

## TURNING ENTREPRENEURS INTO OUTLAWS

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When first asked to participate on a panel about “economic crimes,” I thought I was not really equipped to opine on criminal law since I spend my time in court litigating civil cases to protect constitutional rights. Then I thought a little more about the types of cases I had been working on. I realized, quite to my dismay, that I *am* qualified to discuss criminal law because I have observed our governments at all levels engaging in a disturbing trend of criminalizing innocuous, peaceful economic activities, simply because those activities involve the exchange of money.

I will discuss a local and a federal example of these attacks on economic liberty. At the local level, cities across the nation are turning responsible homeowners into criminals, simply for renting out their homes to overnight guests.<sup>1</sup> Home sharing, often facilitated via platforms like Airbnb<sup>2</sup> or HomeAway,<sup>3</sup> involves hosts opening their homes to overnight guests in exchange for money. You might think of it as a short-term rental or vacation rental. Despite technology making this practice more apparent and prevalent today, it has actually existed since the country’s Founding.

People have allowed overnight guests to stay in their homes for centuries—sometimes in exchange for money, but also in exchange for chores, meals, or other work or goods.<sup>4</sup> This gives

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1. See, e.g., PACIFIC GROVE, CAL., MUN. CODE §§ 7.40.010–7.40.200 (2019); CHL, ILL., MUN. CODE §§ 4-13-100, 4-13-260(a)(9), 4-13-270(c), 4-14-010, 4-14-040(b)(8)–(9), 4-14-060(d)–(f), 4-14-080, 4-14-090, 4-14-100, 4-16-230 (2019); MIAMI BEACH, FLA., CODE OF ORDINANCES §§ 142-905(b)(5), 142-1111 (2019); SEATTLE, WASH., MUN. CODE §§ 6.600.010–6.600.150 (2019).

2. *About Us*, AIRBNB NEWSROOM, <https://press.airbnb.com/about-us/> [https://perma.cc/EW56-DGC7] (last visited Sept. 10, 2019).

3. *Company Information*, HOMEAWAY, <https://www.homeaway.com/info/about-us/company-info> [https://perma.cc/3HED-C6CB] (last visited Sept. 10, 2019).

4. See Jamila Jefferson-Jones, *Airbnb and the Housing Segment of the Modern “Sharing Economy”: Are Short-Term Rental Restrictions an Unconstitutional Taking?*, 42

homeowners additional money, which they can use to pay their bills or make improvements to their homes.<sup>5</sup> It also gives travelers a wider variety of options in terms of price, location, and style of housing, and it allows them to experience local communities more intimately. The only thing that has changed between the Founding period and today is the burst of technology that has allowed homeowners and visitors to use online platforms to communicate. This development has made the practice of home sharing easier than ever before. This practice is also more accountable than ever before because all parties have access to more information. For instance, it is easier than ever for renters or neighbors who have a bad experience to leave feedback.<sup>6</sup> Further, homeowners can be more selective about who stays in their homes, and they are able to make sure that those people are knowledgeable about local laws.

Cities, however, are responding to the growth in home sharing in a very different way. Rather than welcoming this economic activity, officials are instead imposing draconian new rules on this long-established practice.<sup>7</sup> It has always been legal to allow an overnight guest to stay in your home for free, to let a friend to sleep on your couch, to have house sitters, or to have someone stay in your home and take care of your pets while you are out of town. However, in a growing number of cities, it is now not just illegal, but in many jurisdictions it is an

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HASTINGS CONST. L.Q. 557, 562–64 (2015); *see also* WALT WHITMAN, A COLLECTION OF RECENTLY DISCOVERED WRITINGS 22–24 (Joseph Jay Rubin & Charles H. Brown eds., 1950).

5. Christopher Koopman, *Airbnb ruling deprives struggling New Yorkers of a steady income*, N.Y. POST (Oct. 21, 2016, 10:58 PM), <https://nypost.com/2016/10/21/airbnb-ruling-deprives-struggling-new-yorkers-of-a-steady-income/> [https://perma.cc/P7QE-ST6E].

6. *See, e.g., How can I Stay Neighborly as a community member*, HOMEAWAY, <https://help.homeaway.com/articles/how-can-i-stay-neighborly-as-a-community-member> [https://perma.cc/2TEH-LRKH] (last visited Sept. 10, 2019); *Trust & Safety: Hosting*, AIRBNB, <https://www.airbnb.com/trust/> [https://perma.cc/R2M7-9V8T] (follow “Hosting” hyperlink) (last visited Sept. 10, 2019).

