



The Need for Communication Research in Regulatory Science: Electronic Cigarettes as a Case Study

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Regulatory science is the practice of using the scientific method to gather information and develop new tools to inform the decision-making process of federal regulators. In 2010, the U.S. Food and Drug Administration (FDA), in conjunction with the National Institutes of Health, proposed new initiatives to promote enhanced regulatory science efforts. The focus of these efforts was the advancement of biomedical research to improve patient safety and treatments. Communication scholars have weighed in on efforts related to *communications* policy through the subfields of political, health, and media communication. Likewise, a role for communication science certainly exists in regulatory science work. This commentary identifies several areas where communication scholars can leverage their expertise in regard to regulatory science research. Although this commentary uses tobacco regulatory science and electronic cigarettes (one segment of a large trend of emerging tobacco products) as an illustration, the purpose of the commentary is to encourage communication researchers to consider their role in regulatory science more broadly.

Communication in Tobacco Control Versus Tobacco Regulatory Science

To better understand regulatory science, its distinctions from policy should be acknowledged. Tobacco is a leading cause of preventable death in the United States and elsewhere. To minimize these mortality rates, tobacco control efforts include both government policies and nongovernmental programs that address tobacco use and attempt to reduce its burden on public health. For example, the World Health Organization proposed MPOWER (Monitor tobacco use and prevention policies; Protect people from tobacco smoke; Offer help to quit smoking; Warn people against the dangers of tobacco; Enforce bans on tobacco advertising, promotion, and sponsorship; Raise taxes on tobacco) as a tobacco control strategy. In the United States, the Family Smoking Prevention and Tobacco Control Act of 2010 provides regulatory authority to the FDA to monitor the manufacturing, distribution, and marketing surrounding traditional tobacco products (i.e., cigarettes and smokeless tobacco). In line with the Tobacco Control Act, both the FDA and the National Institutes of Health have incorporated regulatory science to inform decision making related to domestic tobacco control. This can range from research investigating addiction and adverse effects to tobacco products to the economics underlying the tobacco marketplace. Several aspects of tobacco control related to communication remain underexamined. For example, understanding how tobacco product packaging can communicate harm or how to reduce the influence of tobacco marketing are regulatory science questions that can be readily addressed by communication research and scholars.

An area particularly ripe for communication research in regulatory science surrounds emerging tobacco products, such as electronic cigarettes (e-cigarettes). At present, not much is known about the risks affiliated with or discourses surrounding these products. Emerging tobacco products (i.e., electronic cigarettes, hookah) remain exempt from the present FDA mandates. To close these gaps in regulatory authority, the FDA proposed a "deeming rule" in April 2014 that would provide the FDA with authority to classify new and emerging tobacco products to be subject to current regulation. At present, the comments surrounding the proposed legislation are under review, and the FDA is expected to respond to the concerns before a final rule is issued, as early as 2015. Should the authority to regulate emerging tobacco products be approved, much information is needed to help inform FDA decisions regarding regulatory practices of these products. For example, should electronic cigarettes and other emerging tobacco products become subject to regulations that are equal to or stricter than those that currently apply to cigarettes and smokeless tobacco? How do people talk about these emerging tobacco products? How do we discuss their potential risks?

A central problem in the regulation of emerging tobacco products is that their adoption and use patterns are changing faster than our ability to understand them. This uncertainty affects both public health practitioners and communication scholars. The novel nature of emerging tobacco products poses difficulties in communicating risk and crafting policies when many of the effects and social contexts underlying these tobacco products are underexplored. Practitioners must communicate and policy makers must regulate these products with limited information and assumptions. If emerging tobacco products are classified as under the jurisdiction of the Tobacco Control Act, then many communication-related regulations will also be put in place, such as monitoring the advertising and marketing of these products. This commentary provides an overview of key questions in communicating emerging tobacco product information, specifically questions related to the most novel of these products—electronic cigarettes. E-cigarettes are used to illustrate the host of communication challenges posed by an uncertain and evolving tobacco environment. While biomedical researchers take time to thoroughly examine adverse health effects of these products, communication scholars can work quickly to shape the discourse surrounding these products and convey the risks associated with their use.

