# 12

# Clouded Judgment

## *Preventing Conflicts of Interest in Drug Courts*

*Jody Lyneé Madeira, Barbara Andraka-Christou, Lori Ann Eldridge, and Ross D. Silverman*[*]

### 12.1 THE GROWING RELATIONSHIP BETWEEN PHARMACEUTICAL AND MEDICAL DEVICE MANUFACTURERS AND DRUG COURTS

United States' pharmaceutical companies and medical device manufacturers are marketing their products directly to drug courts – with controversial results.[1] These activities can be associated with court policies and staff beliefs that are anti-agonist – opposed to forms of medications for opioid use disorder (MOUD[2]) containing opioids. Anti-agonist beliefs and policies can harm client outcomes when judges narrow MOUD options to one medication, or partner with providers who prefer one medication.

In the Greenwood City, Indiana, drug court overseen by Judge Lewis Gregory, patients received a neurostimulation medical device called the Bridge to assist them with detoxification before transitioning to Vivitrol. Judge Gregory began using the device in February 2017 after meeting with the manufacturer, Innovative Health Solutions (IHS). His court also only used Vivitrol because he "was certainly not going to do a medication-assisted treatment program with drugs which people used to get high."[3] But IHS did not receive FDA marketing authorization until November 2017, and existing research used controversial methodology and lacked IRB oversight.[4] Were

[*] This chapter was supported in part by funding for the Indiana Addictions Law and Policy Surveillance Project (Silverman, PI) via the Indiana University Addictions Grand Challenge.

[1] Jake Harper, To Grow Market Share, A Drugmaker Pitches Its Product to Judges, NPR (Aug. 3, 2017), www.npr.org/sections/health-shots/2017/08/03/540029500/to-grow-market-share-a-drugmaker-pitches-its-product-to-judges; Jake Harper, Questions Raised about Study of Device to Ease Opioid Withdrawal, NPR (May 2, 2018), www.npr.org/sections/health-shots/2018/05/02/602908208/questions-raised-about-study-of-device-to-ease-opioid-withdrawal.

[2] MOUD is sometimes referred to as medication-assisted treatment (MAT).

[3] Scott L. Miley, Device Said to Stem Opioid Withdrawal Pain, Tribune Star (Nov. 19, 2017), www.tribstar.com/news/local_news/device-said-to-stem-opioid-withdrawal-pain/article_3d97061f-e8d1-5b6f-ae9b-74965c09a62a.html.

[4] Jody Lyneé Madeira, Vulnerable Patients – Easy Targets for Companies Willing to Sacrifice Ethics for Profits, The Hill (May 21, 2018), https://thehill.com/opinion/healthcare/388634-vulnerable-patients-easy-targets-for-companies-willing-to-sacrifice-ethics.



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such concerns raised with the decision makers? Perhaps not, given that these decisions were occurring in a court rather than in a clinical setting. In the Hocking County Municipal Vivitrol Drug Court near Athens, Ohio, Judge Fred Moses decided to only allow clients to access the non-agonist medication Vivitrol – a choice he made after meeting Vivitrol's manufacturer, Alkermes, at a professional conference and asking sales representatives to send the court's affiliated clinician free starter doses.[5] This decision ran counter to medical standards and professional guidance supporting client access to all types of MOUD.[6]

Manufacturer relationships with criminal justice institutions and drug courts represent a new frontier. Alkermes sales representatives have marketed Vivitrol to court officials in numerous states, including Missouri, Massachusetts, Ohio, West Virginia, Alaska, and Indiana, and administered injections to parolees in Michigan, Illinois, Wisconsin, Vermont, New Hampshire, and Pennsylvania; it has also lobbied state and national policy makers for laws favoring Vivitrol.[7] As of 2017, Vivitrol was used in 450 publicly funded initiatives, such as court and parole programs, in 39 states.[8] While manufacturer-court relationships are relatively novel, their conventional counterpart, the pharmaceutical sales representative-physician marketing efforts, has generated a robust body of scholarship that is helpful in understanding their potential consequences.

One might assume that effective gatekeepers keep watch over these relationships and their consequences, including the FDA, federal and state legislatures, state court systems, and/or legal and medical professional associations that at least ensure that public officials receive accurate and complete information about MOUD. But these gatekeepers are nonexistent, lack important knowledge, or are susceptible to manufacturer influence. Meanwhile, these industries are attempting – and succeeding – at persuading local communities and states to use limited or less-effective MOUD options.

