

## GOVERNMENT HEALTH CARE FRAUD ENFORCEMENT: TRENDS IN 2018

2017 saw a significant escalation in the federal government crackdown on health care fraud claims, especially against compounding pharmacies.<sup>1</sup> Allegations of allegedly false claims dominated the DOJ's 2017 investigatory efforts.<sup>2</sup> Continuing this emphasis on perceived health care fraud, in 2018 the DOJ made public its vigorous attack on what it views as the participants in the opioid crisis, with Attorney General Jeff Sessions declaring, "[o]ur great country is currently in the midst of the deadliest drug crisis in our history," and pointed the finger at "some trusted medical professionals like doctors, nurses and pharmacists [who] have chosen to violate their oaths and exploit this crisis for cash."<sup>3</sup> As a result, the DOJ has kept compounding pharmacies intensely under its microscope.<sup>4</sup> In most instances, the anti-kickback statute remains preeminent, but the DOJ also expanded its focus to the compounding pharmacies' role in opioid distribution – an apparent effort to respond to two hot-button issues, compounding pharmacies and the opioid crisis, with a single stroke.

The article provides a high-level look into recent compounding pharmacy investigations and prosecutions, starting with the government's full-throated statements about pursuing even lower-dollar offenders, and then moving to cases reflecting 2018 trends. Ultimately, the main thrust of the article is this: the best medicine is prevention – it may be time for a legal checkup to ensure your pharmacy or medical practice avoids the DOJ crosshairs.

### GOVERNMENT INVESTIGATIONS ARE NOT LIMITED TO "DEEP POCKET" OFFENDERS.

Landmark, high-dollar health care fraud cases make the news, but they can fuel the misconception that the government only targets wealthy offenders and large-scale schemes. In fact, the DOJ and the Department of Health and Human Services – Office of Inspector General recently stated they are not focused just on "deep pocket" targets, but also on individuals perceived to be causing lower-dollar damage to the health care system.<sup>5</sup> As one U.S. Attorney's office stated, "[a]ll pharmacies, whether large or small, will be held accountable."<sup>6</sup> Likewise, U.S. Attorney Jay E. Town declared, "[w]hether \$10 million or \$10,000, those who

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<sup>1</sup> The authors previously published a 2017 article offering a primer on recent compounding pharmacy prosecutions, including commonly investigated activities: "[Compound Pharmacy Crackdown - New Trends In Government Enforcement.](#)"

<sup>2</sup> See *id.*

<sup>3</sup> Quoted in USDOJ Press Release Number 18-383 (March 29, 2018) (available at: <https://www.justice.gov/opa/pr/houston-physician-and-pain-management-clinic-owner-convicted-running-pill-mill-provided>); see also *National Enforcement Action Brings Charges against 601 Individuals Responsible for Over \$2 Billion in Fraud Losses and 84 Opioid Cases Involving 13 Million Illegal Dosages*, US DOJ website (June 28, 2018) (available at: <https://www.justice.gov/usao-ndal/pr/five-nw-alabama-compounding-pharmacy-employees-charged-multi-million-dollar>).

<sup>4</sup> See, e.g., USDOJ Press Release Number 18-536 (On April 26, 2018, the owner of a Florida pharmacy was sentenced to 180 months in prison and ordered to pay \$54M in restitution for submitting false compound-pharmacy-reimbursement claims to private insurance companies, Medicare, and TRICARE.).

<sup>5</sup> See, e.g., the "Yates Memo": <https://www.justice.gov/dag/file/769036/download>

<sup>6</sup> USDOJ Press Release Number CAS18-0627-Zalavadiya (June 27, 2018) (available at: <https://www.justice.gov/usao-sdca/pr/lakeside-pharmacy-pays-75000-failing-keep-accurate-records-opioids>).

intend to defraud the federal government, especially our DOD components, will be joining [convicted and sentenced defendants] soon.”<sup>7</sup>

As such, the government signaled it is not using a purely dollars-and-cents analysis about who they pursue and ultimately charge. So even if you consider yourself a lower-dollar player in the compounding pharmacy space, you may still be a mark for investigation or prosecution.

