E-Cigarettes as Consumer Products

Stanton A. Glantz, PhD

ABOUT THE AUTHOR

Stanton Glantz is a retired University of California San Francisco (UCSF) professor of medicine and founding director of the UCSF Center for Tobacco Control Research and Education.

Balfour et al.¹ argued for balancing the risks and benefits of e-cigarettes, based on the value of e-cigarettes as cigarette smoking—cessation aids for adult smokers. In particular, they cited our meta-analysis of e-cigarettes and smoking cessation² to support their statement, "Other researchers have found regular and frequent e-cigarette use to be associated with increased smoking cessation, while infrequent use was not."¹(p1663)

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Like the discussion by Balfour et al. of the health effects of e-cigarettes, including the effects of nicotine on children,³ this statement is a highly selective reading of our article.

Specifically, although it is correct that we found that daily e-cigarette use was associated with significant increases in cigarette cessation (odds ratio [OR] = 1.529; 95% confidence interval [CI] = 1.158, 2.019), we also found that nondaily use was associated with significantly less quitting (OR = 0.514; 95% CI = 0.402, 0.656). Most importantly, among all users, there was no significant association between e-cigarette consumer product use and quitting (OR = 0.947; 95% CI = 0.772, 1.160), the key conclusion in our article.

Balfour et al. ignored this primary conclusion and instead focused on criticizing our earlier meta-analysis, ⁴ which was superseded by the new article² that was based on more than twice as many studies and was specifically designed to address the limitations of the earlier work.

We did find that the randomized controlled trials of free e-cigarettes provided in smoking-cessation trials (often combined with counseling) were associated with increased cessation.² As Balfour et al.,¹ Samet and Barrington-Trimis,³ and we² recognized, randomized controlled trials are relevant for assessing

medicines, not consumer products. Indeed, Balfour et al. recognized, "Noteworthy is the lack of trials by e-cigarette manufacturers in pursuit of regulatory agency approval to use e-cigarettes for smoking cessation, likely reflecting the profitability of selling e-cigarettes as consumer products, rather than medicinal devices." (p1663) These randomized controlled trials are not, however, relevant to the US Food and Drug Administration Center for Tobacco Products' decision of whether to authorize sale of e-cigarettes as consumer products in the United States.

Balfour et al. ignored our primary conclusions: "As consumer products, in observational studies, e-cigarettes were not associated with increased smoking cessation in the adult population" and, so, "E-cigarettes should not be approved as consumer products." ^{2(p.e1)}

CORRESPONDENCE

Correspondence should be sent to Stanton A. Glantz, PhD, 1474 24th Ave, San Francisco, CA 94122 (e-mail: stanton.glantz@sonic.net). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

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CONFLICTS OF INTEREST

The author reports no conflicts of interest.

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Balfour et al. Respond

David J. K. Balfour, DSc, Neal L. Benowitz, MD, Suzanne M. Colby, PhD, Dorothy K. Hatsukami, PhD, Harry A. Lando, PhD, Scott J. Leischow, PhD, Caryn Lerman, PhD, Robin J. Mermelstein, PhD, Raymond Niaura, PhD, Kenneth A. Perkins, PhD, Ovide F. Pomerleau, PhD, Nancy A. Rigotti, MD, Gary E. Swan, PhD, Kenneth E. Warner, PhD, and Robert West, PhD

ABOUT THE AUTHORS

David J. K. Balfour is retired from the Division of Systems Medicine, School of Medicine, University of Dundee, Dundee, UK. Neal L. Benowitz is with the Department of Medicine, School of Medicine, University of California, San Francisco. Suzanne M. Colby is with the Department of Psychiatry and Human Behavior, Alpert Medical School, Brown University, Providence, RI. Dorothy K. Hatsukami is with the Department of Psychiatry and Behavioral Sciences, Medical School, University of Minnesota, Minneapolis. Harry A. Lando is with the Division of Epidemiology and Community Health, School of Public Health, University of Minnesota, Minneapolis. Scott J. Leischow is with the College of Health Solutions, Arizona State University, Phoenix. Caryn Lerman is with the Norris Comprehensive Cancer Center, Keck School of Medicine, University of Southern California, Los Angeles. Robin J. Mermelstein is with the Department of Psychology, University of Illinois-Chicago. Raymond Niaura is with the Department of Epidemiology, School of Global Public Health, New York University, New York, NY. Kenneth A. Perkins is with the Department of Psychiatry, School of Medicine, University of Pittsburgh, Pittsburgh, PA. Ovide F. Pomerleau is with the Department of Psychiatry, Medical School, University of Michigan, Ann Arbor. Nancy A. Rigotti is with the Department of Medicine, Massachusetts General Hospital, Harvard Medical School, Boston, MA. Gary E. Swan is with the Stanford Prevention Research Center, Department of Medicine, Stanford University School of Medicine, Palo Alto, CA. Kenneth E. Warner is with the Department of Health Management and Policy, School of Public Health, University of Michigan, Ann Arbor. Robert West is with the Department of Behavioural Science and Health, University College London, London, UK.

Stanton Glantz writes that "the key conclusion" in his and his colleagues' meta-analysis was that "among all [e-cigarette] users, there was no significant association between e-cigarette consumer product use and quitting [smoking]." This finding derives from the authors combining daily e-cigarette users, who show significantly increased smoking cessation rates, with nondaily users, who have significantly lower quit rates. We consider it illogical to merge the two. In our article, we say that the difference in quit rates could reflect self-selection: daily e-cigarette users may be

more motivated to quit smoking, whereas some infrequent vapers may use e-cigarettes as a temporary nicotine source where smoking is prohibited. The point is that people who want to quit smoking and use e-cigarettes frequently exhibit a statistically significantly increased odds of quitting, just as with daily versus infrequent adherence to nicotine replacement therapy. We suggest that regular vaping may help a subset of smokers—not all smokers—to quit. We see e-cigarettes, properly regulated, as representing a potentially important addition to the

armamentarium of smoking cessation treatments and policies.

On the basis of their key conclusion, Glantz and his colleagues drew a second "principal conclusion," namely, that "Ecigarettes should not be approved as consumer products."^{1(p.e1)} We disagree. First, as noted, the key conclusion on which this second conclusion rests inappropriately merges the experiences of daily e-cigarette users with those of nondaily users. Second, approval of e-cigarettes as consumer products should derive from review of all the evidence. In our article, we enumerate four distinct types of evidence that, combined, resulted in our conclusion that e-cigarettes likely increase smoking cessation. We consider the evidence strong, if not definitive (as stated in the article). One of those types of evidence is randomized clinical trials, which, Glantz acknowledges, find e-cigarettes more effective for quitting smoking than Food and Drug Administration-approved nicotine replacement therapy products. However, Glantz considers RCTs not relevant to the use of e-cigarettes as consumer products. We disagree. Although not sufficient on their own, randomized clinical trials can provide valuable evidence regarding product safety, use patterns, and the impact on other tobacco product use, among other things.

Unlike Glantz, many of us have never taken a position on e-cigarettes. Indeed, we have diverse views on the range of e-cigarette issues. Our article reflects our collective review of the evidence and many conversations about its interpretation.

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