Having both too much, and too little free speech

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Evidence-based medicine sounds like a good and straightforward thing: after all, it stands for the idea that clinical medicine should aspire to base its practice on the best available scientific evidence of what works and what does not, and that clinicians should have such information readily available to them when working with patients. I want to suggest here that creative judicial interpretations of the First Amendment are making it hard to practice such medicine. There are two halves to the worry: one is based on too much free speech and the other on too little, but both make it difficult to use evidence in a clinical setting with patients.

For too much free speech: consider that the growth of corporate free speech rights (especially post *Citizens United*), is now being applied to pharmaceutical advertising. In a 2012 case, an appellate court overturned the conviction of a pharmaceutical representative for marketing the drug Xyrem for off-label use, as long as his speech was "truthful." At the beginning of March 2016, the FDA reached a settlement with Amarain that the company is free to "engage in truthful and non-misleading speech" about potential uses for its product, even if those are unapproved. The product in question is fish oil, and the debate was over whether it could be advertised to reduce the risk of cardiac events, and not just as an intervention for patients with very high triglyceride levels. In the abstract, this might sound perfectly reasonable: after all, only doctors can actually prescribe off-label, and surely they should be able to use the best evidence available to make those decisions, right? The problem is that in the world we live in, it is not clear that the speech in question is "truthful and non-misleading." The research Amarin cited in support of the off-label marketing was clearly paid for by Amarin. This is a common phenomenon, and it led one of evidence-based-medicine's early champions, John Ionannidis, recently to publish a piece in the *Journal of Clinical Epidemiology* called "Evidence-Based Medicine has been Hijacked," which argued, among other things, that "the industry runs a large share of the most influential randomized trials. They do them very well … It is just that they often ask the wrong questions with the wrong short-term surrogate outcomes, the wrong analyses, the wrong criteria for success (*e.g.*, large margins for noninferiority), and the wrong inferences … The industry is also sponsoring a large number of meta-analyses currently. Again, they get their desirable conclusions" (internal citations omitted). In a follow-up interview in *Retraction Watch*, he adds that part of the problem is declining public funding for research, which puts that research in the hands of industry, which has to answer to sales and marketing departments.

None of this is a new complaint, but it generates very specific problems for off-label marketing, because it pulls the rug out from under the reasons given not to ban it: in such a context, how can one possibly identify correctly which claims are

"truthful and non-misleading?" All the "truth" has been manufactured, and evidence going the other direction never gets funded or published.

So what about the too little free speech argument? Let's set aside the complications of reproductive health debates, and look at firearms. Florida's statute banning doctors from asking patients – including those with children – about firearms in the house, absent specific reasons to think "that the patient is suicidal or has violent tendencies," was upheld by an appellate court last summer. The appellate court overturned a lower court opinion finding that the law "aims to restrict a practitioner's ability to provide truthful, non-misleading information to a patient." Are guns in the home clinically relevant? A recent *New York Times* analysis concluded that hundreds of children die – usually accidentally – because adults leave unsecured, loaded firearms where children can access them. The children then unintentionally shoot themselves or each other. The *Times* cites CDC statistics to the effect that gun accidents were the ninth-leading cause of unintentional deaths of children ages 1-14 in 2010; applying evidence of inconsistent and under-reporting, gun accidents would make the top five or six. One could be forgiven for thinking that these deaths are almost entirely preventable. Despite this, the gun lobby is sponsoring more such laws.

In sum, we have two situations where selective judicial application of the First Amendment is being used to undermine the ability of clinicians to responsibly exercise evidence-based medicine and their own professional judgment in the context of doctor-patient relationships. In one, the problem is generated by too many free speech rights on the part of Pharma companies to peddle their products in off-label ways that are not backed by even a scintilla of objective evidence. In the other, the clinical relation is undermined by prohibiting speech on guns, despite the presence of clinically-relevant evidence that gun-owning parents need to be very, very careful to control access to their firearms, and that many aren't. Again, the doctor's ability to use her professional judgment is undermined in ways antithetical to any sort of evidence-based medicine: when the evidence doesn't exist, you have to nonetheless use it; when it's solid, you have to ignore it.