#### **KEY CASES OF 2018:**

##### **MEDICALLY UNNECESSARY BILLINGS AND SHADY REFERRAL SCHEMES LED TO GUILTY PLEAS.<sup>8</sup>**

The DOJ targeted billings by Global Compounding Pharmacy, an Alabama-based compound pharmacy, for medically unnecessary prescription drugs and compounded medications (typically opioids) that often were never purchased or distributed to beneficiaries.<sup>9</sup> The U.S. Attorney’s Office for the Northern District of Alabama charged five employees, including a district and operations manager, with participating in the conspiracy to “generate prescriptions and defraud health care insurers and prescription drug administrators out of tens of millions of dollars.”<sup>10</sup> The charged defendants resided in from Texas, Florida, Alabama, and Georgia.<sup>11</sup>

The scheme involved a multi-faceted plan to bill for fraudulent, often high-dollar compounding prescriptions that Global would fill and bill for reimbursement.<sup>12</sup> To maximize proceeds, Global engaged in additional fraudulent practices, including automatically refilling and billing for prescriptions, regardless of patient need, and waiving co-pays to incentivize patients to accept unnecessary refills.<sup>13</sup> To generate a high volume of prescriptions, Global also hired representatives who were married or related to doctors and other prescribers and encouraged them to volunteer at doctors’ offices where they would review patient files and push Global’s products to patients.<sup>14</sup> The defendants all pled guilty and are awaiting sentencing.<sup>15</sup>

The message of this prosecution is that even where a patient has a valid prescription, automatically refilling and billing the prescription without a medical necessity evaluation can be deemed to be illegal. Likewise, when seeking referral sources, representatives working on behalf of the pharmacy should not have ties to the prescribers that suggest collusion or favoritism.

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<sup>7</sup> US DOJ website (March 27, 2018) (available at: <https://www.justice.gov/usao-ndal/pr/compounding-pharmacy-owner-sentenced-five-years-prison-105-million-health-care-fraud>).

<sup>8</sup> US DOJ website (June 28, 2018) (available at: <https://www.justice.gov/usao-ndal/pr/five-nw-alabama-compounding-pharmacy-employees-charged-multi-million-dollar>).

<sup>9</sup> *Id.*

<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> *Id.*

### **FAILURE TO MAINTAIN ACCURATE RECORDS RESULTED IN PHARMACY OWNER LIABILITY.<sup>16</sup>**

A Lakeside, California pharmacy and its owners paid \$75,000 to resolve allegations that they failed properly to account for highly addictive and frequently abused opioids, including fentanyl.<sup>17</sup> The DOJ's settlement with Leo's Archana Corporation Lakeside Pharmacy arose from a DEA investigation and audit into the pharmacy's dispensing practices.<sup>18</sup> Based on the DEA's inventory audits, inspections, and other investigative activities, the government asserted that Leo's Lakeside Pharmacy violated the Controlled Substances Act (CSA), which applies to all registered controlled substances handlers, including pharmacies.<sup>19</sup> The CSA subjects registered pharmacies to strict requirements regarding inventory control and recordkeeping.<sup>20</sup> The alleged violations include failure to keep accurate records associated with pharmaceutical fentanyl, oxycodone, and hydrocodone.<sup>21</sup>

In a statement, U.S. Attorney Adam Braverman stated, “[t]his settlement illustrates the United States Attorney's Office's continued commitment to combatting the opioid epidemic on all fronts.”<sup>22</sup> He continued, “[p]art of our strategy is making sure that registered opioid handlers keep accurate records of these highly addictive and extremely dangerous drugs.<sup>23</sup> All pharmacies, whether large or small, will be held accountable.”<sup>24</sup>

The substance of this case is that compounding pharmacies and their personnel—even lower-level players—must closely monitor inventory. All pharmacies are subject to a DEA audit, and recordkeeping failures easily open a pharmacy to liability just as much as other, more nefarious schemes might.

### **MISLABELING DRUGS, FILLING SUSPICIOUS PRESCRIPTIONS, AND OWNING AFFILIATED COMPOUNDING PHARMACIES CAN CREATE ISSUES, EVEN FOR LEGITIMATE BUSINESSES.<sup>25</sup>**

A federal judge sentenced the owner of Southern Compounding, a Decatur, Alabama compounding pharmacy, to five years in prison for conspiring to defraud a federal health insurance program.<sup>26</sup> The changes stemmed from the distribution of misbranded products.<sup>27</sup>

The defendant owned Southern Compounding and Apotheca Supply, which was licensed to relabel and repackage pharmaceutical drugs, and owned a 20% membership interest in a Medworx Compounding

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<sup>16</sup> USDOJ Press Release Number CAS18-0627-Zalavadiya (June 27, 2018) (available at: <https://www.justice.gov/usao-sdca/pr/lakeside-pharmacy-pays-75000-failing-keep-accurate-records-opioids>).

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*; see text of statute CSA here: <https://www.deadiversion.usdoj.gov/21cfr/21usc/>

<sup>20</sup> USDOJ Press Release Number CAS18-0627-Zalavadiya (June 27, 2018) (available at: <https://www.justice.gov/usao-sdca/pr/lakeside-pharmacy-pays-75000-failing-keep-accurate-records-opioids>).

<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> US DOJ website (March 27, 2018) (available at: <https://www.justice.gov/usao-ndal/pr/compounding-pharmacy-owner-sentenced-five-years-prison-105-million-health-care-fraud>).