This chapter examines the growing relationships between medical device and pharmaceutical manufacturers and drug courts, arguing attention must be paid to reveal and interrogate potentially detrimental influences that can harm client outcomes. Section 12.2 describes the manufacturer-drug court relationship, explores treatment team beliefs about MOUD, and explores two examples. Section 12.3 applies a conflict-of-interest framework to assess these relationships and discusses how treatment teams can be "moral entrepreneurs" that make non-evidence-based choices against clients' best interests. Section 12.4 poses potential solutions to this dilemma.

[5] Alec MacGillis, The Last Shot, ProPublica (June 27, 2017), www.propublica.org/article/vivitrol-opiate-crisis-and-criminal-justice.
[6] See discussion infra Section 12.3.
[7] Harper, Drugmaker, supra note 1.
[8] MacGillis, supra note 4.

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## 12.2 THE RELATIONSHIP BETWEEN DRUG COURTS AND MEDICAL MANUFACTURERS

States have created drug courts as a therapeutic alternative to incarceration in cases involving nonviolent, low-level criminal charges.[9] Instead of incarceration, drug court clients can live and work in the community if they follow drug court requirements, including treatment policies. Studies suggest that, on balance, drug court program participation is more effective than incarceration at preventing drug use relapse and reincarceration.[10] The Trump Opioid Crisis Commission commended drug courts as a "central component of the pretrial diversion process,"[11] encouraging their implementation in all ninety-three Federal district courts and every US county.[12]

### 12.2.1 *Drug Court Staff Beliefs Regarding Treatment for Substance Use Disorder*

Drug courts typically do not provide treatment directly, but rather set treatment policies, establish relationships with community substance use disorder (SUD) treatment providers to whom they refer clients, and monitor treatment adherence. Participant noncompliance with drug court policies can result in program expulsion and incarceration. Drug courts are operated by teams headed by a judge.[13] Court teams may also include a program coordinator, court case manager, prosecutor, probation/parole officer, law enforcement official, counselor, and clinical case manager.[14] Most team members lack medical training, most teams lack physicians, and counselors and clinical case managers engaged on treatment teams typically are employed by a partnering health care organization, and not the court. To date, little is known about how drug court teams set treatment policies, especially with respect to opioid use disorder (OUD) treatment.

The gold standard of care for OUD is MOUD with methadone, buprenorphine, or naltrexone.[15] Methadone and buprenorphine (including but not limited to Suboxone) are opioid agonists that activate the brain's mu opioid receptors,

[9] Celinda Franco, Drug Courts: Background, Effectiveness, and Policy Issues for Congress (2010), https://fas.org/sgp/crs/misc/R41448.pdf.

[10] Ojmarrh Mitchell et al., Assessing the Effectiveness of Drug Courts on Recidivism: A Meta-Analytic Review of Traditional and Non-Traditional Drug Courts, 40 J. of Crim. Justice 60–71 (2012).

[11] The President's Commission on Combating Drug Addiction and the Opioid Crisis, Final Report, at 73, www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.

[12] Id. at 10.

[13] Barbara Andraka-Christou, What is Treatment For Opioid Addiction in Problem-Solving Courts? A Study of 20 Indiana Drug & Veterans Courts, 13 Stan. J. Civ. Rights & Civ. Lib. 189–254 (2017); Nat'l Assoc. of Drug Court Professionals, 2 Adult Drug Court Best Practice Standards (2015).

[14] Andraka-Christou, supra note 12; Nat'l Assoc. of Drug Court Professionals, supra note 12.

[15] Nat'l Acads. Of Sci., Eng'rs, & Med., Medications for Opioid Use Disorder Save Lives (2019); Substance Abuse & Mental Health Servs. Admin., Treatment Improvement Protocol 63: Medications for Opioid Use Disorder (2018).

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decreasing opioid cravings and preventing painful withdrawal symptoms. Agonist treatment is associated with as much as a 50 percent decrease in mortality from overdose.[16] In contrast, naltrexone is a non-opioid antagonist that blocks opioids from activating the brain's mu opioid receptors. Vivitrol, approved for OUD treatment in 2010, is an intramuscular injectable extended-release version of naltrexone that is more effective than a placebo at preventing return to drug use, including for criminal justice system participants.[17]

While few studies to date have directly compared the efficacy of buprenorphine or methadone to Vivitrol, buprenorphine and methadone appear more effective at preventing overdose deaths, do not necessitate complete detoxification, and are more cost-effective.[18] Additionally, Vivitrol is harder to start because it requires complete detoxification from opioids.[19] According to one randomized controlled comparative study, it was harder to initiate patients onto Vivitrol than oral buprenorphine, creating a relatively higher rate of return to drug use for patients randomized to Vivitrol as compared to oral buprenorphine; however, patients who successfully initiated onto Vivitrol had comparable rates of return to drug use as those on oral buprenorphine.[20] Therefore, patients may need detoxification support and/or high motivation levels to successfully start Vivitrol.[21] Two more recent studies found that agonists were more protective against opioid overdose than Vivitrol.[22] Lastly, at approximately $1,300 per thirty-day dose, Vivitrol is significantly more expensive, and far less cost-effective, than other OUD medications.[23]

