Published in final edited form as:

J Law Med Ethics. 2015 ; 43(0 1): 95–98. doi:10.1111/jlme.12227.

Bridging the Gap between Science and Law: The Example of Tobacco Regulatory Science

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In the 20th century, public health was responsible for most of the 30-year increase in average life expectancy in the United States.¹ Most of the significant advances in public health (e.g., vaccinations, water fluoridation) required the combined effort of scientists and attorneys. Scientists identified public health threats and the means of controlling them, but attorneys and policymakers helped convert those scientific discoveries into laws that could change the behavior of industries or individuals at a population level. In tobacco control, public health scientists made the groundbreaking discovery that smoking caused lung cancer, but attorneys and policymakers developed and implemented the policies and litigation strategies that helped reduce smoking rates by more than half over the past 50 years.

The need for attorneys and scientists to collaboratively tackle public health problems is as great as ever. With courts increasingly demanding higher levels of evidentiary proof in public health cases,² scientists and attorneys need to work together to ensure that policy measures can be defended in court. This requires collaboration at the onset of the research process, so that the researchers can anticipate and address questions that reviewing courts are likely to ask. Unfortunately, barriers to interdisciplinary communication, combined with time and funding constraints, make such collaboration difficult.

This article discusses the need for better collaboration between attorneys and scientists generally and in the context of tobacco regulation.

I. Scientists and Attorneys

The need to “bridge the gap” between academics and attorneys has been widely acknowledged.³ Nearly 25 years ago, law professor Harold Green noted the “substantial gulf between the scientific and legal disciplines” and suggested that scientists often have the “perception that lawyers are merely meddlers with little capacity to be of assistance to

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science,” while the legal profession frequently fails to recognize the importance of engaging with scientists to tackle pressing public policy issues.⁴

This gulf still exists, largely because each community is focused on its own priorities and does not often think to engage the other. In our experience, researchers are primarily focused on advancing the science and are driven by gaps in the literature, the search for novel research questions and methodologies, and funding availability. Furthermore, scientists have little professional incentive to ensure that their research is translated into law and policy. They are likely to view the development of law and policy as someone else’s role, even though they may be frustrated by the disjuncture between evidence-based practice and policy.⁵

In contrast, attorneys/policymakers often deal with much shorter time horizons than researchers. They want to use science to support their policy approach or legal arguments, but cannot wait for the development of new evidence.⁶ Generally, they care less about scientific *truth* than about identifying available evidence that will support their position.⁷ Most attorneys have limited knowledge of the research process and may be frustrated by what they see as the tendency of scientists to focus on narrow, technical questions that do not inform the broader policy questions at issue.⁸

This gap hinders advances in public health. Critical research is not being translated to policymakers, and the courts lack access to (or understanding of) the science relevant to important public health decisions. Although science and policy will never be fully aligned (e.g., due to differences between science-based policy and political ideology), significant public health advances can nonetheless occur when scientists and attorneys work together to inform policy development.

A recent example of the real-world effect of this gap is the *R.J. Reynolds v. FDA* decision from the U.S. Court of Appeals for the D.C. Circuit.⁹ In that case, the court struck down Food and Drug Administration (FDA)’s proposed graphic health warnings for cigarette packages and advertisements on First Amendment grounds. This case was an important reminder that public policies, even if supported by considerable evidence, are vulnerable to legal challenges unless researchers anticipate and answer the doctrinal questions the courts are likely to ask. Additionally, it highlighted the failure of communication between science and law. In seeking evidence that the graphic health warnings “directly caused” smoking rates to fall, the court failed to comprehend the difficulty of establishing causation in real-world settings, where the influence of graphic warnings cannot possibly be disentangled from the impact of other tobacco control policies and the general decline in tobacco use.¹⁰ Although it is quite possible that the court was ideologically predisposed to rule against FDA, the case is a reminder that policymakers and scientists need to better explain the scientific evidence (including its limitations) and to directly connect the science to the applicable legal standards.¹¹

