerated perception of youth e-cigarette use. While the percentage of youth that currently use combustible cigarettes are always clearly differentiated from the percentage of youth that have ever tried combustible cigarettes, the same care is not taken when discussing e-cigarettes. While preparing this document I examined a large number of communications from CDC to determine the number of youth who had ever tried combustible cigarettes in 2011 or 2012, but could not find this data. The majority of references to youth smoking rates are of current use, while the majority of references to e-cigarettes use rates are of ever use. This creates an inflated perception of youth e-cigarette use.

## Thorough Consideration of All Research Outcomes-

While much emphasis is given to the increase in never smoking youth that have tried e-cigarettes, this study and CDC fail to consider other implications of the data collected, or serious confounding factors that impact the validity of the results and conclusions.

As youth smoking and youth intention to smoke have dropped significantly while e-cigarettes have gained popularity, and a very small portion of youth that have never smoked have experimented with e-cigarettes (0.9%), the data reviewed supports a conclusion that, to date, there is no e-cigarette to combustible cigarette gateway occurring. This conclusion is not considered. By releasing selected, limited findings that support CDC's gateway narrative weeks or months before releasing the entire results, and failing to acknowledge this possible conclusion, CDC appears to be intentionally creating a distorted public perception of the effects of e-cigarettes on youth smoking trends.

Of youth that had never smoked cigarettes, significantly more had tried other combustible tobacco products than had tried e-cigarettes (7.7% vs 0.9%). Even the number that used combustible products other than cigarettes in the last 30 days was significantly greater than the number of e-cigarette ever users (2.6% vs 0.9%). Although it is known that other combustible tobacco products (such as little cigars) are used like cigarettes by some youth, there is no consideration given to what portion of never smoking youth that have tried e-cigarettes are actually smokers that use combustible tobacco products other than cigarettes. Failing to consider and investigate this possibility compromises the integrity of the findings.

Additionally, CDC has failed, in their analysis of NYTS data and communication with the public, to consider the possibility that youth e-cigarette use has resulted in less use of combustible cigarettes. Repeated analysis and discussion of the data concerning the gateway theory, in absence of analysis and discussion concerning the possibility of e-cigarettes reducing youth smoking violates the principle of "thoroughly considering all research outcomes."

**"CDC has a responsibility to conduct the best science and is committed to disseminating scientific findings and results without being influenced by policy or political issues."**

**(CDC Guidance on Scientific Integrity, pg 3)**

The study and subsequent communications from CDC demonstrate not only poor science, but dissemination of findings to the public influenced by the highly politicized public e-cigarette debate and a desire to support, rather than undermine, previous policy recommendations.

#### Poor Science-

Problems with the study include:

-Students were counted as intending to smoke for answers of 'probably not' to both questions about possible future smoking behavior, a combination of 'probably not' and 'definitely not', and a combination of either 'probably not' or 'definitely not' and no answer, undermining the validity of conclusions.

-Acknowledgement of some limitation determining intention based on number of questions, but no acknowledgement of issues arising from counting answers of 'probably not' as intention to smoke.

-Authors note precedent in previous papers for how they determined 'intention to smoke in next year', but it is clearly not a useful measure based on the data from the previous years. Comparing this measure of intention to smoke in never smoking youth from previous years, with actual smoking behaviors in subsequent years clearly demonstrates that this definition of intention to smoke is not a useful measure.

-Multiple references to e-cigarettes 'use' when meaning 'ever use', creating an inflated impression of the number of youth that currently use e-cigarettes.

-While all other findings are presented as percentages, the number of youth that had tried e-cigarettes but not combustibles was presented in weighted population estimates. Using the (estimated) number 260,000 rather than the finding of 0.9% gives inappropriate weight to this small segment of the population.

-Overstating accuracy of adjusted population numbers given the small sample size (for this group), complexity of survey and confounding factors.

-Multiple assertions that the number of never smoking youth that had used e-cigarettes tripled between 2011 and 2013. Information is presented as if the number of never smoking youth that use e-cigarettes is growing significantly. However, because ever use was being measured students that tried an e-cigarette in 9th grade in 2011 would also be counted in 2013 even if they never tried another.