[16] Marc R. Larochelle et al., Medication for Opioid Use Disorder After Nonfatal Opioid Overdose and Association with Mortality, 169 Annals of Int. Med. 137 (2018); Thomas Santo Jr. et al, Association of Opioid Agonist Treatment with All-Cause Mortality and Specific Causes of Death Among People with Opioid Dependence: A Systematic Review and Meta-analysis, 78 JAMA Psychiatry 979–993 (2021).

[17] Donna M. Coviello et al., A Multisite Pilot Study of Extended-Release Injectable Naltrexone Treatment for Previously Opioid-Dependent Parolees and Probationers, 33 Substance Abuse 48–59 (2012); Michael S. Gordon et al., A Phase 4, Pilot, Open-Label Study of VIVITROL® (Extended-Release Naltrexone XR-NTX) for Prisoners, 59 J. Substance Abuse Treatment 52–8 (2015); Brantley P. Jarvis et al., Extended-Release Injectable Naltrexone For Opioid Use Disorder: A Systematic Review, 113 Addiction 1188–209 (2018).

[18] Sarah E. Wakeman et al., Comparative Effectiveness of Different Treatment Pathways for Opioid Use Disorder, 3 JAMA Network Open (2020); Jake R. Morgan et al., Overdose Following Initiation of Naltrexone and Buprenorphine Medication Treatment for Opioid Use Disorder in a United States Commercially Insured Cohort, 200 Drug & Alcohol Dependence 34–9 (2019).

[19] Joshua D. Lee et al., Comparative Effectiveness of Extended-Release Naltrexone Versus Buprenorphine-Naloxone For Opioid Relapse Prevention (X:BOT): A Multicentre, Open-Label, Randomised Controlled Trial, 391 Lancet 309–18 (2018).

[20] Lee et al., supra note 19.

[21] Id.

[22] Morgan et al., supra note 19; Wakeman et al., supra note 19.

[23] Wash. State Institute for Pub. Pol'y, Substance Use Disorders Benefit-Cost Results, http://www.wsipp.wa.gov/BenefitCost/Pdf/7/WSIPP_BenefitCost_Substance-Use-Disorders.

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Unfortunately, drug court OUD treatment policies may run contrary to best practices. A 2013 study found that up to 50 percent of adult drug courts prohibit methadone and buprenorphine; and a 2021 study found that judges are more likely to have favourable policies toward Vivitrol as compared to buprenorphine or methadone.[24] The substance and accuracy of court teams' treatment policies relate to program member beliefs about treatment safety, efficacy, and diversion potential.[25] Compared to agonist treatments, court staff appear to have relatively more positive beliefs about Vivitrol,[26] despite emerging data suggesting that agonist treatments are comparatively more effective at preventing overdose death.[27]

Device and pharmaceutical manufacturers (Industry) may directly inform court staff beliefs about MOUD. From 2010 to 2017, as the opioid epidemic exploded, few OUD treatment education options were available to courts beyond industry representatives.[28] Media articles,[29] a qualitative study of Indiana courts,[30] and a quantitative study of Florida courts[31] suggest that many court staff receive information about OUD treatments directly from pharmaceutical companies, especially Alkermes. For example, in a convenience sample of 121 Florida court staff, 36 percent reported receiving training from Alkermes, 24 percent from a buprenorphine manufacturer, and 11 percent from a methadone manufacturer. Among those who received training from a medication manufacturer, 55 percent received training from at least two companies. Another recent study found that, after controlling for opioid overdose deaths in an area, drug courts' location was significantly and positively associated with pharmaceutical payments to physicians for MOUD (tracked under sunshine laws),[32] suggesting that pharmaceutical companies may target physicians in areas where they know drug courts make referrals.

[24] Harlan Matusow, Medication Assisted Treatment in US Drug Courts: Results from a Nationwide Survey of Availability, Barriers and Attitudes, 43 J. Substance Abuse Treatment (2012); Barabara Andraka-Christout et al., Criminal Problem-Solving and Civil Dependency Court Policies Regarding Medications for Opioid Use Disorder, Subst Abus. 1–8 (2021).