What Are Electronic Cigarettes?

E-cigarettes are electronic nicotine delivery systems (sometimes referred to as ENDS). They are devices that can be refilled with vaporized liquids that include nicotine (Odum, O'Dell, & Schepers, 2012). They are posited to be less harmful than traditional smoking products because they do not contain tobacco or chemicals (Odum et al., 2012). However, little research has examined the health effects of e-cigarettes, mostly because of the novelty of the products. E-cigarettes pose interesting challenges for tobacco control researchers. Advancements in e-cigarettes are outpacing our understanding of their health effects, use patterns, and the communication surrounding these products. These products are, in many ways, redefining who is at risk; they have a complicated role in tobacco control; and they are proliferating in use faster than the products can be understood.

Who Is at Risk?

Central to crafting messages intended to communicate risk is an understanding and identification of the population most vulnerable to that risk and targeting messages that specifically address these populations (Kreuter & Wray, 2003). For e-cigarettes, it is unclear who constitutes the at-risk population. Some existing tobacco users are integrating emerging tobacco products and are evolving into multiple tobacco users. Nonsmokers may be enticed by the potentially less harmful effects of ENDS. The shifting norms of new adopters of ENDS complicate message strategies, and multiple groups of tobacco users may be at increased risk with the availability of ENDS such as e-cigarettes.

Existing tobacco users appear to have more interest in e-cigarettes than in other forms of tobacco such as smokeless tobacco (Berg, Haardoerfer, Escoffery, Zheng, & Kegler, 2015). A few studies have found that the tendency to try and use e-cigarettes was highest among current tobacco users (Giovenco, Lewis, & Delnevo, 2014; King, Alam, Promoff, Arrazola, & Dube, 2013; Pearson, Richardson, Niaura, Vallone, & Abrams, 2012). The use of e-cigarettes by existing tobacco users could contribute to a new and troubling tobacco norm of multiple product use among younger people. Lee, Hebert, Nonnemaker, and Kim (2014) found that more than 10% of U.S. adults use multiple tobacco products, with multiple tobacco use being common among younger individuals. A longitudinal study of young adults conducted by Richardson, Williams, Rath, Villanti, and Vallone (2014) revealed that multiple tobacco product use was the most common pattern among tobacco users over time, and that the multiple tobacco products included emerging tobacco products.

Former tobacco users also may find e-cigarettes appealing. A survey in Great Britain found that 21% of current and former smokers who quit within the last year use e-cigarettes (Brown et al., 2014). A longitudinal Internet-based survey found that 76% of former smokers were using e-cigarettes daily (Etter & Bullen, 2014). This use of e-cigarettes among former smokers may be due to the desire to use e-cigarettes as a cessation tool, easing tobacco users into nonsmoking. Nonsmokers are at risk as well. Sutfin, McCoy, Morrell, Hoepfner, and Wolfson (2014) found that 12% of college student e-cigarette users had never tried another form of tobacco. A general population sample of British adults revealed that e-cigarette use increased from 2.7% to 6.7% between 2010 and 2012 (Dockrell, Morrison, Bauld, & McNeill, 2013). The prevalence of ENDS among younger Americans also is troubling. E-cigarette use doubled for both middle school students and high school students between 2011 and 2012 (Camenga et al., 2014). Chapman and Wu (2014) found e-cigarette use was highest among young adults. Students were primarily introduced to e-cigarettes by media and friends, with peer influence being a strong factor in e-cigarette use (Cho, Shin, & Moon, 2011).

Thus, the vulnerable populations are not well defined. More research on potentially high-risk e-cigarette populations would guide practitioners and policy makers when curbing e-cigarette marketing efforts. Researchers should extend their work on prevalence and use rates and further examine the contexts in which the products are used. Such an examination can help communication scholars understand how to target messages and to which populations.