II. Tobacco Regulatory Science

An opportunity to address the gap between science and law is in the emerging field of tobacco regulatory science, “the scientific discipline that supports the evaluation of the risks

and benefits of tobacco regulatory decisions and provides a robust scientific foundation for regulatory policies.”¹² In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act, giving the newly established FDA Center for Tobacco Products (CTP) broad authority to regulate how tobacco products are designed, manufactured, sold, and marketed.¹³ Although researchers have focused on questions involving tobacco for years, there are important research gaps, new products, and regulatory questions that FDA must address.

FDA prioritized research gaps and partnered with the National Institutes of Health (NIH) to fund new scientific research. The largest investment has been in the Tobacco Centers of Regulatory Science (TCORS) programs, through which FDA has committed \$273 million in funding to support 14 academic research centers.¹⁴ (Both authors are conducting research supported by TCORS centers.)

The TCORS program, along with other research funded by FDA CTP, provides an ideal opportunity to enhance collaboration between researchers and attorneys. By its nature, tobacco regulatory science is interdisciplinary; meeting FDA’s needs requires an understanding not only of the scientific questions, but also of FDA’s regulatory authority, the regulatory process, and how research can inform FDA’s work. Importantly, significant FDA regulatory actions will undoubtedly be challenged in court by the tobacco industry and its allies. As the earlier discussion of the *R.J. Reynolds* case suggests, it is therefore crucial that attorneys work with scientists from the beginning of the research process to help anticipate the relevant legal tests and ensure that the research is addressing the questions that the courts will ask. Working together, attorneys and scientists can (a) ensure that research studies are designed with a clear understanding of how they will inform FDA actions (and do not relate to potential actions that are outside the scope of FDA’s authority); (b) think creatively about new ways that FDA could use its authority; (c) clearly communicate to FDA how research findings could inform regulatory decisions; and (d) present their findings in ways that are understandable to non-scientific audiences and, most importantly, to courts.

III. An Example: Virtual Store Experiments

An example of the intersection of science and policy is the research being conducted by one of the authors (Kim) on testing potential regulations of tobacco marketing at the point-of-sale (POS). Retail is the most important marketing channel for the tobacco industry, as it spends nearly 95% of its \$8 billion annual advertising budget on POS promotions, advertising, and retailer incentives.¹⁵ Research confirms that youth exposed to POS marketing are more likely to have positive attitudes about smoking, experiment with smoking, and become established smokers.¹⁶ However, there is limited research examining the potential impact of POS tobacco marketing restrictions.

To survive legal review, policymakers would have to demonstrate the likely impact of any proposed regulatory measure. Although there has been substantial POS regulation in other countries, it is hard to disentangle the effect of any single regulation, because multiple regulatory interventions (e.g., taxes, advertising restrictions) are often implemented at the same time.

To address these challenges, Kim and colleagues developed a “virtual store” application to study how tobacco advertising, promotions, and displays influence consumer behavior—and how regulatory interventions might counter those effects. Using customizable interactive gaming software, Kim and colleagues developed a 3-D interactive store environment that could be modified to reflect the influence of different regulatory requirements. In separate experiments, youth and adults completed shopping tasks in the different virtual store conditions. The researchers observed whether the study participants attempted to purchase tobacco and then asked them questions about their experience and their perception of the store environment. By randomizing participants to different store conditions, the researchers were able to do what cannot be done in the real world—isolate the effect of a particular regulatory intervention while holding other variables constant.¹⁷

The “virtual store” design is a promising example of policy-relevant research that can directly inform regulatory decision-making. Among its other advantages, it enables policy options to be experimentally tested in a relatively short amount of time. Thus, Kim and colleagues have already been able to conduct experiments that have informed ongoing policy debates,¹⁸ and, in the future, the program could be adapted to test additional regulatory options. Restricting promotions at the POS (or requiring the display of health warning messages) would, like the graphic health warnings case, raise thorny First Amendment questions.¹⁹ Kim and colleagues therefore consulted with attorneys and policymakers when considering which options to evaluate, and, moving forward, the virtual store experiments present a perfect opportunity for researchers and attorneys to collaboratively design additional research studies that anticipate likely legal challenges.

