



Letter

Objectivity and Evidence in the 2016 Surgeon General's Report on E-Cigarettes

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Introduction

The most recent Surgeon General's Report (SGR), "E-cigarette use among youth and young adults", was released in December of 2016.¹ The 2016 SGR follows the legacy of SGRs that began in 1964.² The 1964 SGR is not only respected for its positive impact on public health, but also its methodological rigor. As noted in the 2014 SGR, the 1964 SGR included a "transparent methodology and depth of analysis, including a systematic gathering and review of the data and a synthesis of the findings for causality based on prior criteria".^{3(p21)} Upon a first inspection, the 2016 SGR appears to embody the same objective review of evidence with the involvement of more than 100 experts and close to 1000 references. A more careful read, however, reveals important areas where the report falls short.

Objectivity

One of the more surprising shortcomings of the 2016 SGR is located early in the document when the reader is informed that recent studies were included if they conformed to conclusions that had already been reached, or as stated: "...selected studies from 2016 have been added during the review process that provide further support for the conclusions in this report." (see Chapter 1: "Scientific Basis of the Report"^{1(p5)}). While efforts to include recently published studies are commended, especially when evaluating rapidly changing technology such as e-cigarettes, the selection of evidence to align with preset conclusions represents a type of bias known as "confirmation bias." Confirmation bias is defined as "The seeking or interpreting of evidence in ways that are partial to existing beliefs, expectations, or a hypothesis in hand."^{4(p175)} The degree to which confirmation bias impacted the conclusions of the 2016 SGR requires a more in-depth analysis than is possible in this brief commentary, but the potential for such bias should not be overlooked given the negative impact it can have on science, medicine, and policy.⁴

Evidence

There is additional evidence that the 2016 SGR falls short of providing a comprehensive overview of the literature. For example, two recent

publications that found evidence that age-of-purchase restrictions on e-cigarettes can contribute to increased use of combustible cigarettes by adolescents were not included in the report.^{5,6} In a separate section of the report titled "Attention and Cognition"^{1(pp106–107)}, only one citation addressed the effects of nicotine on human cognition out of 12 studies cited. The 11 remaining citations examined the effects of nicotine in rodents (7 studies) or in humans exposed to smoked tobacco only (4 studies). This is surprising given that a considerable body of research has examined nicotine's effects on human cognition as reviewed in a 2010 meta-analysis of nicotine's effects on performance.⁷ That meta-analysis included 15 studies that assessed the acute effects of nicotine alone, not smoked tobacco, on cognitive performance of young people with a mean age between 19 and 24 years across studies (see Tables 2–10 of ref. ⁷ for mean age by study). Unfortunately, neither the meta-analysis nor any of these 15 studies were addressed in the 2016 SGR.

Similarly, the 2016 SGR did not account for the only human study to-date that has followed infants exposed to nicotine in utero over an extended period of time after delivery.⁸ That study, a randomized controlled trial based in England and known as the SNAP trial (Smoking and Nicotine in Pregnancy), examined the effects of nicotine replacement therapy (NRT) on smoking during pregnancy. The study found that infants born to women that had used NRT during pregnancy were more likely to have unimpaired development at a 2-year follow-up compared to infants who had been in a placebo group. SNAP authors noted that this difference could be due to reduced smoking in the NRT group early in pregnancy. A potential implication of this finding is that prenatal exposure to combusted tobacco is more harmful than other forms of noncombusted nicotine exposure such as NRT. Such findings are essential for understanding the unique challenges and opportunities that are associated with addressing smoking and nicotine exposure during pregnancy, a topic that was reviewed at length in a recent Themed Issue of Nicotine and Tobacco Research.⁹

Conclusions and Recommendations

The above concerns highlight serious methodological oversights that greatly restrict the ability of the 2016 SGR to offer an objective

review of the best available evidence related to the health effects of nicotine, tobacco, and e-cigarettes. Incomplete or biased messaging on the effects of these and other nicotine products must be avoided at all costs in order to support the public in making personal choices that are informed by the best available evidence.¹⁰ An emphasis on objectivity and evidence is essential for correcting oversights in the 2016 SGR and reinstating the SGR's legacy as a health communication tool that serves the public.

Declaration of Interests

My employer, PinneyAssociates, works on smoking cessation and tobacco harm minimization (including nicotine replacement therapy and electronic vapor products) for Nicovum USA, Reynolds American Innovation, Inc., and RAI Services Company, all subsidiaries of Reynolds American Inc. However, we do not consult on conventional, combustible cigarettes. PinneyAssociates has also consulted to NJOY on electronic cigarettes in the past 3 years. Commercial interests including RAI had no input in to any facet of this work, from its conception, analysis, writing, nor submission.

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References

1. U.S. Department of Health and Human Services. *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2016.
2. Advisory Committee to the Surgeon General of the Public Health Service. Washington: U.S. Department of Health, Education, and Welfare, Public Health Service, Center for Disease Control; 1964. *PHS Publication No. 1103*.
3. U.S. Department of Health and Human Services. *The Health Consequences of Smoking—50 Years of Progress. A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2014. Printed with corrections, January 2014.
4. Nickerson RS. Confirmation bias: a ubiquitous phenomenon in many guises. *Rev Gen Psychol*. 1998;2(2):175–220.
5. Pesko MF, Hughes JM, Faisal FS. The influence of electronic cigarette age purchasing restrictions on adolescent tobacco and marijuana use. *Prev Med*. 2016;87(June):207–212.
6. Friedman AS. How does electronic cigarette access affect adolescent smoking? *J Health Econ*. 2015;44(December):300–308.
7. Heishman SJ, Kleykamp BA, Singleton EG. Meta-analysis of the acute effects of nicotine and smoking on human performance. *Psychopharmacology (Berl)*. 2010;210(4):453–469.
8. Cooper S, Taggar J, Lewis S, et al.; Smoking, Nicotine and Pregnancy (SNAP) Trial Team. Effect of nicotine patches in pregnancy on infant and maternal outcomes at 2 years: follow-up from the randomised, double-blind, placebo-controlled SNAP trial. *Lancet Respir Med*. 2014;2(9):728–737.
9. Bauld L, Oncken C. Smoking in pregnancy: an ongoing challenge. *Nicotine Tob Res*. 2017;19(5):495–496.
10. Kozlowski LT, Sweanor D. Withholding differential risk information on legal consumer nicotine/tobacco products: the public health ethics of health information quarantines. *Int J Drug Policy*. 2016;32(June):17–23.