[25] Andraka-Christou, supra note 12; Matusow et al., supra note 24.

[26] Andraka-Christou, supra note 12; Barbara Andraka-Christou et al., Court Personnel Attitudes Towards Medication-Assisted Treatment: A State-Wide Survey, 104 J. Substance Abuse Treatment 72–82 (2019); Barbara Andraka-Christou & Danielle Atkins, Beliefs About Medications for Opioid Use Disorder Among Florida Criminal Problem-Solving Court and Dependency Court Staff, 46 Am. J. Drug & Alcohol Abuse 749, 749–60 (2020).

[27] Lee et al., supra note 19; Morgan et al., supra note 18; Wakeman et al., supra note 19.

[28] The National Judicial Opioid Task Force, a collaboration of representatives from the Conference of Chief Justices and State Court Administrators was formed in 2017 and published its recommendations concerning treatment best practices in November 2019. See Nat'l Judicial Opioid Task Force, Courts as Leaders in the Crisis of Addiction (Nov. 18, 2019), www.ncsc.org/~/media/Files/PDF/Topics/Opioids-and-the-Courts/NJOTF_Final_Report_111819.ashx.

[29] Harper, supra note 1.

[30] Andraka-Christou, supra note 12.

[31] Barbara Andraka-Christou et al., Receipt of Training about Medication for Opioid Use Disorder from Pharmaceutical Manufacturers: A Preliminary Study of Florida Criminal Problem-Solving and Dependency Court Staff, 39 Drug & Alcohol Rev. 583, 583–587 (2020).

[32] Id.

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Some court staff's understanding of substance use may reflect cultural and personal perspectives about addiction, "viewing it as moral weakness that call[s] for tough paternalism."[33] According to Andraka-Christou, judges have differing conceptions of sobriety, from living life without any substances (including medications) to living life without misusing substances.[34] Some court staff view agonists merely as "trading one drug for another" or "not really quitting."[35] Court staff beliefs about MOUD may also reflect beliefs and practices of the treatment providers with whom they collaborate, with one study of a convenience sample of court staff finding that half felt their collaborating provider did not encourage agonist MOUD.[36]

Despite the effectiveness of agonist MOUD at decreasing overdose death and return to drug use, several studies have documented hostile court staff attitudes towards agonist treatment,[37] particularly methadone,[38] due to its perceived diversion and misuse potential, distrust of methadone providers (often located in high-crime areas), and misunderstandings about medication safety and efficacy.[39] Court staff view buprenorphine slightly more favorably, but may require or strongly encourage clients to transition off upon entering the program[40] despite medical studies indicating that longer-term buprenorphine use is more effective than shorter-term use.[41] As with methadone, court staff appear to distrust providers and worry about potential client misuse or diversion of buprenorphine.[42] One Ohio drug court judge stated, "the Suboxone zombies aren't getting better … The people who want the Vivitrol are the ones who want to get healthy and get better."[43]

Court staff have more favorable beliefs about Vivitrol because it cannot be misused or diverted and lacks an opioid ingredient.[44] Judges are critical of its cost, however, even though clients can get free samples or discounts through state-funded programs or Alkermes. One judge stated, "we work really closely with the drug rep from Alkermes … and they 've been very supportive in finding us, giving us discounts for some of our people, even providing a month or two of free doses."[45]

33 MacGillis, supra note 4.
34 Barbara Andraka-Christou, The Opioid Fix: America's Addiction Crisis and the Solution They Don't Want You to Have Ch. 6 (2020).
35 Id.
36 Barbara Andraka-Christou & Danielle N. Atkins, Whose Opinion Matters about Medications for Opioid Use Disorder? A Cross-Sectional Survey of Social Norms Among Court Staff, 42 Substance Abuse (forthcoming 2021), available online at www.tandfonline.com/doi/abs/10.1080/08897077.2020.1846666?journalCode=wsub20.
37 Andraka-Christou, supra note 12; Andraka-Christou et al., supra note 28; Matusow et al., supra note 24.
38 Andraka-Christou et al., supra note 26; Andraka-Christou & Atkins, supra note 26; Matusow et al., supra note 24.
39 Andraka-Christou, supra note 12.
40 Id.
41 Andraka-Christou, supra note 12, at 232–233.
42 Id. at 234.
43 MacGillis, supra note 4.
44 Andraka-Christou, supra note 12, at 235.
45 Id. at 236.

