The Never-Ending Saga of Off-label Promotion

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Abstract: The concern of misbranded products leading to patient harm and potential fraud is inarguable. The FDA has held a long-standing position on off-label communication; however, in light of recent federal lawsuits that have increased the uncertainty of its enforceability, as well as the growing need for data-driven medicine, the agency has been under pressure more than ever to update their regulatory position. This article will outline industry’s response and the long-awaited guidance from the FDA around off-label communication.

As the Update reported in the August 2017 issue, the U.S. Food and Drug Administration’s (“FDA’s”) 23rd Commissioner, Dr. Scott Gottlieb recognizes and indeed publically acknowledges FDA’s long-standing practice of medicine exception noting that “while the FDA may limit what drug companies may say about their products to the uses that appear on the drug’s official label, physicians may prescribe their drugs for any condition they choose.” He further stated during his confirmation hearings “that doctors are appropriately trained to make medical decisions based on the best interest of their patients.” Consequently, prescribing medicines off-label is a common practice, but with life science companies prohibited from sharing information about off-label uses, do physicians get the best available information to make sound clinical decisions?

The growing need for comprehensive information about the value of treatments and for patients to have prompt access to therapies continues to pressure the FDA to update its regulatory position around off-label communication. The life science industry, doctors, patients advocates and lawmakers have long awaited the FDA to formally recognize that these

1 FRA Life Sciences offers a broad set of services to help companies identify global compliance risks and develop practical, yet effective, solutions. www.forensicrisk.com
3 Id.
4 Id.
discussions are not just about sales strategies, marketing tactics, and negotiations, but more so focused around responsible sharing of truthful and accurate information within the bounds of the First Amendment. In an era of data-driven medicine, complex therapies, and intense clinical and technological advancement, few would argue that valuable information that could impact public health now goes beyond just data produced from clinical trials.

Despite the need for comprehensive information or a clear position from regulators, as frequently happens, the industry has been provided little guidance and vague direction that is open to broad interpretation. In this article, we will review industry’s response to the continued lack of clarity around off-label communication, and the FDA’s guidance issued earlier this year in efforts to update their regulatory position.

Key Principles to Responsibly Share Off-Label Information – The PhRMA / BIO Principles

On July 16, 2016, responding to the continuing lack of guidance concerning off-label communication, the Pharmaceutical Research and Manufacturers of America (“PhRMA”) and the Biotechnology Innovation Organization (“BIO”), in an unprecedented maneuver, published their own industry-practice ‘principles’ about sharing off-label information to healthcare professionals (“HCPs”) and payers.

The joint publication entitled “Principles on Responsible Sharing of Truthful and Non-misleading Information about Medicines with Health Care Professionals and Payers’ (“PhRMA / BIO Principles”), was intended to preserve the FDA’s interests around ‘intended use’ without infringing upon the First Amendment rights of life science companies. It also was in fact an industry “shot across the bow” of the FDA to get on with the guidance process by providing the Agency with an updated framework of off-label principles.

The foundation of the PhRMA / BIO Principles is based on the organization’s understanding that HCPs and payers can make better informed decisions if they had access to the full range of emerging information about therapies being developed, such as investigational products. As mentioned above, the PhRMA / BIO Principles explicitly recognize premise that “scientific knowledge and new findings go far beyond...clinical trials, often are outside the scope of the parameters established [by the FDA] ...and often outdate the FDA-approved labeling.”

Key Concepts of the Principles

The PhRMA / BIO Principles are set around three key standards that outline association members’ commitment to accurate, truthful and non-misleading scientific communication:

- **Commitment to Science-based Communication** – this reiterates the non-promotional nature of information communicated, and reinforces the importance to have “scientifically and statistically sound methodologies” to support the data. This includes real world evidence and post-hoc analysis on specific sub-populations.

- **Commitment to Provide Appropriate Context about Data** – companies must provide the context of the information within their communication, which includes limitations to the data and analysis conducted to mitigate risk of the HCP or payer to potentially reach misguided conclusions about efficacy or safety of the therapy.

- **Commitment to Accurate Representation of Data** – in line with the first two commitments, the information must be represented accurately. This includes disclosing any limitations to the methodologies or analyses performed.

