



The US Department of Justice's Targeting of Medical Speech and its Public Health Impacts

By Scott Gottlieb, MD

American medical knowledge is constantly evolving, and medical professionals should be trusted to intelligently weigh available information to properly treat their patients. The US Department of Justice (DOJ) threatens to offset the balance of medical information flow through continued expansion in the scope of False Claims Act probes into drug makers that allegedly promote their products for “off-label” uses. Though objectionable promotion exists, DOJ investigations rarely—if ever—go to federal court, and instead cause biopharmaceutical companies to clamp down on potentially useful medical discourse for fear of being investigated. To promote the exchange of straightforward, truthful medical information, the DOJ must encourage more thorough determination of whether alleged off-label information is actually standard medical convention, remove the penalty of exclusion from public health programs for corporate integrity agreement companies, and establish clearer boundaries for useful medical information sharing.

The US Department of Justice (DOJ) routinely touts the cumulative amount of money it has recouped for taxpayers as a result of its investigations against biopharmaceutical companies, alleging that the companies promoted their products illegally for off-label uses (those medical uses of a drug that have not been formerly approved by the Food and Drug Administration). But Americans should ask whether there are also public health costs in the form of less-informed patients and doctors as a result of this legal wrangling and the ensuing chill that it puts on some useful medical discourse.

Years of this sort of enforcement activity have curtailed a lot of the unscrupulous promotional activity. This is especially true when it comes to the big drug makers. Prosecutors' actions have played a key role in restraining dodgy behavior that was, at one time, pervasive. While there are

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Key points in this Outlook:

- While hundreds of US Department of Justice (DOJ) probes have been brought against biopharmaceutical companies accused of promoting their products for off-label uses, none of these “whistle-blower” cases has gone to trial in federal court.
- A fear of investigation has put many drug makers on the extreme defensive, curtailing even lawful information sharing, which in turn threatens to stifle medical discourse and create less-informed doctors and more vulnerable patients.
- When pursuing these cases, the DOJ should better clarify whether sharing certain types of off-label information is legal and considered appropriate by health authorities, and establish clearer boundaries for distributing medical information.

still bad actors, fewer drug makers are committing infractions that, in many cases today, are far less obvious.

This is because many of the big drug makers have cleaned up their activities. They are bent on reducing the chance of incurring the financial and reputational costs of being investigated for alleged violations of government rules that restrict certain kinds of information sharing. There are still bad actors and cases of questionable activity. But many of the current investigations regard behavior that occurred a decade ago.

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Taken as a whole, the drug firms have in place today very restrictive procedures meant to prevent allegations of unlawful promotion. To avoid even inadvertent violations by individual employees, this has typically meant that drug makers are erring on the side of extreme caution when it comes to exchange of information, and curtailing broad areas of communications.

For example, in some cases, companies will not even share rigorous and peer-reviewed scientific journal articles with doctors for fear that these reprints could contain some off-label information and thus could be used as evidence in investigations brought by prosecutors. This increasingly cautious behavior by drug makers has, in turn, meant that prosecutors bringing modern-day investigations have had to target more doubtful evidence in the new cases they bring—communications activities where it is murkier as to whether the speech violates Food and Drug Administration (FDA) regulations. In some cases, this includes communications that straddle the line between unlawful promotion and commercial speech that may be legally protected under the First Amendment.

The result? There could be some public health downsides to the current probes, and the behavior that they instigate at companies fearful of investigations, and then bent on reducing the companies' risk under these legal regimes. Moreover, because these investigations never go to court, the allegations constitute the entire legal

action. As a result, there is never a definitive test of whether the alleged activity is permissible or even appropriate. Companies are unable to risk challenging the government.

These results are all worth considering as the DOJ continues to refine its policy governing these legal efforts. The DOJ is already going to have to reconsider its legal strategy after the significant legal defeat it suffered this month in one of these off-label cases, which targeted an individual, not a company, and where the individual was willing to press the case in court. In *United States v. Caronia*, the US Court of Appeals for the Second Circuit said the “government cannot prosecute pharmaceutical manufacturers and their representatives under the [Food, Drug and Cosmetic Act] for speech promoting the lawful, off-label use of an FDA-approved drug.”¹ The case concerns Alfred Caronia, a former sales consultant at Jazz Pharmaceuticals. He was convicted in 2008 of conspiracy to introduce a misbranded drug into interstate commerce based on audio recordings in which he promoted the off-label use of narcolepsy drug Xyrem (sodium oxybate).

