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## Communication Regulatory Science: Mapping a New Field

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### Abstract

Communication regulatory science is an emerging field that uses validated techniques, tools, and models to inform regulatory actions that promote optimal communication outcomes and benefit the public. In the opening article to this special issue on communication and tobacco regulatory science, we 1) describe Food and Drug Administration (FDA) regulation of tobacco products in the US; 2) introduce communication regulatory science and provide examples in the tobacco regulatory science realm; and 3) describe the special issue process and final set of articles. Communication research on tobacco regulatory science is a burgeoning area of inquiry, and this work advances communication science, informs and potentially guides the FDA, and may help to withstand legal challenges brought by the tobacco industry. This research has the potential to have a major impact on the tobacco epidemic and population health by helping implement the most effective communications to prevent tobacco initiation and increase cessation. This special issue provides an example of 10 studies that exemplify tobacco regulatory science and demonstrate how the health communication field can affect regulation and benefit public health.

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The first nationwide report on smoking and health was released on January 11, 1964, by Luther L. Terry, the US Surgeon General at the time, and linked smoking to chronic bronchitis, lung cancer, and mortality (US Department of Health and Human Services, 1964). While the evidence of harms from smoking was beginning to emerge at that time, it has grown enormously in the more than 50 years since that report. We now know that smoking causes diseases of nearly every organ of the body, and that even in the 21<sup>st</sup> century the Surgeon General continues to causally link smoking to yet more diseases. All told, smoking causes more than 480,000 deaths each year in the United States (US) and continues to be the number one preventable cause of death in the US (US Department of Health and

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Human Services, 2014). Of the young people alive today, 5.6 million are expected to die prematurely as a result of tobacco use (US Department of Health and Human Services, 2014).

What has been done at the national level to communicate with the public about the health risks of smoking? After the publication of the 1964 Surgeon General's report, the US Congress passed laws in the 1960s requiring a text-only health warning on cigarette packages. In 1984, the Congress attempted to strengthen the health warnings by replacing the single health warning with four rotating cigarette pack warnings. In 1998, the Master Settlement Agreement between 46 state attorneys general and the tobacco industry resulted in the creation of the American Legacy Foundation, which developed and implemented the national *Truth* anti-smoking campaign (Farrelly, Davis, Haviland, Messeri, & Healton, 2005). In 2009 the Affordable Care Act created the first federally funded anti-smoking mass media campaign—*Tips from Former Smokers*—which told the stories of the debilitating health consequences of smoking from the perspective of real people (McAfee, Davis, Alexander, Pechacek, & Bunnell, 2013).

These efforts—along with numerous state and local tobacco control media campaigns and policies such as clean indoor air laws and tobacco taxes (Bonnie, Stratton, & Wallace, 2007)—have reduced smoking rates from 42% in 1965 to 15.1% in 2015 (Centers for Disease Control and Prevention, 2016; US Department of Health and Human Services, 2014). Despite this enormous progress, more than 42 million Americans continue to smoke cigarettes, and the burden of smoking and smoking-related disease disproportionately affects disadvantaged groups, such as those with lower levels of education (US Department of Health and Human Services, 2014). Moreover, the emergence of non-cigarette tobacco products—including various forms of cigars, waterpipe tobacco, and e-cigarettes—has created a diversified tobacco product landscape and made the problem of tobacco that much more complex. While cigarette smoking has been decreasing, use of many novel and emerging tobacco products such as e-cigarettes and waterpipe tobacco is increasing, especially among young people (Singh et al., 2016), posing new challenges for tobacco prevention and control efforts.

In the current article, we 1) discuss Food and Drug Administration (FDA) regulation of tobacco products; 2) introduce communication regulatory science; and 3) provide an overview of this special issue on communication and tobacco regulatory science.