7. *See, e.g., Ben Lane, Airbnb takes Boston to court over city “draconian” short-term rental rules*, HOUSINGWIRE (Nov. 16, 2018, 11:49 AM), <https://www.housingwire.com/articles/47424-airbnb-takes-boston-to-court-over-citys-draconian-short-term-rental-rules/> [https://perma.cc/US86-GM3Y]; Ally Marotti, *Chicago’s Airbnb home-sharing rules are ‘draconian,’ lawsuit says*, CHI. TRIB. (Nov. 16, 2016, 6:30 AM), <https://www.chicagotribune.com/business/ct-airbnb-shared-housing-lawsuit-1116-biz-20161115-story.html> [https://perma.cc/3EFF-MPMM].

actual crime, to rent your home short term in exchange for money.<sup>8</sup>

These cities treat home sharing itself as the crime—regardless of whether a particular guest is causing any kind of nuisance like making excessive noise, littering the yard with trash, or parking where they should not.<sup>9</sup> These are very difficult laws for cities to enforce.<sup>10</sup> Of course, the reason for that difficulty is the exact reason why the practice should not be a crime—although there are occasional problems with short-term rentals (as is true of long-term rentals, or owner-occupied homes), most of the time there are not. Usually, neighbors cannot tell whether somebody is renting their home to a short-term renter because the guest uses that home for a residential use—in the same manner a homeowner or long-term renter would—and goes about his business in a residential way. Unless the guest causes a disturbance, neighbors usually do not have reason to know whether somebody is staying in that home in a short-term manner (and thus violating the law) or a long-term manner (and is not). Therefore, cities have a difficult time enforcing these laws outside of the very small number of instances where occupants are actually causing nuisances (and thus are already violating other laws), so they have to resort to drastic measures.<sup>11</sup> And cities get away with such extreme actions because anti-home-sharing laws are laws prohibiting economic activity. Law schools teach students that, in the eyes of courts, economic rights are not really rights at all.<sup>12</sup> Courts are

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8. See, e.g., PACIFIC GROVE, CAL., MUN. CODE § 7.40.140 (2019); CHARLOTTE, N.C., CODE OF ORDINANCES § 13-44(a) (2019); ARLINGTON, VA., CTY. CODE OF ORDINANCES § 64-12 (2011); SEATTLE, WASH., MUN. CODE § 6.600.130 (2019).

9. *Supra* note 8.

10. See Associated Press, *Honolulu Adds Inspectors to Help Enforce Vacation Rental Law*, U.S. NEWS (Aug. 16, 2019, 11:45 AM), [https://www.usnews.com/news/best-states/hawaii/articles/2019-08-16/honolulu-adds-inspectors-to-help-enforce-vacation-rental-law?src=usn\\_tw](https://www.usnews.com/news/best-states/hawaii/articles/2019-08-16/honolulu-adds-inspectors-to-help-enforce-vacation-rental-law?src=usn_tw) [<https://perma.cc/T3GM-G8SJ>]; see also Kyra Gurney & Taylor Dolven, *Huge fines, midnight busts: Inside Miami Beach's war on short-term rentals*, MIAMI HERALD (Mar. 11, 2019, 1:47 PM), <https://www.miamiherald.com/news/local/community/miami-dade/miami-beach/article226269295.html> [<https://perma.cc/4KJC-G6FZ>]; *Protecting Your Right to Share Your Home: Mendez v. Chicago*, GOLDWATER INST. (Nov. 15, 2016), <https://goldwaterinstitute.org/mendez-v-chicago/> [<https://perma.cc/KVS5-ENX3>].

11. See Associated Press, *supra* note 10.

12. See, e.g., Louis Henkin, *Economic Rights Under the United States Constitution*, 32 COLUM. J. TRANSNAT'L L. 97, 102–03, 107–09, 112–13, 119 (1994).

willing to rubber stamp infringements on economic rights, treating them more like mere privileges and permissions from the government.<sup>13</sup>

This problem is compounded when cities impose massive fines on anyone who violates these anti-home-sharing laws. The City of Miami Beach, which was founded on tourism<sup>14</sup> and depends on tourism as its lifeblood, has decided to outlaw and criminalize the renting of one's home to short-term overnight guests in almost every place in the city.<sup>15</sup> If you violate that law and have somebody stay in your home overnight, you can be fined up to \$100,000 per night.<sup>16</sup> This is not an overnight guest who is causing any sort of problem—the violation is simply that you've let somebody stay in your home overnight. A fee for home sharing just a few nights could quickly add up to the entire value of a host's home.