-While the authors state that the number of never smoking youth that have tried e-cigarettes has tripled, the respective percentages weren't offered for comparison only the (presumably less accurate) weighted population numbers.

-Of youth that had never smoked cigarettes, significantly more had tried other combustible tobacco products than had tried e-cigarettes (7.7% vs 0.9%). Even the number that currently use other combustible tobacco products was significantly greater (2.6% vs 0.9%). Since the study seeks to measure intention to smoke in never smoking youth that have tried e-cigarettes, it seems responsible to report what portion of this group use or have used other combustible tobacco products as a significant portion (or, theoretically the entirety) of this group could actually be smokers that use other combustibles, such as little cigars, rather than cigarettes.

-Misuse of odds ratios creating the appearance of a larger effect than is warranted by the data.

-Discussion section implies that data set is evidence that e-cigarettes will lead to increased smoking, and thus warrants policy actions, with little to no discussion of evidence that e-cigarette ever use is very low amongst never smoking youth, and even with an increase in overall e-cigarette use, youth smoking rates have fallen significantly.

-A significant amount of discussion is devoted to the effects of nicotine on adolescents, and the term Electronic Nicotine Delivery System (ENDS) is used, but the survey did not differentiate between nicotine containing and non-nicotine containing e-cigarettes. The authors did not acknowledge this limitation.

-Authors state, "Use of a broader definition of tobacco products in future research that incorporates not only cigarettes, but also other combustible, smokeless tobacco products and ENDS, will help capture the increasing number of youth who do not smoke cigarettes but use other products such as flavored little cigars and hookahs, (King, Tynan, Dube, & Arrazola 2014), smokeless tobacco or ENDS." Not only do the authors make this statement based on a citation that, presumably (based on placement), only references other combustible products, but fail to acknowledge that using one definition to encompass high risk combustible products and relatively low risk e-cigarettes would further confound future analysis of the e-cigarette use on use of combustible tobacco products.

-While authors acknowledge that the cross-sectional nature of the study prevents conclusions as to a causal relationship between e-cigarette use and intention to smoke, they argue that a causal relationship in either direction could lead to increased smoking, but fail to acknowledge the possibility that there could be no effect or that e-cigarettes could be protective against youth smoking (ie, youth with smoking intentions using e-cigarettes rather than combustible cigarettes). Authors also fail to acknowledge that as of yet, increased e-cigarette use is associated with decrease in smoking rates. (It should be noted that this concern is secondary, as these relationships cannot be properly analyzed until smoking intention is measured in a useful way.)

Evidence of influence of policy and political issues on dissemination of results-

Rather than releasing the 2013 NYTS data to the public with an overall summary of the findings, this study and the CDC press release are the first information the public has received about the results. Not only does this limit the ability of the broader scientific community to comment on the validity of the findings, but it allows CDC to frame the results of the 2013 NYTS in a way that supports the “e-cigarettes are a gateway to smoking” narrative that CDC Director Frieden and CDC Office on Smoking and Health Director McAfee have been promoting.

While, in reality, youth smoking and youth intention to smoke have dropped significantly as e-cigarettes have gained popularity, and a very small portion of youth that have never smoked have experimented with e-cigarettes (0.9%), this information is not being presented to the public. By releasing selected, limited and distorted findings that support CDC’s gateway narrative weeks or months before releasing the entire data set and an overview of results, CDC appears to be intentionally creating a distorted public perception of the effects of e-cigarettes on youth smoking trends.

Using weighted population estimates and the term ‘tripled’ when communicating the number of never smoking youth that have tried e-cigarettes to the public, without also noting that this group represents less than 1% of never smoking youth, gives undue weight to the significance of the findings.

Further, the CDC press release states that 43.9% of never smoking youth that had tried e-cigarettes “said they intended to smoke conventional cigarettes within the next year.” It is not only misleading, but false to report that students who answered ‘probably not’ when asked about future smoking said they intended to smoke.

In the study, the authors say they “cannot determine causal or temporal direction of association between e-cigarette use and intention to smoke”, however, the lead author states in CDC press release “The increasing number of young people who use e-cigarettes should be a concern for parents and the public health community, especially since youth e-cigarette users were nearly twice as likely to have intentions to smoke conventional cigarettes compared with youth who had never tried e-cigarettes.” While not explicitly stated, this statement implies that e-cigarette use leads to intention to smoke.

