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## Surgeon General's Reports on Tobacco: A Continued Legacy of Unbiased and Rigorous Synthesis of the Scientific Evidence

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The author of a recent letter, who declared interests related to the tobacco and electronic cigarette industries, critiqued the objectivity and evidence related to the 2016 US Surgeon General's Report, *E-cigarette Use Among Youth and Young Adults*.<sup>1</sup> The 2016 report was compiled using a longstanding, peer-reviewed, and comprehensive process to safeguard the scientific rigor and practical relevance of US Surgeon General's Reports on Tobacco. In this commentary, we describe that process in detail, including specific components that clarify and correct the assertions made in the aforementioned critique.

### Scope, Role, and Impact of the US Surgeon General's Reports on Tobacco

In 1964, Luther Terry, M.D., Surgeon General of the United States, released *Smoking and Health: Report of the Advisory Committee of the Surgeon General of the Public Health Service*.<sup>2</sup> In what is widely recognized as a historic moment for public health, this seminal report established the foundation for a lasting series of evidence reviews with powerful conclusions that are generally referred to as the Surgeon General's Reports on Tobacco. As noted in the 2014 Surgeon General's Report, *The Health Consequences of Smoking—50 Years of Progress*, the 1964 report was a pioneering step that established a key role of the government, in collaboration with scientists, to inform tobacco control policy, planning, and practice through the comprehensive and transparent synthesis of scientific evidence. As of December 2016, 33 Surgeon General's Reports on Tobacco have been released by the US Government.

The Surgeon General's Reports on Tobacco comprise an esteemed set of scientific documents on a diverse array of topics. The evidence reviewed and summarized in these reports, as well as the conclusions, have served as a catalyst for programs and interventions to reduce the health and economic burden of tobacco product use. Additionally, the reports

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#### Declaration of Interests

None declared.

offer an important blueprint for the scientific community by highlighting critical evidence gaps to be addressed with future research. Given the roles these reports have played in informing and guiding public health, the 2014 Surgeon General's report concluded: "For 50 years the Surgeon General's reports on smoking and health have provided a critical scientific foundation for public health action directed at reducing tobacco use and preventing tobacco-related disease and premature death" (page 7).<sup>3</sup>

For government reports, particularly those with the visibility and impact of the Surgeon General's Reports on Tobacco, protections are needed to safeguard the process of forming an impartial and rigorous scientific synthesis. This is especially important given that myriad factors may come into play during a report's development, including: political pressures that might introduce bias; coordinated efforts from individuals and groups to have the conclusions support their policy positions or preferences; the recognition that some conclusions can influence decisions on research funding and directions of the scientific community; and the well-intentioned belief of authors that the conclusions should substantiate their own positions.<sup>3,4</sup> Without a process to protect the reports and their conclusions from such influences, the content could be affected by pressures of the moment, rather than solely on the evaluation of scientific evidence through a formal process.

To resist influences that could adversely affect impartiality and scientific rigor, the reports are produced using a balanced, comprehensive, and peer-reviewed process. This process helps ensure that the evidence, rather than the authors' and editors' opinions, defines a report's conclusions.<sup>3,4</sup> As a result of this process, the reports continue to play a key role in establishing the scientific foundation that underlies tobacco control efforts by verifying causal relationships between adverse outcomes and tobacco-related factors, and comprehensively articulating the state of the science on the effectiveness of tobacco control strategies.<sup>3</sup> Notably, these reports have maintained their value through marked shifts in national, state, and local governmental policies and actions toward tobacco product use, opposition from tobacco industry interests, and the sometimes rigorous debates within the tobacco control community.<sup>3</sup>

## Compilation and Dissemination of the Reports

Surgeon General's Reports on Tobacco are developed using an established framework, which has evolved since the 1964 report, for synthesizing and summarizing the most recently available scientific evidence.<sup>2,3</sup> In more recent decades, the framework was refined to include an administrative structure in which the reports are coordinated by the Centers for Disease Control and Prevention's (CDC) Office on Smoking and Health (OSH) in consultation with the Office of the Surgeon General (OSG). Report topics are selected based on many factors, including the breadth of the available scientific evidence, relevance of and need for the information among key stakeholders, including the general public, and time since the topic was last addressed by a previous report. Using these criteria, topics are proposed by OSH and submitted for consideration by OSG. If approved, work is initiated about two years prior to a report's anticipated release date.