Advertising and Marketing

Emerging tobacco products are not currently subject to the communication restrictions that apply to traditional tobacco products. As a result, discourse surrounding e-cigarettes has increased dramatically across multiple media formats. In addition to understanding the content of e-cigarette messages, communication researchers can monitor the explosive increase of advertising and marketing. E-cigarette advertising tripled across magazines, TV, the Internet, and newspapers between 2011 and 2012 (Kim, Arnold, & Makarenko, 2014). And e-cigarette marketing around school campuses has doubled (Sutfin et al., 2013). These advertisements emphasize the positive aspects of e-cigarette use. Grana and Ling (2014) found that nearly all (i.e., 95%) e-cigarette retail websites advertised health claims, including that e-cigarettes were cleaner than tobacco cigarettes, helped smoking cessation, and had no secondhand smoke effects. The websites had numerous appeals to social status and celebrity use that may be particularly engaging youth populations and encouraging people to adopt the use of e-cigarettes (Grana & Ling, 2014). Paek, Kim, Hove, and Huh (2014) similarly found that e-cigarettes were framed with social benefits on YouTube videos.

A few studies have examined how these marketing efforts change perceptions or behaviors. Agaku and Ayo-Yusuf (2014) found that adolescents exposed to tobacco advertisements were more likely to smoke e-cigarettes and use other emerging tobacco products. Individuals are also seeking more information about e-cigarettes. Tobacco control efforts and proposed regulations (i.e., clean air) have been related to search queries related to ENDS such as e-cigarettes (Ayers, Ribisl, & Brownstein, 2011). Researchers have found, for example, an increase in marketing of smokeless tobacco to those typically considered low risk for traditional tobacco products (Dave & Saffer, 2013). Pepper, Emery, Ribisl, Southwell, and Brewer (2014) additionally found that viewing e-cigarette advertisements that modeled use generated interest in using e-cigarettes. Given the increase in e-cigarette messages and also the potential links between these messages and effects, communication scholars should further explore these messages.

Communicating E-cigarette Risk

Despite the relatively little scientific knowledge that exists about the adverse effects of e-cigarettes due to their novelty, preliminary beliefs and attitudes toward e-cigarettes are already emerging among the general public. The sources of such perceptions are due to communications surrounding e-cigarettes and the lack of regulation for claims made about e-cigarettes (unlike traditional tobacco products, which are subject to communication restrictions). These perceptions focus on the benefits of e-cigarettes, trivializing their potential adverse health effects and potentially encouraging adoption. As a result, communication researchers should be vigilant about where the public is getting this information and what is creating these norms and perceptions. An additional burden is on message designers to develop campaign messages that discourage the option of emerging tobacco products without creating a "forbidden fruit effect"—the desire to experiment because one has been informed of a risk involved (see Bushman & Stack, 1996).

Foremost, e-cigarettes are perceived as "healthier" than traditional tobacco products and these perceptions are related to initiation and use. In one study, 51% of survey respondents perceived that e-cigarettes were less harmful than traditional cigarettes, and those who were younger, more educated, and current smokers were more likely to endorse these beliefs (Tan & Bigman, 2014). Pokhrel, Little, Fagan, Muranaka, and Herzog (2014) found that college students who had a positive association with e-cigarettes had greater intentions for e-cigarette initiation, regardless of previous smoking status. Choi and Forster (2014) found that young adults perceived e-cigarettes as a tool for smoking cessation and overall as less harmful than regular cigarettes; however, these perceptions were related to the likelihood of e-cigarette experimentation at follow-up (regardless of smoking status), placing them at risk for initiation and use. Some existing smokers did not use e-cigarettes for quitting, but rather to use nicotine with less negative health implications than other tobacco products (Barbeau, Burda, & Siegel, 2013). McAuley, Hopke, Zhao, and Babaian (2012) also found e-cigarettes to have lower emissions than tobacco cigarettes and to present less risk to public health, in some ways indicating a promising situation for tobacco control advocates. These novel statements may be shielding users from the unknown health effects. Without more knowledge about the benefits and detriments, users, policy makers, and researchers must make decisions based on limited information.