Furthermore, the document outlines nine principles life science companies should exercise when sharing information that is not contained in FDA-approved labeling, all of which follow the lines of the common theme of having all communications backed by sound, scientific data and methodologies, and disclosing limitations (e.g., safety and efficacy profile, sources of information, methodology of research, statistical analysis, etc.). Below is a high-level summary of the nine principles outlined within the PhRMA / BIO Principles:

1. Information is accurate and supported by robust data. Although this is already assumed, the Principles reiterate the importance of having the information supported by medical and scientific methodologies and data. In short, if the information can’t be backed by scientific data that has been scrutinized, then it should not be shared.

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6. Id.

7. Id.

8. The Principles operate in a similar fashion to the now-well-established PhRMA Code on Interactions with HCPs. Association members voluntarily agree to adopt and abide by the principles. The net effect is that the voluntary standard ultimately become industry best practice.

9. Id.
2. Communication must be fair and balanced. This Principle embodies another long-standing FDA position and reiterates the importance for utilizing the FDA-approved labeling as a primary source of information, and adds that both the safety and efficacy profile (e.g., adverse events) of the therapy should be included within the discussion.

3. All off-label information requires scientific substantiation. In line with the first Principle, this one recognizes that data may come from other scientific sources, other than from well controlled clinical trials. As such, communication must have appropriate disclosures about the data sources (e.g., statistical analysis, study limitations, design and implementation, etc.).

4. More truthful and non-misleading scientific information is better than less. This principle speaks for itself. Additionally, it states that should contextual information, caveats, or ‘different outcomes’ be discussed, disclaimers should be put into place.

5. Tailor the communication to the sophistication of the audience. Essentially, one presentation does not fit all. The Principles provide an example of the dynamic audience “ranging from general practitioners to health care professionals who work for payers and routinely review pharmacoeconomic analyses,” and states that the communication should be customized as such. This is consistent with FDA’s message over the years that context matters.

6. Communicate the “most comprehensive and up-to-date clinical information about” the product. Companies should not only look at their own trial data, but should also include information gathered from third-parties (e.g., medical associations, compendia services, etc.).

7. New therapies and indications should be communicated ‘promptly’ to payers. Stating the importance of “prompt access” to new medicines critical to patient care, this Principle supports the sharing of pipeline information, such as research and development, relevant clinical trial data, and status of FDA applications with the appropriate audience.

8. Real-world evidence may be communicated. This includes patient experience and pharmacoeconomic information.

9. Information published in medical or scientific journals should be shared. This is for all uses (on and off-label) and can be done either written or orally.

**FDA Draft Guidance for Industry**

On January 18, 2017, the FDA issued key draft guidance outlining the agency’s current position regarding off-label communication with 1) payers, formulary committees, and similar entities, and 2) communication of information consistent with FDA-required labeling. As outlined below, these documents do not contradict or substantially differ from the key concepts outlined within the PhRMA / BIO Principles. However, while the guidance does not represent a final Agency action, it does finally provide a glimpse into FDA’s regulatory position.

**Draft Payer Communication Guidance**

Guidance on the communication of health care economic information (“HCEI”) has been long-awaited by the life science industry. The draft document, entitled ‘Drug and Device Manufacturer Communications with Payers, Formulary Committees, and Similar Entities – Questions and Answers’ (“Draft Payer Guidance”) goes beyond the allowances under the Food and Drug Administration Modernization Act (“FDAMA 114”) by 1) expanding the HCEI definition, 2) defining the appropriate audience, and 3) expanding HCEI safe harbor about investigational drugs and devices with payers.

Under FDAMA 114, as amended by the 21st Century Cures Act, HCEI is defined as “any analysis (including the clinical data, inputs, clinical or other assumptions, methods, results, and other components underlying or comprising the analysis) that identifies, measures, or describes the economic consequences, which may be based on the separate or aggregate clinical consequences of the represented health outcomes, of the use of a drug.” The Draft Payer Guidance recognizes that economic endpoints cannot be completely separated from clinical endpoints, and thus expands the definition to permit comparative analysis. Since real-world data is often times generated from off-label use, this clarification allows

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10 Id.
11 Id.
12 Id.
15 Id.
communication of HCEI analyses as long as the information relates to at least one on-label indication. Additionally, this draft expressly states that HCEI “does not include any analysis that relates only to an indication that is not approved for the drug.”

When defining the appropriate audience, under the draft guidance, the FDA would now consider an audience who has the range of knowledge to interpret HCEI and can make population-based decisions. In practice, this could include pharmacy benefit managers, drug information centers, pharmacy and therapeutics committees, and other groups who would fall under the payer category. It should be noted that the guidance expressly states that HCPs who make individual prescribing decisions are not included.