When considering 1) the release of this study and CDC’s press announcement before the release of the 2013 NYTS data and general findings 2) presentation of data in a way that creates an exaggerated perception of youth e-cigarette use and experimentation 3) claiming

that youth who responded “probably not” to questions about future smoking said they intend to start smoking and 4) implying that e-cigarette use and experimentation leads to smoking intention, it appears that CDC is attempting to manufacture an e-cigarette to combustible cigarette gateway effect that support the position CDC and FDA have taken on e-cigarettes.

**“Free and timely release of scientific information and data: As stated in the CDC/ATSDR Policy on Releasing and Sharing Data (and consistent with the OMB, HHS, and CDC Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public), public health and scientific achievements are best served when data are released or shared with other public health agencies and researchers in an open, timely, and appropriate way.”**

(CDC Guidance on Scientific Integrity, pg 12)

Rather than first releasing the 2013 NYTS data to the public with an overall summary of the findings, this study and the CDC press release are the first information the public has received about the results. Not only does this limit the ability of the broader scientific community to comment on the validity of the findings, but it allows CDC to frame the results in a way that support the “e-cigarettes are a gateway to smoking” narrative that CDC Director Frieden and CDC Office on Smoking and Health Director McAfee have been promoting.

By releasing selected, limited and distorted findings that support CDC’s gateway narrative weeks or months before releasing the entire 2013 NYTS data set and a summary of results, CDC is creating a distorted public perception of the effects of e-cigarettes on youth smoking trends that will inform public debate and policy decisions. In fact, a group of Senators have already released a statement in response to the study urging policy changes and saying, “If last year’s Centers for Disease Control report on the growing number of kids using e-cigarettes was a call to action, then this new CDC data on the marketing of these dangerous devices is the sound of an alarm.” Vince Willmore, a spokesperson for the Campaign for Tobacco-Free Kids, responded to the study saying, “We hope that studies like this will show the FDA [Food and Drug Administration] that they need to act very quickly.”

**“When CDC learns of confusion about a CDC-issued public health message and determines that clarification or additional information should be published, CDC will take reasonable steps, using plain language, to address confusion.”**

(CDC Guidance on Scientific Integrity, pg 14)

On August 25th, the Washington Post ran an article titled “Adolescents who use e-cigarettes are much more likely to try tobacco, CDC says.” Clearly the NYTS data does not provide a basis for this statement. While this statement furthers the “gateway” narrative and tone of CDC’s press release, it is not supported by evidence. CDC has not taken any action to address this confusion.

On August 26th, an article from Fox News entitled “CDC: E-cigarettes may be tempting non-smoking youths to smoke,” stated, “A report, released by a team at the U.S. Centers for Disease Control and Prevention, lends evidence to the argument that electronic cigarettes encourage youth smoking.” Clearly the NYTS data does not provide a basis for this statement. While this statement furthers the “gateway” narrative and tone of CDC’s press release, it is not supported by evidence. CDC has not taken any action to address this confusion.

On September 1st, the Chicago Daily Herald ran an article entitled “CDC: e-cigarettes more cause youths to smoke [sic]” which stated, “Adolescents who use e-cigarettes are much more likely to smoke conventional cigarettes, according to a study released Monday by the Centers for Disease Control and Prevention.” Clearly the NYTS data does not provide a basis for this statement. While this statement furthers the “gateway” narrative and tone of CDC’s press release, it is not supported by evidence. CDC has not taken any action to address this confusion.

On August 24th, in a story entitled “E-Cigarettes Should be a Last Resort, Heart Doctors Say”, NBC reported, “New research [from CDC] shows that teens are not using e-cigarettes to quit.” Clearly the NYTS data does not provide a basis for this statement. While this statement furthers the “gateway” narrative and tone of CDC’s press release, it is not supported by evidence. CDC has not taken any action to address this confusion.

On August 27th, Wall Street Journal Live aired a story in which Erika Sward, national advocacy assistant vice president for the American Lung Association stated in reference to CDC’s study, “now there is even more evidence that e-cigarettes are a gateway to regular cigarettes.” Clearly the NYTS data does not provide a basis for this statement. While this statement furthers the “gateway” narrative and tone of CDC’s press release, it is not supported by evidence. CDC has not taken any action to address this confusion.