## **Family smoking prevention and tobacco control act**

In 2009, the US Congress passed a groundbreaking law—the Family Smoking Prevention and Tobacco Control Act (FSPTCA)—which gave the FDA the authority to regulate tobacco products in the United States. While initially only authorizing the FDA to regulate cigarettes, cigarette tobacco, smokeless tobacco, and roll your own tobacco, the law allowed the FDA to write rules that would bring additional products under their jurisdiction. Indeed, in 2016, the FDA's deeming rule officially brought cigars, waterpipe tobacco, and e-cigarettes under its regulatory authority (US Food and Drug Administration, 2016).

Traditionally, the FDA has used a standard of “safety and efficacy” for its regulated products (e.g., food, drugs, medical devices, biological products). However, because tobacco products are inherently harmful and therefore cannot be regulated using the safe and effective standard, the FDA must apply a new “public health” standard that takes into account both the net population level impact of tobacco products and the impact of regulatory actions (benefits and risks) on both users and non-users of tobacco products. To achieve this public health standard, the FDA created the Center for Tobacco Products (CTP) to regulate the manufacture, distribution, and marketing of all covered tobacco products. The CTP has overarching goals to 1) prevent people from starting to use tobacco products, 2) encourage tobacco users to quit, and 3) decrease the harms of tobacco product use. The CTP must evaluate not only product toxicity and health risks associated with using tobacco products, but also the impact of tobacco product characteristics and tobacco product marketing on attitudes, beliefs and perceptions about tobacco products as well as behavior. In order to accomplish this, much research is needed, especially for many new and emerging tobacco products for which there is relatively little scientific evidence.

### Communication regulatory science research

As required by the Tobacco Control Act, the FDA must identify and use the best scientific evidence to inform its actions. Moreover, high quality scientific evidence in the communication arena can inform FDA in several ways. First, it can advance our understanding of existing communication practices in the marketplace that may be misleading to consumers. For example, the FDA recently sent letters to cigarette manufacturers asking them to cease using the descriptors “natural” and “additive-free” in cigarette advertising on the basis that those terms can mislead consumers into thinking some cigarettes are less harmful than others. Research on these and other such descriptors has the potential to inform FDA’s current and future actions in this area (O’Connor, Lewis, Adkison, Bansal-Travers, & Cummings, 2017; Pearson et al., 2017). Second, research can identify the most effective communications for the population as a whole and for different subpopulations, and can ensure that such communications have intended effects (and no iatrogenic effects). For example, research has examined themes for tobacco education campaigns aimed at youth, and identified the most promising themes (Brennan, Momjian, & Hornik, 2013). Based in part on this work, the FDA developed and pre-tested messages (Zhao et al., 2016) and launched their nationwide *The Real Cost* campaign to prevent tobacco initiation and disrupt experimentation among youth (Duke et al., 2015). Third, research can provide the evidence base to help withstand legal challenges to actions that the FDA wishes to take, but that may be disputed by the industry. For example, the burgeoning literature on pictorial cigarette pack warnings (Maynard, 2017; Meernik et al., 2016; Noar et al., 2016a) may be useful in the event of additional legal challenges to pictorial warnings proposed by the FDA for cigarette packs.

To generate research to inform its actions, the FDA created an Office of Science within the CTP (Ashley & Backinger, 2012). In addition, the FDA partnered with the National Institutes of Health (NIH) to fund independent tobacco regulatory research that can inform their regulatory actions (Andrews, Choiniere, & Portnoy, 2015). *Tobacco regulatory science* is a distinct scientific discipline that “serves as the critical bridge between tobacco products

and public health by enabling the FDA to assess various products' inherent risks and how they are used, and regulate them accordingly" (Ashley, Backinger, Van Bommel, & Neveleff, 2014, p. 1046). While scientists often design studies to answer a particular research question—that is, advancing an understanding of theoretical mechanisms—regulatory science is designed with the primary goal of informing regulatory actions, while secondary goals may involve understanding theoretical mechanisms.

We define *communication regulatory science* as communication research that uses validated techniques, tools, and models to inform regulatory actions that promote optimal communication outcomes and benefit the public (Ashley et al., 2014). Unlike standard communication research, which may vary from pilot studies to larger, higher quality studies, communication regulatory studies must culminate in the highest quality studies, as such work may inform the policies of national regulatory entities. Also, its primary goal is to inform communications used in regulatory actions, whereas the advancement of the theory and science of communication are secondary aims of the inquiry.