<sup>26</sup> *Id.*

<sup>27</sup> *Id.*

affiliate pharmacy.<sup>28</sup> The defendant conducted the fraud by various means, including improperly contracting with the Medworx pharmacy to refer prescriptions to Southern Compounding, whereby Southern Compounding filled the prescriptions, billed third-party administrators, and sent nearly all the payments back to Medworx.<sup>29</sup> Medworx then returned a portion of those payments to the defendant.<sup>30</sup>

He also paid kickbacks to independent sales representatives (through Medworx) as an incentive to refer TRICARE prescriptions.<sup>31</sup> In doing so, he sold misbranded over-the-counter medications as prescription drugs and failed to reverse claims on prescriptions he knew or suspected were forged.<sup>32</sup> The FDA weighed in on the rebranding issue, stating, "U.S. consumers rely on the FDA to ensure they receive drugs which are safe, effective, and properly labeled."<sup>33</sup>

The takeaways here are many, but the key is to ensure that no violations of the anti-kickback statute occur (see an article previously published by our team on this subject here<sup>34</sup>). The anti-kickback statute defines the parameters of what and how you can pay referral sources – even if for legitimate business purposes, a compounding pharmacy can violate the law by not following these strict guidelines. Likewise, ownership in another pharmacy with which you conduct business can put you on the government's radar, as these arrangements may suggest receipt of illegal revenue as seen in Southern Compounding's case. In addition, the DOJ and FDA sent a message that the branding of products is now a major concern; ensuring accuracy in labeling and bottling is paramount. Lastly, as may be obvious, you should never fill suspicious prescriptions, especially if you expect forgery.

While your conduct may not be as egregious as Southern Compounding's, the intent is irrelevant. If your conduct violates the anti-kickback statute, FDA requirements, or other law, you are equally culpable and subject to jail time and penalties.

### **CONDUCT CAN BE EXTREME, BUT THE DOJ'S FOCUS IS BASIC: LEGALLY EXECUTING ROUTINE MATTERS IS ESSENTIAL FOR COMPOUNDING PHARMACIES.<sup>35</sup>**

Nicholas Borgesano, Jr., the president and owner of A to Z Pharmacy, a Florida compound pharmacy, was sentenced to 180 months in prison and ordered to pay \$54 million in restitution for his role in a compounding pharmacy scheme.<sup>36</sup> As part of sentencing, Borgesano also forfeited several cars, including a 1936 Ford

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<sup>28</sup> *Id.*

<sup>29</sup> *Id.*

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

<sup>32</sup> *Id.*

<sup>33</sup> *Id.*

<sup>34</sup> See "[Compound Pharmacy Crackdown - New Trends In Government Enforcement.](#)"

<sup>35</sup> USDOJ Press Release Number 18-536 (April 26, 2018) (available at: <https://www.justice.gov/opa/pr/owner-florida-pharmacy-sentenced-15-years-prison-100-million-compounding-pharmacy-fraud>).

<sup>36</sup> *Id.*

Deluxe, a 1964 Chevrolet Corvette convertible, a 1967 Chevrolet Camaro, a 1970 Chevrolet Monte Carlo, and a 2008 Lamborghini convertible; several boats, including a Cigarette racing boat; and real properties.<sup>37</sup>

According to his plea agreement, Borgesano owned and operated numerous pharmacies and shell companies that he and co-conspirators used to execute a fraud scheme involving prescription compounded medications.<sup>38</sup> Borgesano acquired and controlled A to Z Pharmacy, Havana Pharmacy, Medplus/New Life Pharmacy, and Metropolitan Pharmacy, all of Miami, and Jaimy Pharmacy and Prestige Pharmacy, both of Hialeah, Florida.<sup>39</sup> He admitted using these pharmacies to submit false and fraudulent reimbursement claims for prescription compounded medications, chiefly pain creams and scar creams. Borgesano and his co-conspirators admitted to manipulating billing codes in the reimbursement claims and submitting reimbursement claims for pharmaceutical ingredients they did not have.<sup>40</sup> They also paid kickbacks and bribes in exchange for prescriptions and patient identifying information used to further the scheme, including to a physician in exchange for the physician signing prescriptions for patients he never saw.<sup>41</sup> Borgesano disbursed proceeds of the fraud scheme through a variety of methods, including by check and wire transfer to co-conspirators' shell companies and through the purchase of assets.<sup>42</sup>

As with the Southern Compounding matters, Borgesano's crimes seem egregious, but they signal that the DOJ still focuses on basic issues affecting all compounding pharmacies: the legitimacy of referrals, medical necessity, kickbacks and incentive pay (anti-kickback statute), and test billings. These themes run throughout the examples cited in this article. Accordingly, even legitimate compounding pharmacies face investigation and potential prosecution if they do not properly vet their prescriptions for accuracy and necessity, do not follow the anti-kickback regulations on incentive pay to referral sources, or submit billings aimed at determining what is covered (so-called test claims for legitimate prescriptions to evaluate what compounds are covered by insurance<sup>43</sup>). Just following industry practices can get you into trouble – what's commonplace is not necessarily legal, even when owners try to operate legitimate enterprises.