Caronia—who was sentenced to one year of probation and one-hundred hours of community service—appealed, arguing that his conviction was based solely on his speech and therefore violated his First Amendment rights. In overturning the conviction, the US Court of Appeals noted that the government did not allege that the executive (whose statements about a drug were at issue in the case) said anything false, but was prosecuting Caronia solely because the government did not approve of his truthful statements.²

Aside from the legal fitness of DOJ strategy, there could be a public health price being paid as companies clamp down on all manner of communications, restricting the flow of even clinically useful information at the same time that they shut down the “promotion” that is viewed as questionable or alleged unlawful. As DOJ reconsiders its tactics and legal policies on the heels of this *Caronia* defeat, it should consider all of the public health issues that are also at stake.

While DOJ attorneys see risk in some of the off-label claims that sponsors have made about products, in other cases, there are equal risks brought about by the suppression of truthful, nonmisleading information. This is especially true for fast-moving medical fields in which the state of clinical practice is defined by what is in the academic literature and not necessarily what appears on a drug label. The issue is whether a more careful

approach to how these investigations are brought, and a legal framework that lets these government claims be the subject of occasional challenge, could strike a better balance between restraining objectionable promotion and enabling useful medical discourse.

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Scope of the Enforcement Activity

The investigations at issue are generally brought under the False Claims Act (FCA). This federal law imposes liability on persons and companies that defraud governmental programs. The law includes a “qui tam” provision that allows people who are not affiliated with the government to file actions on behalf of the government. When these “whistle-blowers” file suits under the FCA, they stand to receive a portion (usually about 15 to 25 percent) of any recovered damages.³ This is meant to provide a financial inducement for people to come forward with evidence of wrongdoing.

The law was passed by the US Congress in 1863, during the Civil War, in response to unscrupulous contractors who sold the Union Army decrepit horses, faulty rifles, and rancid rations and provisions, among other corrupt actions.⁴ The law has been strengthened in recent years and its scope expanded. Congress passed the last major revision in 2009 as part of the *Fraud Enforcement and Recovery Act*.⁵

Settlements with the federal government under the FCA are expected to reach a record high of \$8 billion this year. Much of that money comes from health care-related investigations. Today, one of the most celebrated and common applications of the act involves cases alleging the off-label promotion of prescription drugs.⁶ These qui tam suits, filed against drug makers, typically follow a predictable formula.

The process usually starts with a former employee of a drug company alleging that the manufacturer engaged in deliberate and systematic efforts to promote the off-label

use of one or more of the company’s products to physicians. The employee will normally offer as evidence of the alleged promotion instances in which the company allegedly undertook deliberate efforts to share off-label information with doctors. This often takes the form of medical education programs, sponsored patient registries, investigator meetings, advisory boards, consulting relationships, and medical literature that companies distributed.

The allegation is that these activities constituted promotional activity that “caused” doctors to write prescriptions for a particular drug for the off-label use. This, in turn, triggered Medicare or Medicaid to be billed for applications of the drug that were not approved by the FDA. As a result, the claim against Medicare for payment on the off-label prescription constitutes the “false claim” against the government, since drug makers are not permitted under federal law to promote their products for off-label uses.

While hundreds of such investigations have been brought against drug makers under the FCA, not a single one of these qui tam suits has gone to trial in federal court. This is because the drug makers, for their part, invariably settle these claims. It has now become almost a sure bet that if prosecutors press one of these cases against a manufacturer, they will eventually extract a financial settlement from the drug maker.⁷

In many cases, companies settle because they know full well that they are on shaky legal ground. They do not want to risk decisions in court where highly restrictive precedents may get set. But there is also good reason why companies reflexively settle these cases, even in those instances where they might judge the government’s facts to be weak, or believe that some of the “promotion” that a company undertook—and is being targeted for—is permissible under First Amendment principles that protect truthful and “nonmisleading” commercial speech.

Under the law, if a sponsor challenged prosecutors and lost in federal court, the company could face exclusion from participating in government health programs. Such a sanction would amount to a death penalty for a modern drug maker since federal programs comprise such a big chunk of overall spending. It makes litigating one of these claims simply too big a chance to take.⁸

The DOJ largely knows that these cases will rarely, if ever, be litigated. Since prosecutors recognize that they will not have to defend their allegations in court, the investigations are said to generally undergo less rigorous

scrutiny inside DOJ. Prosecutors can take greater license in terms of the scope of evidence that they fold into these cases. For these reasons, the qui tam cases often produce substantial financial awards without the risk (or financial cost) inherent in a trial. By one estimate, the government recoups \$15 for every \$1 spent on civil qui tam cases that it brings.⁹

The truth is that the government cannot afford to exclude a major drug maker from doing business with Medicare since the drugs are vital products in that they could not be denied to Medicare recipients. Nonetheless, the threat of exclusion is a blunt instrument that can be used to extract easier submission in these cases. If the government were able to hold exclusion over a drug maker as a result of its success at trial, then prosecutors would effectively possess keys to the company. They would be able to extract substantial concessions and control over business operations.