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### 12.2.2 *Examples of Direct-to-Court Marketing: the Bridge and Vivitrol*

Medical device manufacturers market their products directly to drug courts. The National Association of Drug Court Professionals (NADCP) is the primary standard-setting organization for adult drug courts, and heavily influences court staff education. Innovative Health Solutions, the manufacturers of the Bridge, have been a regular presence promoting their product as an adjunct to Vivitrol-based treatment at the NADCP national conference. Even though the device received FDA approval, that status rested solely upon a heavily criticized study that lacked a control group, reported no dropout rate, and lacked IRB oversight. IHS also marketed the Bridge as early as 2016, over a year before receiving FDA approval, engaging in off-label promotion and violating FDA regulations.[46]

As compared to other MOUD manufacturers, Alkermes is most widely known for engaging and "educating" drug court judges. Alkermes initially found that conventional marketing practices were ineffective for Vivitrol[47] and began to cultivate new markets by reaching out to criminal justice officials, drug court judges, and professional associations.[48] In 2014, Alkermes paid $50,000 to become a "champion" sponsor of the NADCP.[49] Alkermes also detailed its strategic targeting of drug court judges and criminal justice institutions at a 2016 analyst and investor event,[50] where CEO Richard Pops described "priming" state "ecosystems" to shape and penetrate markets by aligning messaging to court staff opinions.[51] Alkermes' "road map for future growth" included both a "traditional commercial approach (MD, patient, payer)" and "generat[ing] organic conversations among [a] broad range of stakeholders (criminal justice, policy, caregivers, etc.)"[52] These strategies directly positioned Vivitrol as a novel and superior drug; Alkermes' Vice President of Marketing described "stimulat[ing] organic conversations about 'deserving to know all options' and the potential to end dependence on opioids."[53]

## 12.3 MORAL ENTREPRENEURSHIP AND CONFLICT OF INTEREST

To understand the potential for bias and conflicts of interest in selecting treatment providers and the associated forms of treatment made available to drug court

[46] Harper, Questions, supra note 1.
[47] MacGillis, supra note 4.
[48] Id. at 71.
[49] MacGillis, supra note 4; Harper, Drugmaker, supra note 1; Arlene Weintraub, Alkermes Balks at U.S. Senator's Probe Into "Aggressive" Vivitrol Lobbying and Marketing, FiercePharma (Nov. 7, 2017), www.fiercepharma.com/legal/alkermes-balks-at-u-s-senator-harris-probe-into-vivitrol-marketing.
[50] Alkermes, Alkermes Analyst & Investor Event (September 26, 2016), in Harper, Drugmaker, supra note 1.
[51] Id. at 44.
[52] Id. at 97.
[53] Id. at 99.

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program enrollees, it is helpful to examine these issues in a related context: the industry sales representative-physician relationship. Some experts believe conflicts arise because business and medical ethics differ: businesses, including medical device and pharmaceutical companies, commonly reward vendors to stimulate sales, while such conduct could be problematic or unethical in medicine.[54] The most controversial practices are industry sponsorship of continuing medical education programs (CME) and "detailing," where industry sales representatives (ISRs) "visit physician offices to discuss the availability and suitability of products."[55]

Advocates of close industry-physician relationships describe them as "a full, honest, fair, and balanced discussion of materials" that gives providers "invaluable assistance" in selecting appropriate medications, and providers reciprocate by giving drugs "preferred status on a hospital's formulary."[56] Because physicians cannot keep up with extensive literature and innovations, the ISR visit is an "extremely effective" encounter, providing essential information in five or ten minutes.[57] Thus, pro-industry advocates assert, marketing communications sell products and facilitate "technology transfer."[58] The potential for bias here is clear; but industry advocates argue that "[a]lthough information coming from a commercial source does present the product in the best possible light, physicians are well aware of this bias and correct for it."[59] Moreover, they contend, visits from competing ISRs "expose[] physicians to multiple biases," allowing them to "make a more informed choice."[60] They concede, however, that physicians make prescription decisions by "relating the decision to a personal value system" to which ISRs can appeal.[61]

A 2019 study found that pharmaceutical manufacturers alone spent more than $20 billion marketing to health care professionals in 2016, including $5.6 billion for prescriber detailing.[62] This study also acknowledged their statistics significantly underestimated the amount industry spent on professional marketing, as the authors were unable to acquire data on marketing related to devices, meetings, and events. While independent firms produce CME programs, they have been found to "skew training material in favor of commercial interests" to retain business.[63]

Critics of close industry-physician relationships describe a conflict between product promotion and education and assert that patients' interests are not best served by

[54] Shaili Jain, Understanding Physician-Pharmaceutical Industry Interactions: A Concise Guide (2007).
[55] Id. at 12.
[56] Erin Albert & Cathleen Sass, The Medical Science Liaison: An A to Z Guide 99 (2007).
[57] Mickey C. Smith, Pharmaceutical Marketing: Principles, Environment, and Practice 339 (2002).
[58] Id. at 332, 337.
[59] Id. at 340.
[60] Id.
[61] Id. at 276.
[62] Lisa M. Schwartz & Steven Woloshin, Medical Marketing in the United States, 1997–2016, 321 J. Am. Med. Assoc. 80–96 (2019).
[63] Jim Giles, Drug Firms Accused of Biasing Doctors' Training, Nature (Nov. 20, 2017), www.nature.com/articles/450464a.