Cities look at this as a way to increase revenue,<sup>17</sup> and it is a win-win for them because they get to outlaw the activity and also intimidate residents into giving up their property rights because of the serious consequences. And then, of course, city governments get to pocket the money (if they're actually able to recover it—many people owe the City of Miami Beach large sums of money and are unable to pay it<sup>18</sup>). These people will eventually lose their homes and their livelihoods because the city is going to go after them for those unpaid fines.<sup>19</sup>

This is not only abhorrent public policy—it is also unconstitutional. My colleagues at the Goldwater Institute are challenging these excessive fines in Florida state court under the Excessive Fines Clause of the Constitution of the State of Florida.<sup>20</sup> Many

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13. *See id.*

14. *See* Andres Viglucci, *The 100-year story of Miami Beach*, MIAMI HERALD (Mar. 21, 2015, 11:32 PM), <https://www.miamiherald.com/news/local/community/miami-dade/miami-beach/article15798998.html> [<https://perma.cc/XA33-ZGDL>].

15. MIAMI BEACH, FLA., CODE OF ORDINANCES §§ 142-905(b)(5), 142-1111 (2019).

16. *Id.*

17. Kristine Phillips, *A Florida woman was fined \$100,000 for a dirty pool and overgrown grass. When do fines become excessive?*, USA TODAY (July 22, 2019, 5:40 PM), <https://www.usatoday.com/in-depth/news/politics/2019/07/19/florida-city-hits-homeowners-massive-penalties-supreme-court-excessive-fines/1691703001/> [<https://perma.cc/7CJB-JD4Y>].

18. Gurney & Dolven, *supra* note 10.

19. Phillips, *supra* note 17.

20. FLA. CONST. art. I, § 17; *Challenging the Highest Home-Sharing Fines in the Nation*: Nichols v. City of Miami Beach, GOLDWATER INST. (June 27, 2018), <https://>

state constitutions protect individual liberties to a greater extent than the U.S. Constitution, and the state constitutions have their own provisions protecting individual liberty and stopping government overreach.<sup>21</sup> Florida's Excessive Fines Clause protects people from fines that are "grossly disproportional" to the person's action.<sup>22</sup> If it is not grossly disproportional to be charged \$100,000 for peacefully exercising your property rights and letting somebody stay in your home overnight, then I do not know what is. That is the argument the Goldwater Institute will be making in Florida state court.<sup>23</sup>

One might ask why advocates for economic rights have been turning to the courts instead of the city councils and the state legislatures. There is a legal reason and a practical reason. As a legal matter, it is the responsibility of the courts to uphold their state constitutions and the U.S. Constitution, and citizens should never have to go to a city council or a state legislature and beg them to respect their constitutional rights.<sup>24</sup> That is the job of judges upholding the constitutions, that is why we have constitutions, and that is why we go to court.<sup>25</sup> And as a practical matter, citizens have a tough fight against special interests before city councils and state legislatures. The hotel industry, for example, had an incentive to go to the Mayor and City Commission of the City of Miami Beach and convince them to outlaw and criminalize home sharing.<sup>26</sup>

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goldwaterinstitute.org/challenging-the-highest-home-sharing-fines-in-the-nationnichols-v-city-of-miami-beach/ [https://perma.cc/8TT9-VFXR]. One reason the Goldwater Institute chose to litigate using Florida's Excessive Fines Clause is that the lawsuit began before the Supreme Court had decided *Timbs v. Indiana*, 139 S. Ct. 682 (2019), which finally incorporated the U.S. Constitution's Excessive Fines Clause of the Eighth Amendment against the states. *Id.* at 686–87.

21. Clint Bolick, *State Constitutions: Freedom's Frontier*, 16 CATO SUP. CT. REV. 15, 15–17 (2017).

22. FLA. CONST. art. I, § 17.

23. Since this speech was delivered, a Florida trial court struck down Miami's home sharing ban and its accompanying \$20,000 to \$100,000 fines on state statutory grounds. The court did not reach the constitutional claim. *Miami Beach's \$100,000 Home-sharing Fines Struck Down*, GOLDWATER INST.: DEF. LIBERTY BLOG (Oct. 7, 2019), <https://indefenseofliberty.blog/2019/10/07/miami-beachs-100000-home-sharing-fines-struck-down/> [https://perma.cc/8V3W-D3T2].

24. *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 170, 177, 180 (1803).