The broader policy challenges stem directly from this blunt threat that prosecutors are able to hold over drug makers. Because the sanctions are so severe and discourage firms from challenging allegations, prosecutors can take the risk of weaving into their allegations alleged speech that might be viewed as permissible, if not useful. Since the allegations do not get litigated, there is limited downside to expanding the scope of the facts that get invoked in these investigations—the investigation generally comprises the entire case. The charges will never be subject to judicial review by the courts.

As a result, over time, there has been a cyclical loosening of the kinds of facts that get introduced during these cases as evidence of promotion—in part driven by an industry that is more cautious (leaving prosecutors with fewer glaring infractions) and also driven by prosecutors that take greater liberties in the allegations they make, knowing that they are unlikely to face scrutiny.

Encroaching on Useful Speech?

The critical question is whether the sharing of some of this speech helps promote public health goals, and, as a consequence, whether the restrictive practices that drug makers adopt in response to the legal regimes can sometimes cause harm. Because of the risk of being investigated, most of the large drug firms now tightly control how they promote their drugs to doctors.

Drug makers are therefore clamping down on all manner of communications, restricting the flow of

even permissible information such as journal reprints—errring on the side of extreme caution and curtailing any practice that could plausibly be invoked in promotion cases. As the investigations themselves get more expansive and seek to rope in speech that was until that time viewed as permissible, companies must become even more conservative when judging what activities to curtail to stay ahead of the expanding nature of the investigative activity.

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Many observers point to the restrictions that drug firms agree to, as part of settlements with the government, for the self-policing. In recent years, most big drug makers signed corporate integrity agreements with the government. These legal concessions—made as part of qui tam settlements—are aimed at ensuring future compliance with laws governing off-label promotion. But the agreements focus on process rather than substance, meaning the agreements do not themselves require a more restrictive approach among companies operating under these schemes.

Consequently, any “chill” on the exchange of information does not flow from the settlements themselves, but from self-censorship by drug companies bent on avoiding subsequent investigations. In other words, it is the investigations and the jeopardy they create that has been the major factor in driving behavioral changes. It is this self-policing—rather than the investigations themselves—that may have adverse consequences for public health considerations. While prosecutors do not demand many of the most extensive restrictions, the expansive nature of their legal investigations encourages the behavior.

The risk, in turn, is that the restraint on this communication is leaving doctors less rather than better informed, ultimately making patients more vulnerable. While drug makers are self-imposing the most restrictive practices, the way the investigations get brought and sanctions that prosecutors are able to threaten drug makers with make the self-censorship a predictable, if not compulsory, response.

These questions about any potential public health downside to these legal activities get short shrift, but

they are worth considering as we take continual steps toward optimizing the regulatory framework that governs pharmaceutical promotion. For example, consumers and government agencies are increasingly demanding more information about the comparative value of drugs. Much of this material—when it is generated by the industry—constitutes “off-label” information because the FDA rarely allows comparative claims in its approved drug labeling. To these ends, the existing legal regime may be actively discouraging the generation of the very information that other government agencies are funding and trying to stimulate.

Today, some drug makers will not even distribute reprints of pivotal studies that appear in leading medical journals if those articles contain any mention of an off-label use of their products. Much of this discourse involves bottom-line medical data about clinically acceptable uses of drugs. This includes the studies that formed the basis of the FDA approvals. Since many studies include doses that do not get into the FDA-approved label, this means that almost any journal reprint could be disqualified.