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industry-influenced prescribing practices.[64] Although physicians often believe they are not influenced by marketing, research clearly shows otherwise.[65] These sophisticated promotional activities exploit the professional's vulnerabilities, often at subconscious levels, to create biases[66] and influence prescribing habits in ways that may not best serve the care recipient.

### 12.3.1 *Applying a Conflict-of-Interest Framework*

A conflict-of-interest (COI) framework can structure our understanding of relationships between industry and drug court treatment teams, especially since, as shown above, we know: 1) industry representatives already serve either as significant sponsors or appear as vendors at drug court conferences, and 2) industry has been engaged in court team members education and detailing.

As described by Stark,[67] whose work examined COI as it applied to public officials, and has since been applied to health professionals,[68] motivated bias is a process (FN69), and COIs are broken down into three behavioral stages.[69] First, antecedent acts prepare the target of influence's state of mind for partiality or bias, making the target more likely to exercise responsibility for private or personal interests instead of the interests of the public (or patient/program enrolee).[70] Second, antecedent acts influence the target towards certain perspectives, biases, or affinities.[71] Third, the target behaves in ways influenced by antecedent factors.[72] Industry interactions with court team members are, at minimum, antecedent acts toward more favorable arrangements for the industry (in this case prioritizing one MOUD in court treatment referrals or in court policies).

Stark also distinguishes external influences from internal convictions, differentiating between an internal "genuinely subjective belief or commitment" that might become "an encumbrance when its proximate cause lies without, in the importunings of a litigant, the ministrations of a lobbyist or the pressure of a campaign contributor."[73] For example, lobbying is an external attempt to "mobilize the bias," or "strengthen the commitment members have to an already established position on a given question."[74] Internal convictions are difficult or impossible to

64 Jain, supra note 54, at 4.
65 Id. at 9–10. See also Sunita Sah & Adriane Fugh-Berman, Physicians Under the Influence: Social Psychology and Industry Marketing Strategies, 41 J. L, Med. & Ethics 665, 665–72 (2013).
66 See Sah & Fugh-Berman, supra note 65, at 665–666.
67 Andrew Stark, Conflict of Interest in American Public Life (2000).
68 Daniel S. Goldberg, The Shadows of Sunlight: Why Disclosure Should Not Be a Priority in Addressing Conflicts of Interest, 12 Pub. Health Ethics 202–212 (2018).
69 Goldberg, supra note 68.
70 Sheldon Krimsky, Science in the Private Interest: has the Lure of Profits Corrupted Biomedical Research?, 126 (2004); Stark, supra note 67.
71 Krimsky, supra note 70, at 126.
72 Id.
73 Stark, supra note 67, at 149.
74 Id. at 173.

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disclose and divest; there is no disclosure form, and disclosure itself only suggests "an irremediable capacity to make an unencumbered decision."[75] Someone who discloses beliefs might "develop an encumbering interest" in maintaining them.[76]

### 12.3.2 *Judges as Moral Entrepreneurs*

Sociologist Howard Becker coined the term "moral entrepreneurs" to describe individuals in power who work to construct systems that reinforce their beliefs about deviancy (often through criminalization).[77] For example, a moral entrepreneur who believes that all people who use medications with misuse potential are morally deviant would punish and/or exclude people who utilize these products and develop systems that prioritize the use of medications/devices without misuse potential.

For years, judges and drug court treatment teams have been forging ahead in the opioid epidemic, handling massive increases in the proportion of clients with opioid use disorder, including treatment referrals, without much organized guidance. More research must be conducted on the mechanics underlying the selection of treatment providers for drug court teams. That said, our research has found that program managers, as well as judges, are receiving education from industry representatives.[78]

According to Stark, "in law, business, and medicine, the professional (lawyer, manager, doctor) is thought to have fiduciary or 'role-moral' obligations . . . to pursue and protect certain interests possessed by a defined, identifiable set of principles: clients, shareholders, patients."[79] Because drug courts are structured to facilitate opportunities for program enrolees (clients) to access treatment services that effectively address their SUD and help them avoid incarceration and recidivism, judges and treatment team members, as the creators and managers of these systems of care, are charged with the role-moral obligation to act in clients' best interests. This section focuses explicitly on drug court judges because, in the unique setting of the drug court, they lead teams that select and engage treatment providers, are fiduciaries, and must adhere to ethics codes. Even if a manufacturer communicates directly with other team members, such as court program coordinators, judges will have the final say about court policies.