25. *Id.*

26. Katie Benner, *Inside the Hotel Industry's Plan to Combat Airbnb*, N.Y. TIMES (Apr. 16, 2017), <https://www.nytimes.com/2017/04/16/technology/inside-the-hotel-industrys-plan-to-combat-airbnb.html> [https://perma.cc/3EMA-557Z].

Here are a couple of interesting examples from Arizona. The Town of Jerome, Arizona, is a small, beautiful tourist town that outlawed short-term rentals before the Goldwater Institute and its allies stepped in and fixed the problem.<sup>27</sup> The Jerome Town Council defended its decision to outlaw home sharing by warning that people who are only staying for a short term might put their trash out on the wrong day, which could cause wild javelinas to eat away at the trash and make a mess.<sup>28</sup> No matter that a reasonable person might recognize that residents or the city government could tell these visitors when trash day is, and visitors could probably put their trash out on that day.

Another of the city council's arguments was that the potholes all over the Town of Jerome might hurt short-term guests who do not know they are there.<sup>29</sup> Never mind that the town could just fix the potholes. And the most entertaining argument was that allowing short-term rentals would result in a lack of housing for people who want to serve in city government.<sup>30</sup> I can't make this stuff up.

Even worse, the City of Sedona, another beautiful, popular tourist location, also decided to criminalize home sharing, again before the Goldwater Institute came in and fixed the problem.<sup>31</sup> The city did not argue that there were nuisances, like noise, traffic, or trash problems. Rather, the City of Sedona responded to the aesthetic desires of a few local residents, who argued that the city ought to preserve the community for local artists and families, rather than allowing visiting outsiders in

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27. Christina Sandefur, *Turning Homeowners into Outlaws: How Anti-Home-Sharing Regulations Chip Away at the Foundation of an American Dream*, 39 U. HAW. L. REV. 395, 431–33 (2017); Glenn Odegard, *Preserving History with Home-Sharing in Jerome, Arizona*, GOLDWATER INST.: DEF. LIBERTY BLOG (Aug. 16, 2018), <https://indefenseofliberty.blog/2018/08/16/preserving-history-with-home-sharing-in-jerome-arizona/> [https://perma.cc/7982-64V2].

28. See CHRISTINA SANDEFUR & TIMOTHY SANDEFUR, GOLDWATER INST., PROTECTING PRIVATE PROPERTY RIGHTS: THE PROPERTY OWNERSHIP FAIRNESS ACT 17 (2016), [https://goldwaterinstitute.org/wp-content/uploads/cms\\_page\\_media/2016/2/9/Final%20Property%20Rights%20paper.pdf](https://goldwaterinstitute.org/wp-content/uploads/cms_page_media/2016/2/9/Final%20Property%20Rights%20paper.pdf) [https://perma.cc/F3VU-2QPE].

29. *Id.*

30. *Id.*

31. *Sedona Grand, LLC v. City of Sedona*, 270 P.3d 864, 866 (Ariz. Ct. App. 2012); *Sedona Grand v. City of Sedona*, GOLDWATER INST. (Aug. 2, 2017), <https://goldwaterinstitute.org/sedona-grand-v-city-of-sedona/> [https://perma.cc/MB92-BHAM].

their neighborhoods.<sup>32</sup> Never mind that a tourist city's economy is built on outsiders visiting.<sup>33</sup>

Can you imagine a city criminalizing the peaceful use of its residents' property because neighbors don't want outsiders in the community?<sup>34</sup> While that might be the role of a homeowner association when people contract to determine how to use their properties, a city government should not have that power. It is a dangerous proposition that government not only should be able to decide who is desirable and who is not in a particular community, but also that it should be able to criminalize violations of that judgment. Miami Beach,<sup>35</sup> Nashville,<sup>36</sup> and cities across the country<sup>37</sup> are not only fining people excessively, but

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32. See, e.g., SANDEFUR & SANDEFUR, *supra* note 28, at 17 ("Despite vague references to 'the peace, safety and general welfare of the residents,' city records showed that officials adopted the rental ban in order to protect its 'small-town character' and 'scenic beauty,' not to prevent any public dangers. The complaints officials received from residents all related to general grievances about roadside parking or traffic, or neighbors expressing a desire to live in a 'small town' where 'you know most everyone.' These residents urged the city to ban short-term rentals in order to maintain 'a quiet, friendly, family' neighborhood—not to protect public safety."); Joe Dana, *Sedona's quality of life impacted by home-sharing economy, locals say*, 12NEWS (Aug. 1, 2019, 2:40 PM), <https://www.12news.com/article/news/local/arizona/sedonas-quality-of-life-impacted-by-home-sharing-economy-locals-say/75-50af04a0-bd55-4092-a7a9-b4ee6773385d> [<https://perma.cc/C9GH-FS8D>].