Communication regulatory science can involve communication work that informs regulatory agencies in virtually any arena. Here, we focus on *tobacco* regulatory science and the FDA. While the FDA/NIH is capable of funding any research that informs their tobacco regulatory authority, such agencies have priority areas. In the case of the FDA, published documents suggest that priorities have evolved over time as the science has progressed. For instance, in the original request for applications (RFA) for Tobacco Centers of Regulatory Science (TCORS), communication and marketing were two of seven research interest areas, and the call was fairly broad in terms of studies examining various aspects of understanding communications and marketing about tobacco use (National Institutes of Health, 2012). The science has progressed since that time and regulatory priorities have changed. For example, in the TCORS renewal RFA, communication and marketing are again two of seven research domains, but there is a much stronger emphasis on non-cigarette tobacco products which largely represent the new and emerging products now under FDA's authority (National Institutes of Health, 2017).

## Examples of communication regulatory science research

To provide a concrete example of communication regulatory science in the tobacco realm, we use the example of cigarette pack warnings. Research has demonstrated that the four text-only, Surgeon General's warnings implemented on the side of cigarette packs are seldom noticed by smokers more than 30 years after they were implemented (Borland et al., 2009). The Tobacco Control Act mandated nine new cigarette warning statements for packs, along with images depicting the negative consequences of smoking that would cover 50% of the front and back of cigarette packs. The FDA conducted research to determine the most effective images to pair with the nine text statements (Nonnemaker, Farrelly, Kamyab, Busey, & Mann, 2010), and the FDA/NIH funded additional research to evaluate these nine proposed pictorial warnings. This regulatory science research has revealed much about pictorial cigarette pack warnings that builds the scientific literature and can inform the FDA's actions.

First, studies have indicated that the nine pictorial warnings developed by the FDA are perceived as significantly more effective in motivating quitting smoking and convincing youth not to smoke than text-only warnings (Byrne, Katz, Mathios, & Niederdeppe, 2014; Hammond, Reid, Driezen, & Boudreau, 2013) and they appear to have similar effects across both the general population and population subgroups that vary on race, education, and income levels (Cantrell et al., 2013; Gibson et al., 2015). They are also more likely to attract attention compared to text-only warnings (McQueen et al., 2015) and they increase heavy smokers' intentions to quit smoking (Blanton, Snyder, Strauts, & Larson, 2014).

Unfortunately, legal challenges from the tobacco industry have ensured that the warnings will not be implemented as proposed (Kraemer & Baig, 2013). The FDA is expected, however, to propose new warnings and pursue implementation once again. In the meantime, regulatory science research has responded to criticisms of the warnings in the court cases in ways that can inform the FDA. For example, a large randomized trial tested the ability of pictorial warnings applied to smokers' cigarette packs to impact smoking behavior over a 4 week period—and results indicated that they significantly increased quit attempts compared to the Surgeon General's text-only warnings (Brewer et al., 2016). This study responds to a major court criticism that the FDA had not presented evidence that the warnings would impact smoking behavior. Another study experimentally tested new pictorial warnings that use factual images and stories of real people who have suffered negative health consequences (Brennan, Maloney, Ophir, & Cappella, 2016). This study responds to court criticisms that some of the originally proposed images were non-factual in nature.

Meta-analytic and systematic review work has also brought together the large international research literature on cigarette pack warnings, which can inform and support U.S. policy. Across 37 controlled experimental studies with more than 33,000 participants conducted in 16 countries, pictorial warnings were found to better attract and keep attention, garner stronger cognitive and emotional reactions, elicit more negative attitudes about cigarette packs and smoking, and increase intentions to not start smoking and to quit smoking, compared to text-only warnings. Pictorial warnings were also perceived as more effective than text-only warnings at motivating avoidance of smoking initiation as well as motivating quitting (Noar et al., 2016b).