Industry education from antagonist manufacturers and device companies position their products as morally superior to agonist treatments. In this way, antagonist manufacturers motivate bias against the moral entrepreneur – in this case, the judge – and their existing negative beliefs regarding opioids.

[75] Id. at 241.
[76] Id. at 253; See also Sah & Fugh-Berman, supra note 65.
[77] Howard S. Becker, Outsiders: Studies in the Sociology of Deviance (1963).
[78] Andraka-Christou, Court Personnel, supra note 12.
[79] Stark, supra note 67, at 89.

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Some external standards exist to determine clients' best interests as to MOUD, including medical standards of care or best practices and professional guidance.[80]

A judge who supports recovery should follow medical standards for recovery support, rather than engage as moral entrepreneurs. Narrowing treatment options to Vivitrol and/or the Bridge ignores patients for whom these interventions are contraindicated, including pregnant women. Because Vivitrol is costlier, requires detoxification, and is less protective against overdose, judges preferencing Vivitrol in their systems also create a more difficult recovery road for court clients with limited financial means. As the former head of SAMHSA's Center for Substance Abuse Treatment commented, "what we continue to have is a political philosophy colliding with therapeutic strategies, and that political philosophy has less to do with the individual and more to do with moral views about drug abuse."[81]

Because of the unique nature of the relationship between courts and MOUD manufacturers, it would be difficult to regulate these decisions based upon extant judicial conduct rules. American Bar Association Model Code of Judicial Conduct Rule 2.2 requires judges to "uphold the law" when deciding cases; an accompanying comment states, "[a]lthough each judge comes to the bench with a unique background and personal philosophy, a judge must interpret and interpret the law without regard to whether the judge approves or disapproves or the law in question." Yet, there is no law compelling judges to use the highest and best scientific and medical evidence in judicial decision making. In fact, one might argue that this is not the type of "decision making" the model code envisaged.

## 12.4 IDENTIFYING A RANGE OF POTENTIAL SOLUTIONS

Much can be done to avoid improper influences that may occur in relationships between pharmaceutical manufacturers and drug courts and defuse any potential resulting conflicts. These solutions range from "light" to "heavy." In practice, widespread changes in approaches to court-industry relationships may occur gradually.

An effective "light" solution would be to systematically affirm that a judge's role is overseeing court proceedings as "captain of the ship" and monitoring clients. This role does not, however, include making treatment decisions. Decisions like whether MOUD is appropriate for individual clients, and in which form, must be left to a treatment provider.[82] Judges' comments that they will not allow forms of MOUD that can be diverted or with opioid ingredients reflect inappropriate encroachment on the treatment provider's role. Physicians should receive complementary educational messaging through professional medical associations such as the AMA. Drug

[80] Substance Abuse and Mental Health Services Administration, TIP 63: Medications for Opioid Use Disorder (2021).
[81] MacGillis, supra note 4.
[82] Andraka-Christou, supra note 34, Ch. 6.

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courts should also be encouraged to include local physicians on treatment teams or as consultants. Logically, the ideal medical professional would be a practitioner offering holistic treatment options to whom the drug court judge refers clients seeking MOUD. This may be difficult in several areas of the country, however, based on qualified providers' availability and willingness to serve, although new telehealth and expanded methadone rules may extend access to more distant providers. Additionally, since court staff select the health care providers with whom programs partner, they may opt into relationships with providers who have anti-MOUD attitudes.

Another solution would be to provide judges and staff with alternative educational resources free from industry sponsorship. It is not suggested that judges and staff intentionally invited industry representatives to influence court proceedings in earlier years. Rather, courts' eagerness for informational resources were an educational vacuum that pharmaceutical and medical device manufacturers were prepared to fill. Alternative educational content can be provided online and at professional conferences and are currently coordinated through professional associations such as NADCP and NCSC. Some governmental and non-profit organizations have begun offering MOUD-focused education tailored to judges, including information about the appropriate MOUD decision-making role of court team members.[83]

A more involved solution would be to attach restrictions and requirements to court funding, such as conditioning grant monies on court compliance with best practices of allowing all three kinds of MOUD. Recipients of federal Bureau of Justice Assistance (BJA) grants, for example, have to demonstrate that they will not deny clients access to their programs because of MOUD use.[84] This would provide some federal regulatory oversight enforcing best practices; however, this solution has limited reach as only approximately 200 out of 3,000 drug courts nationwide receive BJA funds. State grants could incorporate similar conditions.