33. See *Tourism revenue increases*, SEDONA RED ROCK NEWS (Sept. 23, 2016), <https://www.redrocknews.com/news/88888896-city-news/42973-tourism-revenue-increases> [<https://perma.cc/Ry3C-HAVK>]; *Tourism's Community Impact*, SEDONA CHAMBER COM. & TOURISM BUREAU, <https://sedonachamber.com/why-tourism/tourisms-community-impact/> [<https://perma.cc/38J6-4N4T>] (last visited Aug. 26, 2019).

34. Christina Sandefur, *Building Community Shouldn't Mean Slamming the Door to Visitors*, GOLDWATER INST.: DEF. LIBERTY BLOG (May 2, 2019), <https://indefenseofliberty.blog/2019/05/02/building-community-shouldnt-mean-slamming-the-door-to-visitors/> [<https://perma.cc/5JS8-XLBQ>].

35. MIAMI BEACH, FLA., CODE OF ORDINANCES §§ 142-905(b)(5), 142-1111 (2019); Taylor Dolven, *The punishment for running an illegal Airbnb in Miami Beach is likely to get a lot worse*, MIAMI HERALD (Aug. 2, 2019, 1:32 PM), <https://www.miamiherald.com/news/business/tourism-cruises/article233436012.html> [<https://perma.cc/9S37-W64U>].

36. NASHVILLE, TENN., CODES OF ORDINANCES § 17.16.070(U) (2019); Sandy Mazza & Adam Tamburin, *Man sentenced to jail after city officials said he operated an illegal Airbnb*, TENNESSEAN (Feb. 26, 2019, 3:30 PM), <https://www.tennessean.com/story/news/2019/02/26/nashville-airbnb-operator-jail-sentence-layton-jones-city-code/2993986002/> [<https://perma.cc/MUD7-4DRQ>].

37. See, e.g., Kate Gibson, *Illegal Airbnb rentals get San Francisco couple \$2.25M fine*, CBS NEWS (Nov. 5, 2018, 6:16 PM), <https://www.cbsnews.com/news/illegal-airbnb-rentals-get-san-francisco-couple-2-25m-fine/> [<https://perma.cc/WEG2-T3TY>]; Sam Tabachnik, *Denver couple charged with felonies for short-term rental violation as city*

they're even putting them in jail for violating these anti-home-sharing rules. Cities are taking away people's livelihoods and taking away their liberties for the "crime" of allowing people to stay overnight in their homes.

This criminalization of harmless economic activity has implications far beyond economic liberty and property rights. Some cities are even outlawing home sharing advertisements, and they're compelling online platforms to turn those homeowners and advertisements over to the police and city government.<sup>38</sup> How are cities able to outlaw these advertisements? Isn't truthful speech protected by the First Amendment? It typically is, but not always when the underlying activity is illegal—especially not when the underlying activity is a crime.<sup>39</sup> If the underlying activity is a crime, then the cities argue that they're also able to outlaw and criminalize the speech because it's speech about something that is criminal and perpetuates that illegal activity.<sup>40</sup> Although courts sometimes embrace this type of reasoning, such an argument can be taken too far. As the Fifth Circuit observed in *Byrum v. Landreth*,<sup>41</sup> if the government can criminalize harmless behavior to empower itself to censor

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*moves to tighten reins on vacation rentals*, DENVER POST (June 14, 2019, 10:37 AM), <https://www.denverpost.com/2019/06/11/denver-short-term-rental-airbnb-arrest/> [<https://perma.cc/NMC4-KJ9B>].

38. Greg Bensinger, *New York Governor Signs Bill Authorizing Fines for Airbnb Rentals*, WALL ST. J. (Oct. 21, 2016, 3:55 PM), <http://www.wsj.com/articles/new-york-governor-signs-bill-authorizing-fines-for-airbnb-rentals-1477079740> [<https://perma.cc/S9SM-QQG8>]; Emma Whitford, *It's Now Illegal To Advertise Your Apartment Short-Term On Airbnb*, GOTHAMIST (Oct. 21, 2016, 3:35 PM), <https://gothamist.com/2016/10/21/airbnb-behave.php> [<https://perma.cc/G2DU-RZF3>].