In addition, syntheses of observational studies have shown that after countries implemented stronger warnings—typically pictorial warnings—increases in attention, thinking about the risks of smoking, and perceptions of foregoing cigarettes were observed when compared to levels before implementation (Noar et al., 2017). These studies have also revealed increases in knowledge about the health risks of smoking and quit attempts and reductions in smoking prevalence when comparing before and after implementation periods (Noar et al., 2016). This line of regulatory communication science research provides evidence to inform the actions of the regulatory practices of the FDA.

## Special issue process

To advance the research in communication regulatory science regarding tobacco products, a call-for-papers for the current special issue was developed in conjunction with the TCORS

health communication working group and subsequently disseminated. The call requested abstracts on empirical, theoretical, and review work on communication research about tobacco regulatory science, broadly defined. The call-for-papers was distributed widely, resulting in 61 abstracts submitted for consideration. The work reported in the abstracts was primarily conducted in the United States (84%) and included authors from six TCORS institutions across the country. The most common communication topics were product warnings (23%), tobacco education advertising/campaigns (20%), pro-tobacco advertising (19%), and social media (19%). Less frequently studied topics included news media (5%), information seeking (3%), modified risk messaging (2%), and narrative communication (2%). Most studies (75%) examined a single tobacco product, while 15% studied multiple products (10% not reporting). The most commonly studied tobacco products were e-cigarettes and cigarettes, appearing in 41% and 31% of studies, respectively. Smokeless tobacco (9%), cigars (6%), and waterpipe tobacco (4%) were studied far less often. The most common method used in studies was an experiment (44%), followed by content analysis (23%) and surveys (17%). A minority of studies used qualitative methods (11%). While 56% of studies used convenience samples, nearly a third (31%) used probability samples and the remainder either did not report this information or it was not applicable.

The 61 abstracts were screened by the special issue editors for possible inclusion. Those deemed most promising were examined by the FDA for regulatory relevance, and this process resulted in 18 abstracts being invited to submit a full paper for review. After peer review, 10 of the 18 were asked to revise and resubmit and these 10 papers represent the content in this special issue.

## Special issue content

The special issue reports on 10 studies examining various aspects of communication regulatory science. Studies examine originally-regulated products such as cigarettes (Byrne et al., 2018; Lazard et al., 2018; Moran et al., 2018) and smokeless tobacco (Wackowski, Manderski, Lewis, & Delnevo, 2018) as well as new and emerging products such as e-cigarettes (Cornacchione Ross, Noar, & Sutfin, 2018; Kim, Popova, Halpern-Felsher, & Ling, 2018; Mays, Villanti, Niaura, Lindblom, & Strasser, 2018; Moran et al., 2018; Walter, Demetriades, & Murphy, 2018; Yang, Liu, Lochbuehler, & Hornik, 2018), little cigars and cigarillos (Cornacchione Ross et al., 2018; Moran et al., 2018; Sutfin et al., 2018), and waterpipe tobacco (Cornacchione Ross et al., 2018; Sutfin et al., 2018). It includes studies that can inform the FDA in several areas of communication, and is organized in three sections.

The first section of the special issue features three studies examining advertising and pro-tobacco information. Tobacco advertising is a critically important issue in tobacco control. For example, in 2014, tobacco companies spent more than 9 billion dollars on advertising for cigarettes and smokeless tobacco in the United States (Federal Trade Commission, 2016). This translates to 25 million dollars per day or about 1 million dollars every hour. Understanding a variety of aspects of tobacco advertising is critical as FDA considers regulatory actions in this area. Moran and colleagues use data from the Population Assessment of Tobacco and Health (PATH) study to examine ethnic and socioeconomic



