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Advancing the evidentiary base for Tobacco Warning Labels: A commentary

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In 2009, the Congress of the United States passed the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. **111–31, 123 Stat. 1776, 1796** (codified at 21 U.S.C. §§ 387-387t (2012)) giving the FDA the authority to regulate tobacco products. The law also specifically mandated warning labels to appear on packs of cigarettes. The FDA responded by developing and testing nine graphic warning labels each addressing a mandated theme and accompanied by an image, sometimes a graphic one. The tobacco companies challenged the mandate in the courts with one appellate court upholding the mandate (*Discount Tobacco City & Lottery v. United States*, 2012). However, in a subsequent 2012 decision *R.J. Reynolds vs. the FDA*, the court sided with the tobacco companies on constitutional grounds and the FDA decided not to appeal.

As the FDA considers revising its warning labels, it is important for social scientists to understand the basis for the court's decision and to provide research evidence that will support the revision process. In a wide-ranging essay by Professor Ellen Goodman (2013) appearing in the *Cornell Law Review*, the complexity and contradictions in the court's decisions are explored in some detail. My intention is to focus on only one of the issues that Goodman raises, namely the importance of showing that tobacco warning labels (TWLs) are effective in changing behavior.

Goodman says that the basis for the decision in *Reynolds vs the FDA* was crucial suggesting that once the court affirmed that the labels were not purely factual but instead “they are primarily intended to evoke an emotional response, or, at most, shock the viewer into retaining the information in the text warning.” (footnote 139 cited in Goodman, 2013, p. 536). This framing of the issue brings the effectiveness of the warning labels into primary focus according to Goodman:

Once the problem was framed in this way ... the government was handicapped by its public health agenda. The court in *R.J. Reynolds* heavily cited FDA statements

that the goal of the warnings was to reduce tobacco use. ... Because of this explicitly normative motivation, the court thought that the government should be judged on how effective the labels were at actually reducing tobacco use.’ (Goodman, 2013, p. 536)

But the court went further than simply changing the criterial focus of the review to conclude “the ‘FDA ha [d] not provided a shred of evidence’ that the warnings would ‘*directly cause*’ a material decrease in smoking.” (Goodman, 2013, p. 537). The irony of the court’s reasoning requiring effective labels but ones without blatant emotional appeals is not lost on reviewers (Goodman 2013):

The more powerful and influential the mandated warnings are, the better their chance of modifying smoker behavior and, therefore, the more likely they are to survive a constitutional challenge. The more forgettable and meaningless the labels, the less likely they will influence smokers and the more vulnerable they are to constitutional challenge. (p. 537)

Goodman’s analysis should lead social and behavioral researchers to seek to provide evidence of the effectiveness of tobacco warning labels on smoking cessation and quit attempts, specifically causal evidence. If that evidence is compelling and generalizable to the cultural milieu of the United States, that evidence should have considerable relevance to the issue of the constitutionality of warning labels.

It is in this context of the legal challenges by tobacco companies to the proposed (and rejected) warning labels in the United States that I want to place the findings offered by Noar, Francis, Bridges, Sontag, Ribisl, & Brewer (2016a). The results of their meta-analysis are not about the FDA’s proposed graphic warning labels but they are about the effectiveness of the broad category of tobacco warning labels. Much prior research has shown that tobacco warning labels are effective in increasing the likelihood of decreasing tobacco use, increasing quit attempts and in general altering dispositions against tobacco use (Gibson et al, 2015; Huang, Chaloupka, & Fong, 2014; Institute for Global Tobacco Control, 2013).

Previous reviews such as those of Hammond (2011) and Hammond, Reid, Driezen, and Boudreau, (2013) indicate the effectiveness of cigarette pack warnings in promoting smoking cessation. However, these reviews were not sufficiently systematic and fail to take into account all of the available research across national boundaries. The approach of Noar et al (2016a) takes a more systematic, meta-analytic approach that is aimed at increasing the confidence of the conclusions that can be drawn.