39. See *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 498 (1948).

40. Kia Kokalitcheva, *Airbnb Threatens to Sue New York If Gov. Signs New Home-Sharing Bill*, FORTUNE (Sept. 7, 2016), <http://fortune.com/2016/09/07/airbnb-sues-new-york-state/> [<https://perma.cc/2H22-CR6Q>] (Assemblywoman Deborah Glick was surprised that the New York law was controversial, because "You can't advertise an illegal activity." (internal quotation marks omitted)); Jessica Soultanian-Braunstein, *Legislation Proposed in NY State Assembly Would Put an End to Online Advertising of Illegal Short-Term Apartment Rentals*, CITYLAND (Mar. 1, 2016), <http://www.citylandnyc.org/23749-2/> [<https://perma.cc/EW4M-MJCU>] (Assemblywoman Linda Rosenthal, who sponsored New York's ban on home sharing advertisements said, "This legislation targets serial illegal hotel kingpins who advertise and rent out multiple units by providing enforcement entitles [sic] with strong new tools to crack down on this egregious law breaking." (internal quotation marks omitted)); Mike Vilensky, *Albany Approves Airbnb Penalties*, WALL ST. J. (June 17, 2016, 7:29 PM), <http://www.wsj.com/articles/albany-approves-airbnb-penalties-1466206171> [<https://perma.cc/MDC5-6YAF>].

41. 566 F.3d 442 (5th Cir. 2009).



people or to intrude on other rights, then our constitutional rights are doubly at risk.<sup>42</sup> We at the Goldwater Institute are certainly making that argument in courts across the country as we stand up to excessive bans and the criminalization of home sharing.

The federal government is also intruding on the economic rights of Americans. The U.S. Food and Drug Administration (FDA) is applying rules to pure speech that were instead designed to regulate economic actions. It is doing this by pursuing strict liability criminal penalties against people in the healthcare industry for doing no more than simply speaking the truth in a way that can ultimately help patients.

Under federal law, a pharmaceutical company that manufactures drugs or medical devices can be charged with a *crime* for simply telling a doctor about a legal, safe, and alternative use for a particular medicine.<sup>43</sup> This is the federal off-label speech rule, also called the FDA gag rule.<sup>44</sup> Most readers have used a medical treatment off label. An off-label treatment occurs when a doctor prescribes a drug that is legally on the market after going through the FDA approval process—which in and of itself is a daunting task<sup>45</sup>—for a purpose, patient population, or dose other than what the FDA approved it for.<sup>46</sup> This is perfectly lawful, it happens all the time, and it's legal, safe, and common.<sup>47</sup>

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42. *Id.* at 447 (finding state's assertion that calling oneself an "interior designer" without receiving a government license is unprotected speech to be circular and would "authorize legislatures to license speech and reduce its constitutional protection by means of the licensing alone").

43. 21 U.S.C. §§ 331, 333, 352 (2012 & Supp. V 2018); *see also* Christina Sandefur, *The FDA's Approach to Off-Label Communications: Restricting Free Speech in Medicine?*, REG. TRANSPARENCY PROJECT (May 10, 2018), <https://regproject.org/wp-content/uploads/RTP-FDA-Health-Working-Group-Paper-Off-Label-Communications.pdf> [<https://perma.cc/6K4S-F9E2>].

44. *See* U.S. FOOD & DRUG ADMIN., GOOD REPRINT PRACTICES FOR THE DISTRIBUTION OF MEDICAL JOURNAL ARTICLES AND MEDICAL OR SCIENTIFIC REFERENCE PUBLICATIONS ON UNAPPROVED NEW USES OF APPROVED DRUGS AND APPROVED OR CLEARED MEDICAL DEVICES (2009).

45. *Id.*; *see also* MARK FLATTEN, GOLDWATER INST., DEAD ON ARRIVAL: FEDERAL "COMPASSIONATE USE" LEAVES LITTLE HOPE FOR DYING PATIENTS 4 (2016), <https://goldwaterinstitute.org/wp-content/uploads/2016/02/Dead-On-Arrival-Report.pdf> [<https://perma.cc/8F99-8PYR>].

46. U.S. FOOD & DRUG ADMIN., *supra* note 44.

47. *See* Carolyn M. Clancy, *Off-Label Drugs: What You Need to Know*, AGENCY FOR HEALTHCARE RES. & QUALITY (Apr. 21, 2009), <https://archive.ahrq.gov/news/>

One in five of all prescriptions are for off-label uses.<sup>48</sup> But here's the oddity in the law: although the treatment is legal and prescribing the off-label treatment is legal, it is often a crime for a manufacturer of that treatment to share truthful, nondeceptive information about off-label treatments with a provider.<sup>49</sup>

Because the manufacturer is usually the party with the most up-to-date information about the treatment, it is in a position to share alternate uses and negative side effects with doctors to guide their off-label treatments.<sup>50</sup> So the FDA gag rule not only harms the companies themselves by depriving them of their free speech rights, but it also harms doctors who may not know about all of the tools available to treat patients. Ultimately, that harms patients because they have less information and their doctors are not fully equipped to help heal them.