All of this also begs the question of whether at least some of this alleged “promotional” activity is legally permissible in the first place. In recent years, the activity used as evidence of promotion has included advisory board meetings that companies sponsored to share information and get scientific feedback from doctors, sponsorship of medical education, and the sharing of clinical-trial results.¹⁰ These allegations are complicated by the fact that there is no standard definition of “promotion” in this context. When this speech is truthful, nonmisleading, and promulgated in an educational context, it is quite possible that the speech would be deemed constitutionally protected by the courts under doctrines that recognize commercial speech as being subject to First Amendment considerations.¹¹

When it comes to drug promotion, this tension between constitutionally permissible commercial speech and the thrust of federal regulatory policies is not new. It came to a head in 1998–99 when, in a series of judicial decisions (in what became known as the Washington Legal Foundation litigation), the federal district court for the District of Columbia recognized that the First Amendment may, and in certain specific instances does, protect a drug maker’s right to disseminate (and a physician’s right to receive) truthful, nonmisleading scientific information regarding off-label uses.¹²

In recent decades, the FDA has lost a series of First Amendment challenges.¹³ A substantial First Amendment

challenge is pending decision by federal court in the ninth circuit.¹⁴ When the FDA’s series of First Amendment defeats are looked at individually—and especially when taken together—they represent a substantial rebuke of the current policies’ approach to the First Amendment.

Legal observers across the political spectrum concede that if the FDA were to definitively lose more challenges, it could not only curtail the *qui tam* actions, but also put at risk the agency’s other regulatory prerogatives. Owing to the FDA’s longstanding concerns around the interplay between its regulatory prerogatives and constitutional protections that are generally afforded to commercial speech, the agency has at times been intentionally ambiguous around its policies regarding certain aspects of commercial speech. The FDA is generally reluctant to promulgate restrictions in regulation or final agency action that would invite a definitive constitutional challenge to its policies.

But similar concerns remain largely absent from the *qui tam* cases. Prosecutors have grown accustomed to the fact that they are unlikely to face court challenges in these cases. Therefore, judges and juries do not scrutinize the constitutionality and appropriateness of the speech. The legal challenge that is pending in the ninth circuit was not brought by a company involved in a *qui tam* investigation. An individual who was the target of a criminal prosecution brought this challenges.

The Public Health Dimension

Drug makers’ self-censorship would present fewer potential tradeoffs in a world in which the information is diffused easily through other channels, and where the FDA rapidly reviews and approves promising new indications for already marketed drugs to get these claims into product labeling. But neither of these latter propositions is generally true.

The FDA will often take years to review and approve new indications, even when the clinical trials are completed, using multiple cycles to review applications. The clinical trials that the FDA often demands require patients to be carefully randomized and placebo-controlled in settings where it is sometimes hard, if not impossible, to get patients to enroll in trials since the study drug is already available to them. This is especially true for studies targeted to serious diseases like cancer.

For serious conditions, if a drug shows promise and is already marketed for other uses, patients will be reluctant

to enroll in studies in which they might get a placebo rather than the active medicine. For these reasons, the FDA's requirements sometimes make it unlikely that a drug's FDA-approved labeling will set forth all that is relevant to the medical community about a drug's potentially beneficial uses.

In view of these facts, the FDA admits that "advances in medical knowledge and practice inevitably precede labeling revision by the manufacturer and formal labeling approval by [the FDA]."¹⁵ This is one reason why such a high percentage of drug prescribing is for off-label uses. The American Medical Association estimates that off-label uses account for 40 to 60 percent of all prescriptions written each year.¹⁶

The inherent lag between the development of new science and FDA approval means that physicians are not always able to wait for the issuance of FDA-approved labeling before prescribing a drug. Consistent with this reality is the FDA's policy that "[g]ood medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgment," regardless of whether the FDA has approved the drug for that specific use.¹⁷ The FDA has recognized that in certain situations, off-label uses or treatment regimens may, in fact, constitute "a medically recognized standard of care."¹⁸

The restrictions on off-label use are premised on a belief that doctors will be misled by the scientific information. In highly specialized fields in which communication concerns truthful, nonmisleading scientific material, physicians should be trusted to properly weigh a wide variety of information. In fast-moving fields of medicine such as cancer, where the science and treatment regimens evolve quickly based on advances published in the medical literature, there will inevitably be off-label use of drugs. The only question is whether the off-label prescribing will be carefully based on the available science.

Drug makers are one of the few groups of actors with the resources to push bottom-line scientific information to doctors. In the absence of this activity, patients will be dependent on the doctors' motivation and time to seek out all this data on their own.

Proposals for Reforming the Process

There is a real danger that the legal risk created by investigations brought under the FCA, as well as the murky boundaries placed on the kinds of activities that

will be invoked as "evidence of promotion" in these cases, have now transformed the drug industry from one that sometimes violated promotional restrictions into one that now restricts even reasonable, if not important, flows of information. To mitigate this risk and create the right public health balance, there are some steps that the DOJ can take in pursuing these cases to strike a more careful balance.