Finally, the draft guidance establishes a new safe harbor for communications with payers about investigational products that now would apply only to “drugs and devices that are not yet approved/cleared by FDA for any use (but which must be approved/cleared to be legally marketed).” This includes product information, factual information from pre-clinical or clinical studies, product pricing, and anticipated timeline for FDA approval, as long as it is clearly stated that the safety and efficacy of the product under investigation has not been established, and information on the stage of the product development.

Draft Off-Label Guidance

The ‘Medical Product Communications That Are Consistent With the FDA-Required Labeling – Questions and Answers – Guidance for Industry’ (“Draft Off-Label Guidance”) addresses circumstances where the communication of information “is not contained in the FDA-required labeling for the product but may be consistent with the FDA-required labeling for the product.” In short, the guidance outlines three factors that will be considered to determine if communication is consistent with FDA-required labeling:

FACTOR 1: Communication must be consistent with the FDA-required labeling. Essentially, this means that information provided must be consistent with i) product indication, ii) the product’s approved patient population, iii) limitations and directions for handling/use, and iv) product dosing and administration.

FACTOR 2: Communication must not make suggestions that alters the benefit-risk profile of the product that may result in harm.

FACTOR 3: Communication around the directions for use must allow the product to be safely and effectively used under the conditions represented.

This represents the first time the agency has provided detailed guidance on how it assesses consistent communication with FDA-approved labeling. Additionally, the draft guidance explicit adopts the concepts, embodied in the PhRMA / BIO Principles, surrounding the provision of more scientific information than less, disclosure of limitations, and appropriate contextual information.

Current Environment and Some Considerations

As was discussed in the August issue of the Update, in addition to the FDA’s activities, there have been Congressional efforts to introduce several bills on off-label communications, as well as Arizona’s efforts to allow off-label promotion. As that issue also highlighted, the FDA delayed its Final Rule in March for one year, and this past July, PhRMA issued a letter, condemning the agency for not fulfilling its own proposal to strike the famous ‘knowledge’ sentence from 21 C.F.R. § 201.128.

In 2015, the FDA explained that it “does not regard a firm as intending an unapproved new use for an approved or cleared medical product based solely on that firm’s knowledge that such product was being prescribed or used by doctors for such use.” Therefore, the Agency proposed to strike the last sentence of section 201.128 which requires a company to provide “adequate labeling” for unapproved uses of a produce that the company “knows, or has knowledge of facts that would give him notice.”
However, in the January 2017 Final Rule, rather than striking the sentence, a revision was put into place, which stated that the “totality of the evidence establishes that a manufacturer objectively intends that a drug [or device] into interstate commerce...is to be used for [an unapproved use], he is required...to provide for the drug [or device] adequate labeling.”27 With their ‘totality of evidence’ standard, is the point of following their guidance moot? Even with robust fair and balanced information to support communication per their own issued guidance, can internal company emails, for example, still put manufacturers in hot water? It is safe to say, this topic, no matter how much guidance is provided to life science professionals continues to be controversial, complicated, and often times heated.

**Conclusion**

Based on the PhRMA / BIO Principles, as well as the FDA guidance, one thing is for sure – truthful and non-misleading communication will need to be supported by robust, comprehensive, and balanced scientific analysis. This adds more layers of complexity when it comes to content. While the courtrooms continue to fight the war on enforcement; compliance professionals, regulatory, and medical functions should consider augmenting their communication to be more scientifically positioned. This includes citing extensive, up-to-date research, conducting robust analysis on the methodologies to gather the data, and being prepared to disclose limitations.

Although the fate of off-label promotion remains unclear, few would argue that documentation to not only support communication, but to show the intent of the communication is key. Updating aspects of compliance programs to include these requirements within, at the very least, current governing documentation, monitoring programs, and training should also be taken into consideration. Although there is no formula to tell what ‘enough’ is, compliance professionals will continue to be challenged if the supporting information is sufficient to truly represent truthful and non-misleading information. 

As the courtrooms and lawmakers continue to battle off-label issues, life science companies are continually navigating through the storm, trying to deliver their common mantra of ‘patient first’ while remaining within the confines of the law. Now, more than ever, compliance professionals will be required to partner closely with their regulatory and medical functions to better understand the content of communication. Although the FDA does not necessarily discount the importance of sharing off-label information, it is abundantly clear that they plan to examine intent with a heightened level of scrutiny.