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<sup>37</sup> *Id.*

<sup>38</sup> *Id.*

<sup>39</sup> *Id.*

<sup>40</sup> *Id.*

<sup>41</sup> *Id.*

<sup>42</sup> *Id.*

<sup>43</sup> See ["Compound Pharmacy Crackdown - New Trends In Government Enforcement."](#)

## **IMPROPER KICKBACKS AND STANDARDIZED PRESCRIPTION FORMS CAN INVALIDATE PRESCRIPTIONS.<sup>44</sup>**

George and Marene Thompkins, the owners of Piney Point Pharmacy in Houston, Texas, were arrested in February 2018 for anti-kickback statute violations, conspiracy to commit health care fraud, health care fraud, wire fraud and conspiracy to launder money.<sup>45</sup> The alleged scheme involved the referral of compounded gel and cream prescriptions to the pharmacy for dispensing and billing under health benefit programs.<sup>46</sup> Specifically, the indictment alleges the Thompkins billed for prescriptions deemed illegitimate because of anti-kickback violations.<sup>47</sup> The prescriptions also were improper, the indictment alleges, because the referral source distributed a standardized prescription order form that directed the number of medication refills to be ordered regardless of medical necessity.<sup>48</sup> If convicted, the Thompkins face 10 to 20 years in federal prison on each of their many counts.<sup>49</sup>

Here, the lesson is that even a legitimate prescription can be deemed illegitimate if the referral source is tainted by improper kickbacks or the prescription is done on a standardized form without a separate medical-necessity evaluation. As with many other examples cited, routine compounding pharmacy practices may lead to liability where the sources of the transactions are tainted or improperly vetted, and where medical necessity is not given full consideration and vetting. Accordingly, a legal review of how your prescription funnel gets filled is vital to ensuring the legitimacy of your compounding pharmacy practice.

## **CONCLUSION**

Compounding pharmacies of all sizes remain targets for the government's health care and opioid crackdown. The broader themes of 2018, as detailed above, reveal a few fundamental trends that carry over from 2017 and before: (1) investigating individual offenders (including non-physician co-conspirators), regardless of whether they have deep pockets; (2) scrutinizing patient prescriptions and treatments for medical necessity and correctness; and (3) examining referral sources for illegal kickbacks, often coupled with evaluations of the sufficiency of patient examinations before prescribing controlled substances. Even if you think your practices are beyond scrutiny, you unknowingly may be opening yourself to liability or worse. Indeed, falling in line with other compounding pharmacy practices is not a solution; the safest course is to thoroughly evaluate your practices and develop a referral, fulfillment, and distribution practice that satisfies the law. The Benjamin Franklin axiom that "an ounce of prevention is worth a pound of cure" is as true today as it was when Franklin said it. He may not have known that advice would one day be applied to health care fraud and compounding pharmacies, but it does not make the instruction any less valid.

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<sup>44</sup> USDOJ Website (February 21, 2018) (available at: <https://www.oig.dhs.gov/sites/default/files/assets/pr/2018/dojpr-022118-compound-king-and-two-others-indicted-multi-million-dollar-conspiracy.pdf>).

<sup>45</sup> *Id.*

<sup>46</sup> *Id.*

<sup>47</sup> *Id.*

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

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Bell Nunnally represents compounding pharmacies and their personnel, physicians, and individuals under investigation for or charged with the activities discussed in the article. The circumstances of your situation are unique and may not be covered by the overview. For further information, or to schedule a consultation, please contact [Jeff Ansley](#) for help.

#### **ABOUT THE AUTHORS:**

[Jeff Ansley](#) is a white collar trial lawyer and the head of Bell Nunnally's White Collar Criminal and Regulatory Defense practice. Jeff has long been a white collar trial lawyer with a special focus on health care fraud, securities enforcement, and other alleged business crimes. Jeff represents targets of government health care investigations and prosecutions and those who wish to avoid becoming targets. His clients include physicians, hospitals, compounding pharmacies and their personnel, and medical organizations and suppliers. In doing so, he has significant experience with matters handled by the Department of Justice, the Health Care Fraud Prevention and Enforcement Team (HEAT), the Medicare Fraud Strike Force, the Department of Defense, and the Health and Human Services - Office of Inspector, among others.

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