E-cigarettes are also portrayed as beneficial as a potential cessation tool. Regulation of e-cigarettes would provide standards and guidelines to maximize the safe uses of these products. However, this regulation also comes at the potential cost of transitioning individuals into multiple tobacco product users should their cessation attempts fail. The attention e-cigarettes receive for being smoking cessation tools or a better alternative to tobacco potentially encourages their increased use. E-cigarettes may be good delivery systems for medicinal use and could be used for purposes separate from their named association with tobacco (Bell & Keane, 2012). Smokers attempting to quit appear to be amenable to using e-cigarettes over nicotine replacement therapy (i.e., patches). Focus groups conducted by Barbeau, Burda, and Siegel (2013) found that smokers regarded e-cigarettes as a potentially useful tool for smoking cessation, because they allowed the smokers to internalize a new identity (i.e., "vaper" vs. "smoker") and have community support for cessation. Additionally, these individuals noted that they had tried using other traditional nicotine replacement therapy (such as gum or patches), but had been unsuccessful (Barbeau et al., 2013).

The narratives of individuals are corroborated in case studies. A case study of tobacco patients who suffered from depression and were prone to relapses revealed e-cigarettes as a gateway to quitting (Caponnetto, Polosa, Auditore, Russo, & Campagna, 2011). A randomized control trial by Bullen and colleagues (2013) found that placebo e-cigarettes (without nicotine) and e-cigarettes (with nicotine) both helped curb smoking behavior. However, they found that this effect was not much different from nicotine patches. Similarly, Etter and Bullen (2011) found that ex-smokers used e-cigarettes to reduce traditional tobacco use and avoid relapsing, and also to give them the ability to use the products where smoking was prohibited. In one study, 60% of smokers said e-cigarettes did help them reduce traditional tobacco smoking (Kralikova, Novak, West, Kmetova, & Hajek, 2013). Siegel, Tanwar, and Wood (2011) found that, while some smokers abstained entirely from cigarettes, more than 65% said they had at least reduced the number of cigarettes used. However, such studies are all recent and long-term effects remain unknown.

Communication scholars have the burden of navigating the presentation of these risks and effects. On the one hand, little is known about the adverse effects of e-cigarettes and their potential appeal among youth and other vulnerable populations. Although they may serve as replacements for detrimental health practices, e-cigarettes certainly do not lead to better health. On the other hand, if e-cigarettes are effective at curbing or at least reducing smokers' use of traditional tobacco, then they are a relatively better alternative (Foulds, Veldheer, & Berg, 2011).

Thus, our understanding of emerging tobacco products such as e-cigarettes is complicated by our discussion of their relativity to the use of traditional cigarettes and smokeless tobacco. Communication researchers need to uncover how to best discuss tobacco products and multiple product use when much of the current discourse has framed ENDS as a potential "positive" in the tobacco environment. Though communicating risk is hindered by the time needed to fully understand the adverse health effects, communication scholars can shape risk perceptions and discourse. Future research should explore what spheres of influence prompt these beliefs, such as social networks or tobacco marketing.

Conclusion

The primary objective of regulatory science is to use empirical research to inform the development and decision-making surrounding policy. The focus of regulatory science is often on the hard sciences such as biological and medicinal research. However, communication scholars also have a place in this work. For novel risks, such as those related to emerging tobacco products (and specifically e-cigarettes), where little is known about the health effects, communication surrounding these issues is at the forefront.

As noted in this commentary, the lack of regulation on how risks can be described in marketing and advertising and discourse that promotes the benefits of e-cigarette use might explain the positive discourse surrounding e-cigarettes and other tobacco products. Researchers and practitioners can inform health policy by understanding several aspects about the communication environment: who is at risk, where they get their information, how to balance the framing of risks, and what restrictions should be placed on communication surrounding these risks. Though the commentary used e-cigarettes as the exemplar and tobacco control as the primary context, these struggles occur for other health issues, such as medical marijuana. It is hoped that this commentary inspires communication scholars to consider their important role and participation in regulatory science.

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