What the Meta-analysis Found

Evaluating the effectiveness of cigarette warning labels in observational studies is a nontrivial undertaking in terms of the logic of inference. Most implementations take place at a national level, although of course they do not need to do so. When implementations are at the national level, the question becomes what is the comparison group against which the national implementation is to be evaluated. One can use pre-post-designs and that is often a reasonable comparison, except of course for test sensitization at the individual level if that is what is being done. In the present study, the authors use a version of pre-post designs

comparing the effects of countries' warnings before and after they are strengthened. Strengthened warnings were accomplished in a variety of ways including changes from text to images, changes in image or text size, increases in prominence and position on the pack, adding additional warning statements, enhancing pictorial warnings, or some combination of these changes. This means that countries being studied had already undergone some intervention with a tobacco warnings including simple textual ones. Thus, it is the change between pre-and post that is being assessed under the assumption that the post-intervention TWL is stronger than the pre-intervention warning.

Of the 32 studies evaluated between 1997 and 2014, 54% came from Australia, Canada, the UK or the United States (as a control). The total sample was greater than 800,000 cases, usually probability samples. The kinds of changes in labels were primarily from text to pictures (64%) and from pictures to strengthened pictures (about 20%). Other changes were in the size of the text, the size of the image on the pack and the repositioning of the image or text on the pack. The meta-analysis showed that strengthening the labels was linked to reductions in cigarette consumption, more quit attempts, and reductions in smoking prevalence. Other effects were also reported on knowledge and beliefs about smoking. The effects for quit attempts and smoking prevalence were mostly due to changes in strength from text to pictorial warnings.

Establishing causality is a crucial issue in social scientific studies generally and in the present case specifically given Goodman's (2013) analysis of the court decisions about the US' TWLs. The authors provide much supportive evidence of causal effect by focusing on studies that are longitudinal, in multiple contexts, with conceptually related but not identical measures of core constructs, and that identify potential confounders that could account for the effects.

But observational data will always be subject to a variety of threats to inference from test-retest sensitization (panel designs), from confounders, the absence of strong, uncontaminated controls, and a wide variety of other limits. Driving causal uncertainty to near zero is impossible in this and many other policy-based interventions. Yet, in what follows I will argue that there is a strong circumstantial case for causal consequence of warnings on tobacco use with sufficient justification to allow deploying some version of cigarette warning labels on grounds of their effectiveness.

Inferring Causality

Are Noar et al.'s results persuasive? Would the public or, more importantly, the courts find these results convincing in showing that implementing tobacco warning labels is a causal factor in decreasing adult levels of smoking? What the authors' data has shown is that the introduction of TWLs covaries with subsequent changes in smoking behavior; that the introduction of TWLs occurs prior to the alterations reported in smoking behavior; that the covariation and temporal ordering occurs in a variety of national contexts, with a variety of interventions, and with a variety of measures of behavioral change. Shouldn't such data be sufficient to establish unequivocally a causal role for TWLs in behavior change?

The answer, of course, is that these data increase our confidence in the effectiveness of TWLs in changing smoking behavior but do not provide a definitive account of TWLs as a causal factor in reducing tobacco use. Why don't they? Every observational study has limitations in its ability to establish causality. Two of the more important ones to the case at hand are confounders and the intervening causal mechanism linking the key predictor (TWLs) and the outcome (reduction of tobacco use).

The presence of confounders is unavoidable in TWL interventions. They vie with the TWLs in their consequences on smoking cessation. They include changing social norms and conventions about the attractiveness, healthfulness, and general acceptance of smoking behavior; legislation increasing the cost of cigarettes through taxation and surcharges; increased education efforts through schools and tobacco control campaigns at national and local levels; in short, any of the linked interventions that would be carried out by those responsible for public health in the targeted country could call into question the causal efficacy of TWLs alone.

In an insightful and clever keynote address at the 2016 International Conference on Computational Social Science, Professor Sendhil Mullainathan of Harvard University invited researchers concerned with policy interventions to distinguish between explanatory and predictive approaches. He labeled explanatory approaches as $\hat{\beta}$ (beta-hat) and predictive approaches as $\hat{y}$ (y-hat), consistent with their roles in typical regression equations. While the goal of scientists often is the identification of causal influences (i.e., $\hat{\beta}$) on the outcome, policy interventions will often have to be satisfied with predictively adequate outcomes (i.e., $\hat{y}$) without necessarily being able to disentangle the causal forces giving rise to the prediction.