disparities in exposure to and impact of tobacco marketing, finding such marketing to play a larger role in tobacco use among African Americans and those of lower socioeconomic status (Moran et al., 2018). They suggest comprehensive tobacco control policies—including campaigns—to attempt to reverse these effects and thereby reduce tobacco-related disparities. Research also shows that adolescents are highly exposed to e-cigarette advertising, and this exposure is associated with higher levels of e-cigarette use (Office of the Surgeon General, 2016). Kim and colleagues examine the effects of e-cigarette advertisements on adolescents' perceptions of traditional *cigarettes* (Kim et al., 2018). They report intriguing findings in that never-smoking adolescents perceived lower risks of *cigarettes* after viewing e-cigarette advertising, compared to a control condition, suggesting that e-cigarette ads could have unintended negative consequences on adolescent perceptions of cigarettes. The authors suggest regulation of e-cigarette advertisements to reduce adolescents' exposure to such ads and prevent potential negative effects. In the third article in this section, Yang and colleagues examine the communication environment around e-cigarettes by looking at information seeking about e-cigarettes and its association with intentions to use (Yang et al., 2018). Using a longitudinal sample of youth and young adults, they find information seeking about e-cigarettes to predict e-cigarette use 6 months later, and information sought or found by youth was often positive or mixed in valence. This is in contrast to information about cigarettes which was typically much more negative in nature, and such information seeking did *not* predict cigarette use 6 months later. They suggest several remedies to make the public communication environment around e-cigarettes less positive, including advertising regulations, campaigns, and product warnings.

The second section of the special issue features four studies on product warnings and risk information. Product warnings have been an important tool for communicating with the public about tobacco product risk, and such warnings have become stronger over time as research has revealed some of the more effective elements (Hiilamo, Crosbie, & Glantz, 2014; Noar et al., 2017). Byrne and colleagues examine responses to variations of text and pictorial cigarette warnings among socioeconomically disadvantaged middle school youth and smokers, testing whether less extensive alternatives that could be more acceptable to the courts—such as text-only or black and white pictorial warnings—would achieve the same goal as color pictorial warnings (Byrne et al., 2018). They report mixed findings regarding whether a less extensive alternative could achieve the government's interest of communicating the health effects of smoking and reducing cigarette smoking, with color pictorial warnings out-performing less extensive alternatives on some outcomes but faring similarly on others. Mays and colleagues report an experiment on e-cigarette warnings among young adults, focusing on the impact of color and size (Mays et al., 2018). While the pattern of results did not exclusively favor one set of warning characteristics, this study is one of the first to show that e-cigarette warning label design affects attention and recall, even when holding warning content constant. Indeed, both of these warning studies provide insights into how differences in warning characteristics (e.g., color, use of imagery) can affect particular outcomes among priority populations. These studies can inform the FDA regarding the design of pictorial warnings for cigarettes and e-cigarettes.

In the modern tobacco landscape, issues surrounding 'risk' are complex as potentially lower risk products such as e-cigarettes and snus appear on the market. How the public

understands tobacco product risk, and how they make decisions based upon that information is in need of greater study (Andrews et al., 2015). Wackowski and colleagues report on an experiment involving smokeless tobacco and news media (Wackowski et al., 2018). They find that a news story which framed snus (a smokeless product) as a safer smoking alternative or one that included both benefits and risks lead to lower perceived harm and greater interest in trying snus compared to risks only and control news stories. This suggests that how news media cover these new products has the potential to shape perceptions of their risk. The authors suggest that the FDA should take care in how they frame their press releases (and other news media vehicles) to the public, which could impact consumer risk perceptions about novel products such as snus. The last article in this section reports on website designs for communicating about chemicals in cigarette smoke. This is an important regulatory topic as the FSPTCA requires the FDA to disclose harmful and potentially harmful constituents (i.e., chemicals) to the public, but to do so in a way that is understandable and not misleading (U.S. Food and Drug Administration, 2012). Lazard and colleagues test website designs with various chemicals, associated health effects, chemical quantities, and visual risk indicators (Lazard et al., 2018). Results indicate the use of particular elements for most effectively communicating about chemicals, including the use of text with icons for communicating health effects and the use of a visual risk indicator for highlighting the most dangerous health effects. This work can serve as an initial example to the FDA as they consider how to disclose information to the public about harmful and potentially harmful chemicals in cigarette smoke.