The five previous examples of the confusion caused by CDC’s press release from major news outlets could reasonably be corrected by CDC. The number of regional, local and

international news outlets that erroneously reported the study as evidence of a gateway effect is unknown, but most likely much larger. Erroneous reporting of the findings of this study by so many news organizations is a clear indicator that the presentation of information was misleading. However, CDC has not taken any steps to correct this.

**“CDC adheres to these principles in its communication with the media and public: - CDC communication is science-based, timely, accurate, respectful, credible, and consistent (STARCC).**

**-CDC embraces intellectual honesty and transparency in its release of information to fully empower public decision making.**

**-CDC does not use trickery or deceptive communication techniques to advance public health recommendations or its reputation.**

**-CDC admits its mistakes, past and present, and takes responsibility for correcting them.**

**-CDC does not withhold information only to avoid embarrassment.”**

**(CDC Guidance on Scientific Integrity, pg 15,16)**

The CDC press release as well as the methodology, analysis and conclusions of the study itself, demonstrate clear violations of these principles.

**“CDC communication is science-based, timely, accurate, respectful, credible, and consistent (STARCC).”**

The study and CDC press release cannot be considered science-based, accurate or credible due to the following factors:

**-Presentation of data in a way that creates an exaggerated perception of youth e-cigarette use and experimentation**

**-Claims that youth who responded “probably not” to questions about future smoking, and reports that they intend to start smoking**

**-Implied that e-cigarette use and experimentation leads to smoking intention**

**-Made conclusions and recommendations far beyond the scope of the study**

**-Misused odds ratios to create the appearance of a larger effect**

“CDC embraces intellectual honesty and transparency in its release of information to fully empower public decision making.”

Rather than releasing the 2013 NYTS data to the public with an overall summary of the findings, this study and the CDC press release are the first information the public has received about the results. Not only does this limit the ability of the broader scientific community to comment on the validity of the findings, but it allows CDC to frame the results in a way that supports the “e-cigarettes are a gateway to smoking” narrative that CDC Director Frieden and CDC Office on Smoking and Health Director McAfee have promoted.

In reality, youth smoking and youth intention to smoke have dropped significantly as e-cigarettes have gained popularity, and a very small portion of youth that have never smoked have experimented with e-cigarettes (0.9%), this information is not being disseminated to the public. By releasing selected, limited and misleading findings that support CDC’s gateway narrative weeks or months before releasing the entire data set and summary of results, CDC is creating a distorted public perception of the effects of e-cigarettes on youth smoking trends that will inform public debate and policy decisions.

“CDC does not use trickery or deceptive communication techniques to advance public health recommendations or its reputation.”

The entire analysis presented in this complaint demonstrates a clear use of trickery and deceptive communication techniques to create the perception that NYTS data is evidence of a e-cigarette to combustible cigarette gateway effect and to create a sense of urgency to enact restrictive regulations.

Defining intention to smoke as including answers of “probably not”, a combination of “probably not” and “definitely not” and “definitely not” or “probably not” and no answer is deceptive. If NYTS data from previous years demonstrated that this measure of intention to smoke were predictive of youth smoking trends, it would be warranted. However, this is clearly not the case. Otherwise, with 22.8% of never smoking youth intending to smoke in 2011, the smoking rate would have increased in 2012 rather than declining.

While the authors did reveal the methodology used to measure intention to smoke in the study, it is not revealed in the CDC press release or comments to the media from CDC authors. In fact, the CDC press release states, “43.9 percent said they intended to smoke conventional cigarettes within the next year.” Even if the definition of smoking intention used was a useful indicator, this statement would be untrue. To say a group ‘showed intention to smoke’ might be warranted if those were the cases. However, there is no circumstance in which it would not be deceptive to report that youth who answered “probably not” to smoking intention questions “said they intended to smoke conventional cigarettes within the next year.” As a member of the public, after reading CDC’s press release and subsequently reading the full study, I felt I had not only been misled, but that I had been tricked.