First, the DOJ can add to its staff manual for front-line prosecutors a clearer requirement that attorneys more thoroughly check with public health authorities both inside and outside the government as to whether the use of a drug that is alleged to have been the subject of off-label promotion falls within or outside standard medical convention. If a use is deemed appropriate by health authorities, prosecutors should be asked to apply more scrutiny as to whether pursuing an investigation based on the dissemination of information around the questioned prescribing could be in conflict with broader public health goals.

Second, if drug companies agree to cooperate under a voluntary corporate integrity agreement (CIA)—which gives the government greater scrutiny over the companies' business activities (including marketing functions)—then the government should agree in return to take exclusion off the table as a potential penalty. Many drug companies agree to CIAs as part of their settlement of cases brought under the FCA. Most of the major drug companies have at one time or another operated under CIAs.

If companies agree to voluntarily operate under CIAs in exchange for eliminating the risk of exclusion, the government will gain greater assuredness that firms will not engage in frivolous, off-label marketing owing to the scrutiny that the CIA affords the government.

In turn, drug companies would be more inclined to strike a proper balance regarding how they share information with doctors. They would also be willing to challenge investigations brought based on alleged off-label promotion when the allegations turn on commercial speech that may be constitutionally protected or serve a broader public health interest. With the risk of exclusion off the table, firms would be able to have their day in court and resolve any lingering legal questions around where the constitutional boundaries rest when it comes to truthful, nonmisleading commercial speech done in an educational context. This should be in everyone's interest. Surely the DOJ does not want to be acting outside the law or using coercive tactics to keep firms out of the courtroom.

Third, the FDA should establish clearer boundaries on what information it deems useful from a public

health standpoint and worthy of being shared, or it should establish those communications that it judges to be outside its legal authority to regulate, such as activities aimed at legitimate medical education. In the early 1990s, the FDA established guidance documents that set forth certain safe harbors that spoke to its aim of enabling certain kinds of commercial communications. These documents are now woefully out of date. The documents should be updated to reflect changes in the industry's practices, the impact of the enforcement activity that has unfolded in the intervening years, new vehicles for communicating information, and the influence of recent First Amendment litigation. The FDA can also establish additional safe harbors, for example, around commercial speech involving comparative effectiveness information targeted at purchasers of health care products such as formulary committees.

Finally, the drug industry needs to be willing to take the prerogative to challenge the facts in some of these cases and have that day in court. When investigations turn on the sharing of truthful, nonmisleading information about widely accepted uses of drugs, in fast moving fields like cancer, there is a legitimate question about whether public health is being served by suppressing this sort of information. However, until these cases are challenged in court, there will remain ambiguity around where the appropriate lines rest, what speech is constitutionally protected commercial speech or clearly violative, and how public health is best served.

In the practice of medicine, treatment decisions are always evolving as a result of the cumulative knowledge available at any given time, which is derived from a mosaic of scientific studies, all of various qualities, content, degrees of rigor, and stages of FDA review. We must trust professionally trained adults in the medical community to carefully weigh available information. Moreover, many patients want to take chances in dealing with vexing conditions that are poorly served by available drugs.

A core principle of America's constitutional speech protections is that the government should not establish what is orthodox, especially when it comes to politics, the arts, religion, and science. The founders recognized that these matters are by their nature iterative, and that it would be dangerous in a democratic society for the government to use its resources to pick a side in these debates. Matters that are subject to their own evolution—a core feature of how new science unfolds—are better addressed by adding voices to the debate, not suppressing them.

Notes

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8. Stephanie L. Trunk, "Sounding the Death Toll for Health Care Providers: How the Civil Claims Act Has a Punitive Effect and Why the Act Warrants Reform of Its Damages and Penalties Provision," *George Washington Law Review* 71 (2003): 159.

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11. Elizabeth A. Blackwell and James M. Beck, "Drug Manufacturer's First Amendment Right to Advertise and Promote Their Products for Off-Label Use: Avoiding a Pyrrhic Victory," *Journal of the Food and Drug Law Institute* 58 (2003): 439.

12. *Washington Legal Found v. Friedman*, 13 F. Supp. 2d 51, 74–75 (D.D.C. 1998); *Washington Legal Foundation v. Friedman*, 36 F. Supp. 2d 16, 18–20 (D.D.C. 1999); *Washington Legal Foundation v. Henney*, 56 F. Supp. 2d 81, 84 (D.D.C. 1999); and *Washington Legal Foundation v. Henney*, 202 F.3d 331, 335–36 (D.C. Cir. 2000).

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