A still more comprehensive solution would be to impose state-level certifications mandating that drug courts adhere to certain standards, such as permitting all three forms of MOUD, agreeing to refer clients to certain licensed facilities that must accept Medicaid, etc. For example, Michigan's certification program[85] requires courts to comply with several standards and best practices, including the BJA's *Key Components*[86] and the National Center for DWI Courts' *Ten Guiding Principles of DWI Courts*.[87] These guidelines require drug courts to allow MOUD use "when

[83] See, e.g., Florida Courts Substance Abuse Response Opioids and Stimulants Solutions, http://www.courtslearn.com.

[84] See, e.g., Bureau of Justice Assistance, Medication Assisted Treatment, https://bja.ojp.gov/sites/g/files/xyckuh186/files/media/document/adc-faq-medication-assisted-treatment.pdf.

[85] Mich. Comp. Laws § 600.1062.

[86] Nat'l Assoc. of Drug Court Professionals, Defining Drug Courts: The Key Components (Oct. 2004), www.ncjrs.gov/pdffiles1/bja/205621.pdf.

[87] Nat'l Center for DWI Courts, The Ten Guiding Principles of DWI Courts, http://www.dwicourts.org/wp-content/uploads/Guiding_Principles_of_DWI_Court_0.pdf.

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appropriate, based on a case-specific determination and handle MOUD very similarly to other kinds of treatment" and assert that "the court does not determine the type, dosage, and duration of" MOUD.[88] Similarly, states can pass statutes or regulations prohibiting MOUD bans within courts, as has already occurred in some states.[89]

Finally, a model sunshine law for drug courts could be an integral component of an effective solution scheme. Federal court and employee rules require financial disclosures for gifts and reimbursements above a certain threshold.[90] Federal laws such as the Physician Payments Sunshine Act, passed in 2010, make financial relationships between medical industrial corporations and physicians more transparent and reveal COIs, requiring pharmaceutical, medical device, biological and medical supply manufacturers who are covered by Medicare, Medicaid and the State Children's Health Insurance Program to track financial relationships with teaching hospitals and physicians and report that data to the Centers for Medicare and Medicaid Services. A mandatory disclosure approach acknowledges the role of those seeking to influence system development (the manufacturers) as well as the system participants. A model state sunshine law could encourage states to re-evaluate decisions made years ago, particularly court policies or referral practices prioritizing Vivitrol over agonist treatments.

A sunshine law by itself, however, will have little impact. Disclosure plays a paramount role in avoiding liability for COI but it alone is not a viable solution. If disclosures are made after antecedent acts produce relationships that enable improper influences, the harm has already occurred. An efficacious intervention should take place before acts can lead to partiality.[91] Disclosure alone does not eliminate problematic relationships, thwart influence, or prevent partial behavior.[92] Disclosure of judicial beliefs regarding MOUD would do little but expose easy marks for manufacturers to exploit. Thus, sequestration – prohibition of most industry engagement with drug court team members – may be more effective than disclosure, because eliminating problematic relationships eliminates COIs.[93] Full sequestration need not be imposed due to First Amendment concerns. Instead, state courts administrators could prohibit court team members from meeting with industry representatives, or accepting free lunches or other items from manufacturers.[94] Additionally, state professional licensing boards (e.g., bar associations) could forbid

[88] State Court Administrative Office, Mich. Assoc. of Treatment Court Professionals, Adult Drug Court Standards, Best Practices, and Promising Practices 53 (Dec. 2019), https://courts.michigan.gov/Administration/SCAO/Resources/Documents/bestpractice/ADC-BPManual.pdf.

[89] See, e.g., 730 ICLS § 166/25 (West 2020) (Illinois).

[90] United States Courts, Judiciary Financial Disclosure Regulations § 330, www.uscourts.gov/sites/default/files/guide-vol02d.pdf; 5 U.S.C. § 101–111.

[91] Goldberg, supra note 65, at 1.

[92] Id.

[93] Id.

[94] Id.

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licensees from applying manufacturer-provided training toward required continuing legal education credits.

Of course, the most effective strategy would be to deploy a web involving many of these proposals. Here, policy makers can follow Alkermes' example, implementing a comprehensive array of educational opportunities and regulatory and oversight measures at local, state, and national levels, in partnership with diverse professional organizations representing law, medicine, and the court system.

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