Black letter First Amendment case law teaches that commercial speech receives less protection than many other types of speech, like political speech.<sup>51</sup> Note that the text of the First Amendment does not make such distinctions.<sup>52</sup> Speech is speech, and it is all protected the same way as far as our Founding Fathers were concerned.<sup>53</sup> However, recent cases have confirmed that commercial speech is still protected speech,<sup>54</sup> so one might wonder how the FDA is able to outlaw, and even criminalize, truthful speech about a lawful practice. From the FDA's perspective, this is speech that is somehow tainted because it is performed to facilitate an economic activity.

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columns/navigating-the-health-care-system/042109.html [https://perma.cc/RS6R-7GBR]; see also Sandefur, *supra* note 43.

48. Clancy, *supra* note 47; Sandefur, *supra* note 43.

49. See Paul Howard & James Copland, *Off-Label, Not Off-Limits: The FDA Needs To Create a Safe Harbor For Off-Label Drug Use*, 110 MO. MED. 106, 108 (2013) ("Companies' fear of federal criminal action to enforce off-label drug promotion is not merely hypothetical. Claims of illicit off-label drug promotion have been among the most commonly asserted Medicaid fraud allegations in federal enforcement actions."); see also Sandefur, *supra* note 43.

50. Howard & Copland, *supra* note 49, at 107.

51. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 561–63 (1980).

52. U.S. CONST. amend. I.

53. *Id.*

54. *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 571 (2011) (dealing with a restriction on sale, disclosure, and use of pharmacy records that reveal the prescribing practices of individual doctors); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 553 (2001) (dealing with a ban on tobacco ads and sales of tobacco within 1,000 feet of schools and playgrounds).

Courts that have heard challenges to this ban on speech regarding off-label uses have stepped up to strike down the FDA gag rule.<sup>55</sup> A prime example of this comes from *United States v. Caronia*,<sup>56</sup> in which the Second Circuit overturned the criminal conviction of a pharmaceutical representative whose only crime was to share truthful information about lawful treatments—all without the presence of fraud or other misrepresentation.<sup>57</sup> The Second Circuit in *Caronia* overturned the conviction on the ground that speech, including speech used in pharmaceutical marketing, cannot be prosecuted under the First Amendment.<sup>58</sup> In other words, the court held that if the conduct is lawful, then the speech is also lawful, and as long as it is not false or misleading, then neither the conduct nor speech may be prosecuted.<sup>59</sup>

In response, the FDA essentially ignored the Second Circuit's ruling and has continued to argue that prosecuting off-label speech does not automatically violate the First Amendment because such speech may be used as evidence of the crime of misbranding under the U.S. Federal Food, Drug, and Cosmetic Act.<sup>60</sup>

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55. See *United States v. Caronia*, 703 F.3d 149, 160 (2d Cir. 2012) (vacating conviction on First Amendment grounds); *Amarin Pharma, Inc. v. FDA*, 119 F. Supp. 3d 196, 198, 226 (S.D.N.Y. 2015).

56. 703 F.3d 149 (2d Cir. 2012).

57. *Id.* at 160 (“Because we conclude from the record in this case that the government prosecuted Caronia for mere off-label promotion and the district court instructed the jury that it could convict on that theory, we vacate the judgment of conviction.”).

58. *Id.* at 160–63 (finding that the government prosecuted directly based on speech and did not use speech as mere evidence of intent to misbrand in violation of United States Federal Food, Drug, and Cosmetic Act (FDCA)); see also *Sorell*, 564 U.S. at 557 (“Speech in aid of pharmaceutical marketing . . . is a form of expression protected by the Free Speech Clause of the First Amendment.”).

59. *Caronia*, 703 F.3d at 160 (“[U]nder the principle of constitutional avoidance, . . . we construe the FDCA as not criminalizing the simple promotion of a drug’s off-label use because such a construction would raise First Amendment concerns.”).