**Coming Soon to a State or Even City Near You**

-Part 1 Pricing Transparency

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**Abstract:** As opposition to and concern about the activities of drug manufacturers continue to mount, increasingly states, and even cities, are stepping in to regulate pharmaceutical companies. This is the first in a two-part series focusing on the notable proposed state and city actions and laws and ordinances that have been or soon will be enacted in 2017. The article will focus on drug pricing transparency disclosure legislation that is being introduced at an ever-increasing rate. The pharmaceutical industry cannot fight each and every state and city action successfully. The truth of the matter is that the industry is losing ground and leadership within companies cannot begin to sacrifice their compliance and legal departments.

“Let’s make sure pharma gets a black eye.”29

It is a basic principle of physics that nature abhors a vacuum, and thus will move quickly to fill the void. The same is true in the compliance world. Since the implementation of the Open Payments system, the Federal government has done little with the data other than post it. Nor has Congress attempted to address other pharmaceutical related issues like pricing.

As a result, both state and local jurisdictions, facing rising costs and addiction epidemics, have stepped to the forefront. Consequently, state transparency, disclosure, and other compliance requirements are increasing; even some cities are getting involved.

26 Id.
27 See Medical Product Communications Draft Guidance, supra at 2.
28 Views expressed in this article are that of the authors and do not necessarily reflect the opinions, positions, or policies of G&M Health, LLC, the company’s other employees, or its clients. Further, the information presented within this article does not constitute legal advice or a legal opinion and should not be interpreted or relied upon as such.
These state and local efforts have been extremely successful too. Thus, a domino-like effect is happening right now and it seems the industry cannot stop the ever-growing compliance demands placed upon every part of the business. This article is the first in a two-part series focusing on the notable proposed state and city actions and laws and ordinances that have been or soon will be enacted in 2017 involving pricing transparency, spend disclosure and more. To aid the readers, at the end of each section, the author has included a table that highlights pending, passed, and current requirements.

**Drug Pricing Transparency**

There are already a handful of jurisdictions that require pharmaceutical manufacturers to report pricing information in some form or another. For example, in 2016, Vermont became the first state to require annual manufacturer reporting for certain high-cost prescription drugs.\(^30\)

On August 10, 2017, the Green Mountain Care Board issued its second list, naming ten (10) prescription drugs on which Vermont incurred "significant health care dollars."\(^33\) Identified manufacturers are required to provide the Vermont Office of the Attorney General justification for why the wholesale acquisition cost ("WAC") increased for that particular drug.\(^32\)

In one piece of good news for the industry, the law protects the information manufacturers provide by exempting it from public inspection and copying under the state’s Public Records Act.\(^33\) Vermont also requires "pharmaceutical marketers" to disclose the average wholesale price ("AWP") and comparative price information to healthcare professionals (i.e., short form and long form).\(^34\)

Often overlooked is New Mexico’s Reporting Prescription Drug Information Act, which requires every manufacturer that sells drugs in the state of New Mexico to file pricing information with state Human Services Department Medical Assistance Division ("MAD").\(^35\) This law has been on the books since 2007, but in speaking with an official from MAD’s Program Policy Bureau, many manufacturers fail to submit this information. However, the process is currently being revised so that manufacturers can submit electronically via Microsoft Excel.\(^36\) Whether this will increase compliance or simply provide New Mexico with additional leverage to pursue the miscreants is yet to be determined.

In 2017, three states (Maryland, Nevada, and Louisiana) were successful in enacting drug pricing legislation, another state is on the verge of enacting its version (California), and a city (Chicago) is continuing its relentless pursuit of the pharmaceutical industry.

**Louisiana (Effective August 1, 2017)**

Louisiana via Act 220 of the 2017 Legislature added a law to require prescription drug manufacturers who engage in “prescription drug marketing” to disclose quarterly to the Louisiana Board of Pharmacy ("BOP") the WAC for the Food and Drug Administration ("FDA") approved drugs marketing in Louisiana.\(^37\) “Prescription drug marketing” is broadly defined to include “educational or marketing information or materials regarding a prescription drug in any form.”\(^38\) Reporting is required on January first, April first, July first, and October first.\(^39\) Technically with the law in effect, the first report is due to the BOP on October 1, 2017, but according to a BOP official, there are no penalties for non-compliance.