IV. Conclusion

To date, most of the literature exploring the gap between scientists and policymakers has focused on enhancing communication and translating science into terms that non-scientists can understand.²⁰ While this might facilitate use of research studies in policymaking, it would not, in and of itself, facilitate the development of policy-relevant research that is conducted with both the regulatory structure and the relevant legal doctrines in mind. For such research to occur, attorneys and scientists must work together from the beginning of the process—and there must be funding mechanisms and professional incentives in place to encourage such collaboration. FDA’s and NIH’s tobacco regulatory science initiative is an ideal setting in which to demonstrate the importance of bridging the gap between science and law.

Acknowledgments

Research reported in this article was supported by grant numbers P50CA180908 and P50DA036128 from the National Cancer Institute, National Institute on Drug Abuse, and FDA Center for Tobacco Products.

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3. See, e.g., Smith K. Beyond Evidence-Based Policy in Public Health: The Interplay of Ideas. Hampshire, UKPalgrave Macmillan2013at 4Choi BCK, et al. Good Thinking: Six Ways to Bridge the Gap between Scientists and Policy Makers. *Journal of Epidemiology and Community Health*. 2009; 63(3):179–80. at 179. [PubMed: 19218254]
4. Green HP. The Law-Science Interface in Public Policy Decisionmaking. *Ohio State Law Journal*. 1990; 51(2):375–405. at 405.
5. See Smith, *supra* note 3, at 4.
6. Schuck PH. Multi-Culturalism Redux: Science, Law, and Politics. *Yale Law and Policy Review*. 1998; 11(1):1–46. at 17, 25 (noting that “the time frame of science is relatively open-ended,” while “[t]he law is usually in much more of a hurry to decide than science is”).
7. Edwards CN. In Search of Legal Scholarship: Strategies for the Integration of Science into the Practice of Law. *Southern California Interdisciplinary Law Journal*. 1998; 8(1):1–38. at 19 (“The last thing a lawyer wants is academic curiosity when it ... jeopardizes her client’s interests. Lawyers are remembered for the cases they win”); see also Schuck, *supra* note 6, at 24 (“For practicing lawyers, the decisive incentive is the need, consistent with both self-interest and professional ethics, to effectively represent the client’s interests, whatever those interests may be.”).
8. See Blumenthal JA. Law and Science in the Twenty-First Century. *Southern California Interdisciplinary Law Journal*. 2002; 12(1):1–53.at 6–7 (noting the tendency of scientists to “focus on specific research issues that, though arguably tractable from a researcher’s point of view, are nevertheless atypical in the legal system”).
9. *R.J. Reynolds Tobacco Co. v. Food & Drug Admin.*, 696 F.3d 1205 (D.C. Cir. 2012).
10. *Id.*, at 1219. Failing to acknowledge the methodological limitations, the majority incorrectly concluded that the lack of studies directly linking warnings to reduced smoking rates “strongly implies that such warnings are *not* very effective at promoting cessation and discouraging initiation.” *Id.*, at 1220. This conclusion was central the court’s holding that the warning labels violated the First Amendment’s protections for commercial speech.
11. The FDA’s case was also weakened by self-inflicted wounds. See Huang J, et al. Cigarette Graphic Warning Labels and Smoking Prevalence in Canada: A Critical Examination and Reformulation of the FDA Regulatory Impact Analysis. *Tobacco Control*. 2014; 23(Supp 1):i7–i12. [PubMed: 24218057]
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20. See, e.g., Choi, *supra* note 3, at 179; Smith, *supra* note 3, at 22.