The third and final section of the special issue reports on three studies about campaigns and messaging. A large literature demonstrates the effectiveness of campaigns to prevent tobacco initiation (Farrelly et al., 2017; Farrelly, Nonnemaker, Davis, & Hussin, 2009) and promote cessation (Durkin, Brennan, & Wakefield, 2012), but this literature is focused on cigarettes. With cigarette use declining, novel and emerging products such as little cigars and cigarillos, waterpipe tobacco, and e-cigarettes have been increasing, especially among youth (Singh et al., 2016). Sutfin and colleagues report on the development of a campaign to discourage youth from using little cigars, cigarillos, and waterpipe tobacco (Sutfin et al., 2018). Through an integrated set of qualitative and quantitative studies, they develop and test messages that emphasize the chemicals in these novel products as a way to discourage use of such products. This work resulted in several principles, including choosing familiar chemicals with negative connotations, pairing chemicals with an unappealing product, and delivering the message with a humorous, sarcastic tone. Testing the efficacy of this approach at the point of sale is the next step. Using a narrative communication approach, Walter and colleagues report on an experiment examining the use of vicarious self-affirmation to impact e-cigarette-related outcomes among young adults (Walter et al., 2018). They expose college students who regularly use e-cigarettes to a story about the negative impact of e-cigarettes that either emphasizes (or not) vicarious self-affirmation. Results indicate that vicarious self-affirmation reduced message derogation and increased self-appraisal and perceived risk, showing promise for this messaging approach for e-cigarettes.

Cornacchione Ross and colleagues' systematic review of health communication for non-cigarette tobacco products is the final article in this special issue (Cornacchione Ross et al., 2018). It examines all health communication studies about non-cigarette tobacco products



published through May of 2016. This review of 45 studies reveals that most communication studies of non-cigarette tobacco products have been about smokeless tobacco, with only a modest number on waterpipe tobacco and just a few on e-cigarettes, cigars, and modified risk products. While studies examined health warnings and public education, most messaging emphasized the health consequences of tobacco product use, with few testing other message themes. Interestingly, not a single study examined public education around e-cigarettes, an area that the FDA has recently announced it will begin focusing on with its national public education campaign for youth, *The Real Cost* (US Food and Drug Administration, 2017b). Only a few studies assessed behavior as an outcome. This review characterizes the landscape of non-cigarette health communication research and notably points to key gaps in the literature for future research.

## Conclusions and future directions for communication regulatory science

The work in this special issue represents an important step forward in advancing the science of communication and tobacco regulatory science. And yet, there is much work to do. The vast majority of work in health communication and tobacco to date has been focused on cigarettes and smoking, but the FDA is tasked with regulating several products now under their regulatory authority, including e-cigarettes, cigars, and waterpipe tobacco. New research can build the corpus of communication regulatory science regarding effective communication about these new and emerging products. This work will advance communication science, inform and potentially guide FDA, and help withstand legal challenges that may be brought by the tobacco industry.

As we look ahead, we see areas of regulatory science that were not covered in this special issue at all or in much depth. Communication regulatory science is becoming more multi-methodological with the rise of methods such as eye tracking (Meernik et al., 2016) and brain imaging (Maynard, Brooks, Munafo, & Leonards, 2017; Wang, Lowen, Romer, Giorno, & Langleben, 2015), and we predict the use of more such diverse methods in the future. Other topics—such as how to communicate about potential modified risk tobacco products (Andrews et al., 2015; O'Connor, 2012) and how the FDA might best communicate with the public about its policy initiatives (US Food and Drug Administration, 2017a)—should be the subject of future research.

Communication research about tobacco regulatory science has the potential to have a major impact on the tobacco epidemic and population health by helping implement the most effective communications to prevent tobacco initiation and increase cessation. We believe the current special issue contributes to this goal. We look forward to the next generation of tobacco communication regulatory studies which will optimize communication approaches, prevent tobacco initiation and increase cessation, and help build a healthier nation for all.

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