Beginning with the 1979 report and continuing to the present,<sup>5</sup> the rigor of the process was enhanced through the addition of senior scientific editors drawn from the academic and scientific communities that, when selected, are not employees of the US Government. These individuals are selected based on their established knowledge, publication record, and expertise on the topic of the report. The senior scientific editors are tasked with ensuring the accuracy of the scientific content of the report and providing independent oversight for the process of considering and addressing reviewers' comments.

Once selected, the senior scientific editorial team is responsible for constructing a general outline of the report and identifying broad areas of focus for individual chapters. They are also tasked with helping to identify lead authors for each chapter, who have been more recently called contributing editors.<sup>6</sup> The identification and selection of these individuals is informed by a literature review conducted by a third party contractor hired by CDC OSH to facilitate the report's compilation. Following their selection, the contributing editors convene with the senior scientific editorial team during an in-person meeting and provide an outline of proposed content for their respective chapters. In some instances, contributing editors may subsequently recruit additional authors with specific expertise to contribute to the chapter content. Processes are put in place to ensure that all editors and authors are established experts who can provide an unbiased and scientifically rigorous synthesis of the most current evidence on the report topic.

Following the meeting of the senior scientific editorial team and lead authors, the authors are tasked with reviewing and assembling the relevant evidence base. In instances where previous Surgeon General's Reports on Tobacco have already broached a given topic in detail, priority is given to the inclusion of newly identified science in the more recent report, while duly citing what has already been comprehensively discussed in previous reports. Based on the compiled scientific findings, the authors are then tasked with crafting conclusions supported by the evidence; this process helps to reduce inaccuracies that may occur when authors synthesize the evidence and reach conclusions based on their recall of what the literature shows, rather than on the evidence actually contained in that literature. A critical and essential aspect of this role is the critical assessment of statements that an exposure "causes" an outcome; causal determinations are made using established criteria.<sup>4</sup> However, conclusions are not limited to just causal determinations, and frequently include non-causal narrative related to recommendations for research, policies, or other actions. Once a chapter draft is completed by the authors, it is provided to the senior scientific editorial team; this allows for independent consideration of the presented evidence to evaluate the basis for the conclusions and to revise them, as appropriate.

Initial review of the chapter content by the senior scientific editorial team is followed by external peer-review of individual chapters. Peer-reviewers are identified through both literature reviews and recommendations from the senior scientific editorial team and authors based on relevant expertise. The peer-review process includes individuals selected to review specific chapters, as well as individuals with broader expertise in the tobacco control field who are selected to review the entire report. Effort is made to include a balance of reviewers who reflect a diversity of perspectives on a particular topic. Once comments from all peer-reviewers are considered, the report begins scientific clearance within CDC and the US

Department of Health and Human Services. The review and clearance process includes cross-agency review by other US Government departments and agencies. The senior scientific editorial team is tasked with incorporating revisions during the entire review process, and authors are routinely contacted to verify the accuracy and appropriateness of any edits.

Throughout the review process, the report content is revised to include studies and information not available at the time the chapters were initially drafted; updates are made until the report is submitted for publication, which occurs at least 4 weeks before the report's release. Given the breadth of each report and extent of review up until this period, prioritization for updates at this point is given to research that is salient to the topics addressed in the report conclusions. These updates are made to reflect the full scope of available evidence, including new findings that confirm, refute, or refine the initial content. Based on the preponderance and quality of scientific evidence, conclusions are revised accordingly. Throughout the writing and review process, deference is given to peer-reviewed, scientific research that is free from tobacco industry interests. As noted in the 2014 Surgeon General's Report, the tobacco industry has a well-documented record of manipulating scientific information and the extent of the harms from cigarette smoking.<sup>3</sup>

Once the report has completed review via the aforementioned process, it is cleared for release by the Secretary of the US Department of Health and Human Services. At that time, CDC OSH works in consultation with OSG to coordinate the release of the report and prepares supporting materials such as consumer guides and fact sheets. Traditionally, reports are released by the Surgeon General via a press conference, which is attended by US Government officials; report editors, authors, and reviewers; and national, state, and local tobacco control practitioners.