60. See 21 U.S.C. § 352(f)(1) (2012) (defining misbranding as lacking directions for approved use); 21 U.S.C. § 352(q)(1) (2012) (defining misbranding as false or misleading advertising); 21 C.F.R. § 201.5 (2019) (defining intended use as “directions under which the layman can use a drug safely and for the purposes for which it is intended”); 21 C.F.R. § 201.128 (2019) (defining intended use as “the objective intent of the persons legally responsible for the labeling of drugs[, which is] . . . determined by such persons’ expressions or circumstances surrounding the distribution”); see also Ralph Hall & Eric Marshall, *FDA Explains Decision Not to Seek Rehearing in Caronia*, BEYOND HEALTHCARE REFORM (Jan. 23, 2013), <https://>

That is a distinction that only a lawyer can love, but that is how the FDA operates.<sup>61</sup>

The FDA takes this distinction even further by using the off-label gag rule to convict individuals of criminal conspiracy, including conspiracy to misbrand pharmaceuticals and send them into interstate commerce.<sup>62</sup> Although, as the Second Circuit held in *Caronia*, it is legal for a salesperson to speak honestly about off-label uses, it is legal for doctors to prescribe the product, and it is legal for a company to ship the product to the doctor, when those three things together come together, they become the crime of criminal conspiracy.<sup>63</sup>

In *United States v. Park*,<sup>64</sup> the Supreme Court held that the government can not only hold individual sales representatives liable, but it can actually extend that liability all the way up to the executives of the company.<sup>65</sup> The Court's holding means that executives who do not order improper conduct, or even know about it, could be held liable merely because they have the potential authority to stop it. By creating criminals out of people who are trying to sell off-label products to patients who need treatment, the FDA is preventing customers from getting the help they need.

In closing, consider this guiding principle: if it is legal and safe to perform an activity, it should be legal to do that activity

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s3.amazonaws.com/documents.lexology.com/8a57dab3-d96f-40d3-8e45-5a473c69ed43.pdf [https://perma.cc/25LY-LUX5].

61. Further, FDA guidance construes nondeceptive off-label promotion as evidence of misbranding if it can demonstrate that the drug is being sold for an unapproved intended use. See, e.g., U.S. FOOD & DRUG ADMIN., *supra* note 44 ("An approved drug that is marketed for an unapproved use (whether in labeling or not) is misbranded because the labeling of such drug does not include 'adequate directions for use.'").

62. See, e.g., 21 U.S.C. § 331(a) (2012); 18 U.S.C. § 371 (2012); *United States v. Scully*, 877 F.3d 464, 468 (2d Cir. 2017) (involving charges against defendants for conspiracy to misbrand pharmaceuticals while sending into interstate commerce in violation of 18 U.S.C. § 371 and 21 U.S.C. § 331); *United States v. Ellis*, 326 F.3d 550, 553 (4th Cir. 2003); *United States v. Haas*, 171 F.3d 259, 264 (5th Cir. 1999); *United States v. Mitcheltree*, 940 F.2d 1329, 1332 (10th Cir. 1991); *United States v. Torigian Labs., Inc.*, 577 F. Supp. 1514, 1517–18, (E.D.N.Y. 1984).

63. See e.g., MARK FLATTEN, GOLDWATER INST., GAGGED: FEDS USE CRIMINAL CHARGES, THREATS TO SILENCE DRUGMAKERS 2–3 (2019), <https://goldwaterinstitute.org/wp-content/uploads/2019/02/Gagged-Report-2019-02-26-Flatten.pdf> [https://perma.cc/9FKT-9F8T].

64. 421 U.S. 658 (1975).

65. *Id.* at 670–71 (citations omitted).

in exchange for money.<sup>66</sup> If it is lawful to allow an overnight guest in one's home for free, it should be lawful to allow an overnight guest in one's home in exchange for money. If it is lawful to share truthful, helpful information about a product, then it should be lawful to exchange that information to facilitate a transaction. Money does not magically transform a harmless activity into a harmful activity, and money certainly should not transform a harmless activity into a crime.

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66. *See, e.g.*, RANDY E. BARNETT, *RESTORING THE LOST CONSTITUTION: THE PRESUMPTION OF LIBERTY* 80, 82, 213–16 (rev. ed. 2014); JOHN STUART MILL, *ON LIBERTY* 75–76 (Stefan Collini ed., Cambridge Univ. Press 8th prt. 2012) (1859) (“As soon as any part of a person’s conduct affects prejudicially the interests of others, society has jurisdiction over it, and the question whether the general welfare will or will not be promoted by interfering with it, becomes open to discussion. But there is no room for entertaining any such question when a person’s conduct affects the interests of no persons besides himself or needs not affect them . . .”).