The CDC press release employs deceptive communication techniques by using weighted population estimates and the term ‘tripled’ when communicating the number of youth who have never smoked but have tried e-cigarettes to the public, without also noting that this group represents less than 1% of never smoking youth. This presentation, gives undue weight to the significance of the findings and creates the perception that e-cigarette use in never smoking youth is an epidemic. It is likely that many members of the public would feel tricked if, after reading CDC’s press release, they found out that only 0.3% of never smoking youth have used an e-cigarette in the last 30 days.

Additionally, by using the term “use” inconsistently, CDC continues to create an exaggerated perception of youth e-cigarette use. While the percentage of youth that currently use combustible cigarettes are always clearly differentiated from the percentage of youth that have ever tried combustible cigarettes, the same care is not taken when discussing e-cigarettes. While preparing this document, I examined a large number of communications from CDC to determine the number of youth who had ever tried combustible cigarettes in 2011 or 2012, but could not find this data. However, the majority of references to youth smoking reference current use, while the majority of references to e-cigarettes reference ever use. This creates an inflated perception of youth e-cigarette use.

Finally, while the study and CDC’s press release emphasize the effects of nicotine on adolescents, and the term Electronic Nicotine Delivery System (ENDS) is used, the survey did not differentiate between nicotine containing and non-nicotine containing e-cigarettes. Neither the study nor the CDC press release acknowledge this limitation.

The deceptive nature of CDC's presentation of the 2013 NYTS through the study and CDC's press release appear to be a clear attempt to advance CDC and FDA's public health recommendations. The announcements from CDC have already resulted in an increased urgency to enact restrictive regulations of e-cigarettes.

A group of Senators released a statement in response to the study urging policy changes and saying, "If last year's Centers for Disease Control report on the growing number of kids using e-cigarettes was a call to action, then this new CDC data on the marketing of these dangerous devices is the sound of an alarm." Vince Willmore, a spokesperson for the Campaign for Tobacco-Free Kids, responded to the study saying, "We hope that studies like this will show the FDA [Food and Drug Administration] that they need to act very quickly." Erika Sward, national advocacy assistant vice president for the American Lung Association stated in reference to CDC's study, "now there is even more evidence that e-cigarettes are a gateway to regular cigarettes."

"CDC admits its mistakes, past and present, and takes responsibility for correcting them."  
and "CDC does not withhold information only to avoid embarrassment."

While, in reality, youth smoking and youth intention to smoke have dropped significantly as e-cigarettes have gained popularity, and a very small portion of never smoking youth have experimented with e-cigarettes (0.9%), this information is not being presented to the public. To date, no data has emerged to indicate that e-cigarettes are contributing to youth smoking. By releasing selected, limited and distorted findings that support CDC's gateway narrative weeks or months before releasing the entire 2013 NYTS data set and summary of results, CDC is creating a distorted public perception of the effects of e-cigarettes on youth smoking trends.

Rather than releasing the 2013 NYTS data to the public with an overall summary of the findings, this study and the CDC press release is the first information the public has received about the results. Not only does this limit the ability of the broader scientific community to comment on the validity of the study's findings, but it allows CDC to frame the results in a way that supports the "e-cigarettes are a gateway to smoking" narrative that CDC Director Frieden and CDC Office on Smoking and Health Director McAfee have promoted.

As a member of the public, I am outraged and dismayed by the lack of scientific integrity and intention to mislead the public that CDC has displayed. The American people, the public health

community, legislators, health practitioners and regulatory bodies rely on CDC for accurate, unbiased information. By using deceptive language and only revealing selected data to the public, CDC has attempted to spin the 2013 NYTS results to support a political agenda rather than providing a comprehensive, intellectually honest overview of the findings.

It is imperative that this study and CDC's press release be retracted and that CDC issue an apology for breaching the public's trust. Additionally, actions must be taken to ensure that CDC does not continue to misrepresent findings related to e-cigarette use. The public debate about e-cigarettes will likely continue for sometime, and it is appropriate for CDC to make recommendations. However, these recommendations must be based on an intellectually honest review of scientific and epidemiological evidence. By misrepresenting the results of the 2013 NYTS, CDC has not only undermined the credibility of its own position on e-cigarettes, but threatens to undermine the integrity of the entire public debate on this issue.

I look forward to your prompt response in this matter.

Sincerely,

/s/