## 2016 Surgeon General's Report on E-cigarette Use Among Youth and Young Adults

In 2016, the Office of the Surgeon General released *E-Cigarette Use Among Youth and Young Adults*.<sup>6</sup> This most recent report is the first Surgeon General's Report on e-cigarettes, specifically, and the first federal report to comprehensively review the public health impact of these products on young people. However, the broader potential public health impact of e-cigarettes was previously outlined in the 2014 Surgeon General's Report, which noted that the increasing availability of e-cigarettes raises the question of the utility of these products for helping to reduce the harm caused by combustible tobacco use among adult smokers; this assertion was based on the general consensus that exclusive use of e-cigarettes poses a lower health risk to the individual than the extremely high health risks of combustible tobacco smoking.<sup>3</sup> On balance, the 2014 report also noted that "a public health standard is critical because strategies that reduce potential harm from toxicant exposure to individual users of tobacco products could adversely affect other individuals and public health" (page 873).<sup>3</sup> The 2014 report did not specify a role for e-cigarettes or discuss strategies to minimize adverse effects among youth and young adults. However, it outlined considerations for the future, and reinforced the importance of further research on the individual and population

level health impact of these products, including the full range of potential benefits and harms.<sup>3</sup>

One potential harm related to e-cigarettes noted in the 2014 report was experimentation of tobacco product and nicotine use among young people.<sup>3</sup> Faced with an unprecedented 900% increase in current e-cigarette use among US youth during 2011–2015,<sup>6</sup> there was a clear need at the time of the report’s compilation for a comprehensive review of the available scientific evidence, including policies and strategies that are available to reduce the public health threat posed by e-cigarettes among young people. To address this need, the 2016 report focused on the history, epidemiology, and health effects of e-cigarette use among youth and young adults; marketing and promotion of e-cigarettes; existing and proposed public health policies regarding the use of these products by youth and young adults; and actions that can be taken to protect young people from e-cigarettes. In keeping with the longstanding tradition of Surgeon General’s Reports on Tobacco, the report outlined evidence pertaining to tobacco control policies and strategies intended to reduce the public health risks among the population of focus, and provided an important blueprint for the scientific community by highlighting evidence gaps.<sup>6</sup> The 2016 report was focused specifically on youth and young adults given the dramatic rise in use among this population, but did briefly acknowledge important issues related to e-cigarette use in adult populations, including any gains that might be made if the products facilitated a decline in conventional smoking among adults. Further, when articulating current scientific gaps, the report called for further research to characterize the potential net harms and benefits of e-cigarettes on individual and population level health, including their potential effectiveness for smoking cessation. This discussion set a foundation for a more nuanced review of this issue, as the science continues to emerge, in subsequent Surgeon General’s Reports.

The 2016 report was compiled using the previously described approach for prior Surgeon General’s Reports on Tobacco. Some of the report’s senior scientific editorial team had served a comparable role for the youth-focused 2012 Surgeon General’s Report, *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*.<sup>7</sup> The senior scientific editorial team initially met with contributing editors in February 2015, and writing, review, and editing of the report occurred through November 2016. The process to compile and review the report included 4 senior scientific editors, 7 contributing editors, 23 contributing authors, 26 other contributors such as analysts, 64 peer-reviewers, and over 50 additional reviewers from CDC, the US Department of Health and Human Services, and other federal departments and agencies. The report was released on December 8, 2016 during a press conference in Washington, DC.

For the first time in the history of Surgeon General’s Reports on Tobacco, a “Call to Action” section was added to the 2016 report, which presents 6 goals and related strategies to guide local, state, and national efforts to reduce e-cigarette use among young people. The inclusion of the plain language Call to Action was part of a broader effort to enhance the readability, relatability, and utility of the Surgeon General’s Reports on Tobacco for a broader set of stakeholders, including the general public. To that end, an interactive website (<https://e-cigarettes.surgeongeneral.gov/>) and Public Service Announcement were also launched in coordination with the report’s release. These efforts served to complement the longstanding

legacy of these scientifically rigorous reports, while ensuring that the content continues to inform and guide the tobacco control landscape, researchers, and the public.

Consistent with previous Surgeon General's Reports on Tobacco, the content in the 2016 report reflects the evidence base available at the time of publication. The framing and content of the conclusions are reflective of the brief time that e-cigarettes have been in the US marketplace, the rapidly changing patterns of use of these products, and existing scientific gaps. Despite these factors, the report notes that the available evidence related to youth and young adults is enough to take action. In addition to the growing body of scientific literature on e-cigarettes documented in the report, the tobacco control field has decades of science documenting what works to effectively prevent tobacco product use among young people. The report notes that it is critical to apply these strategies to emerging tobacco products, including e-cigarettes, to protect our nation's young people from this preventable health risk.<sup>6</sup>

## Conclusion

Surgeon General's Reports on Tobacco serve a critical role in informing and protecting the public from the known and preventable risks associated with tobacco product use and secondhand smoke exposure. A longstanding, peer-reviewed, and comprehensive process is used to safeguard the scientific rigor and practical relevance of the reports. It is critical that the established process for writing these reports continues, while ensuring that the reports and their content remain salient to key audiences as the landscape of tobacco product use and control, and society more generally, modernizes and evolves.

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