The tangle of interventions that often surround TWLs (a.k.a. confounders) makes the unequivocal separation of potential causes of the desired outcome virtually impossible. The authors of the TWL meta-analysis are well aware of this issue and try to offer considerations of covarying factors in various contexts but in the end must admit that there are insufficient cases where one or more covarying interventions (e.g., increase taxes on cigarettes) are present and absent across the cases study. The authors do conclude that the data "precluded a systematic analysis of the impact of strengthening warnings in the absence of changes to these other policies" but believe that synergies among policy components could enhance effects although more research is needed. These are less robust conclusions than would be desirable in a perfect world where *both* $\hat{y}$ and $\hat{\beta}$ inferences were possible.

In the domain of policy research such as TWLs, focusing on real-world tests, behavioral outcomes exhibiting some consistency across multiple samples and across national boundaries may be the best test that can be expected within this specific domain. When combined with results from experimental tests allowing random assignment (Noar, Hall, Francis, Ribisl, Pepper, & Brewer, 2016) and field tests with random assignment and behavioral outcomes (Brewer, Hall, Noar, Parada, Stein-Seroussi, Bach, Hanley & Ribisl, 2016), a more complete, albeit piecemeal, picture emerges, moving the research map closer to both $\hat{y}$ and $\hat{\beta}$ evidence of predictive and causal accounts.

A second, less obvious, class of factors undermining the causal claims from observationally based meta-analyses is the absence of causal mechanism – that is, an explanatory theory – linking the predictor and consequent. Consider an analogy: One can use some simple trigonometry to measure the height of a flagpole from information on the length of the shadow cast by the flagpole and the angle of the sun relative to the surface of the earth. In the sense of deductive- nomological explanation, the height of the flagpole would be explained (i.e., predicted) on this basis even through our sense of understanding of how the flagpole came to be X meters high would be nil. One of the ways that our sense of the causal link between TWLs and smoking cessation would be enhanced is to rely on an explanatory mechanism linking the two.

To find that predictor and consequent covary and that they exhibit temporal order and are robust across national boundaries and operational definitions does not provide evidence about how the predictor produces or brings about the consequent. No single study can do it all, obviously, especially in this era of shorter and shorter research articles, but it would not be unfair to say that the mere existence of “changed warnings” on packs of cigarettes is insufficient to produce behavioral changes especially given that avoidance tactics and defensive reactions, wear-out, and inertia and habit mitigate reactions to TWLs.

To advance “ $\hat{\beta}$ claims” in the context of large-scale policy interventions would be aided by a good causal explanation. Good causal explanations of puzzling phenomena craft precise and coherent arguments in support of the account offered and offer reasons for dismissing competing causal accounts (Miller, 1987). In lieu of direct, unconfounded tests of $\hat{\beta}$ causal claims, good causal arguments are demanded. Good causal accounts show themselves by their ability to account for puzzling facts, by offering successful arguments against competitors, and by providing deep causal explanations that connect without contradiction to bodies of accepted knowledge in other domains of inquiry (Cappella, 1997).

The present meta-analysis works hand-in-hand with two other systematic reviews of the effects of cigarette warning labels. One is a review of the *experimental* literature published by (Noar, Hall, Francis, Ribisl, Pepper, & Brewer, 2016) that shows pictorial warnings had greater effectiveness than text warnings on a variety of outcomes including emotional reactions, intentions to avoid smoking and intentions to quit. Another meta-analysis by the same group that is not yet published provides additional evidence on the mediating effects of the labels’ consequences. These mediating effects include factors such as attention, cognitive elaboration, and the perceived effectiveness of the tobacco warning labels (Noar, Francis, Bridges, Sontag, Ribisl, & Brewer, 2016b). An experimental intervention testing warning labels on smoking behaviors in a U.S. sample (Brewer et al., 2016) explores some of the effects of labels on quit attempts hinting at the causal mechanisms including emotional reactions, cognitive elaborations and conversation with others. Together with the meta-analysis published in *Social Science & Medicine*, an emerging picture of the causal effectiveness of warning labels emerges that is difficult to ignore.

Establishing causality in the public policy domain is a process fraught with threats to inference. No single study can make the case, not even a meta-analysis across studies. The goal must be a cumulative picture that gives precedence to predictive adequacy of the policy

intervention (the $\hat{\gamma}$ component) complemented by causal evidence derived perhaps from less generalizable but more controlled tests (the $\hat{\beta}$ component). The combination allows the inference of causality to be made with more confidence than would be allowed from any of the parts alone.

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