In speaking with an official from the BOP, they have been recommending inquiring companies to report the WAC in a Microsoft Excel spreadsheet, together with the following fields:

1. Brand Name;
2. Generic Name;
3. Strength and Form;
4. Whether the drug is a brand name or a generic;
5. NDC;
6. Therapeutic Category;
7. Per-Unit wholesale acquisition cost of the drug; and
8. Package Size.

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32 VT. STAT. ANN. tit. 18, § 4635(b)(1).
33 Id. at § 4635(e).
34 Id. at § 4633(a), (b).
35 See N.M. STAT. ANN. § 27-2E-1(A) (requiring “[a] person who manufactures a prescription drug, including a generic prescription drug, that is sold in New Mexico shall file with the human services department: (1) the average manufacturer price for the drug; (2) the price that each wholesaler or pharmacy benefit manager doing business in this state pays the manufacturer to purchase the drug; and (3) the price paid to the manufacturer by any entity in an arrangement or contract that sells or provides prescription drugs in New Mexico without the services of a wholesaler”).
36 See Reporting Prescription Drug Information Act, N.M. HUM. SERV. DEPT (Nov. 9, 2007), http://www.hsd.state.nm.us/uploads/files/Providers/ Fee%20For%20Service/Pharmacy/Reporting%20Prescription%20Drug%20Information%20Act.pdf. Manufacturers should not submit the required information to Julie McKeay; instead, companies should submit the information to Sonya R. Miera, R.Ph. (Sonya.Miera@state.nm.us).
37 LA. STAT. ANN. § 40:2255.11.
38 LA. STAT. ANN. § 40:2255.12.
40 Until the website is created, the BOP is recommending companies to send the information to Benjamin Whaley, R.Ph., BOP Chief Compliance Officer (bwhaley@pharmacy.la.gov).
It was suggested that the BOP formally place a notice with this guidance on its public website. Additionally, the official interviewed stated Act 220 is not contingent upon grant funds or website development. Louisiana addressed the website issue via Act 236, also enacted in 2017, which requires the BOP to create a website to post the WAC information.

Finally, while the definition of “prescription drug” is based on the Federal Food, Drug, and Cosmetic Act’s definition for a drug, which includes “animal drugs,” Louisiana intends only to collect the WAC for human drugs. Nor does the BOP intend to promulgate regulations.

Maryland (Effective October 1, 2017)

Maryland was successful in enacting a law prohibiting price gouging, which also contains a WAC disclosure component. The state has set its sights on “essential off-patent or generic drugs,” which are defined as prescription drugs, including drug-device combinations, for which all exclusive marketing rights have expired, that is available for sale in the state, and either appears on the World Health Organization’s most recent Model List for Medicines, or has been designated by Maryland’s Secretary of Health and Mental Hygiene as an “essential medicine.”

The Maryland Medical Assistance Program (“MAP”) is directed to notify the state attorney general of any increase that would result in:

- an increase of fifty percent (50%) or more in the WAC within the previous year or
- result in an increase of fifty percent (50%) or more in the price paid by MAP in the previous year, and
- either a thirty (30) day supply, full course of treatment, or made available only in quantities that do not correspond to a thirty (30) day supply of an essential off-patent or generic drug would cost more than eighty dollars ($80).

Manufacturers of these drugs would be required to submit a report within forty-five (45) days following a request from the attorney general with information such as the cost of production and reasons for the increase. Additionally, the attorney general has been granted the authority, should it choose, to require the manufacturer to reimburse consumers, including a third-party payor, any money it acquired as a result of a violative price increase.

In June of 2017, the Association for Accessible Medicines (“AAM”), the generic drug manufacturers’ trade association, filed suit against the state of Maryland seeking a declaration that HB 631 violates the United States Constitution (i.e., under the dormant Commerce Clause and the Fourteenth Amendment) seeking both a temporary restraining order and permanent injunction from implementing or enforcing HB 631. According to Reuters, the Attorney General’s office believes it will survive the legal challenge and is continuing to move forward with implementation by working with John Hopkins University to identify price spikes.

Nevada (Effective October 1, 2017)

According to an official from the Nevada Department of Health and Human Services (“NDHHS”), the local Nevada Culinary Union (the “Union”) was able to best the industry’s lobbyists. How so?

It turns out, “[t]he Culinary Union, through the Culinary Health Fund, is one of the largest healthcare consumers in the state. . . . [a]nd provides health insurance coverage for over 143,000 Nevadans, the Culinary Union’s members [numbering at 57,000 workers] and their dependents.” Additionally, the Union had the support of the casino gaming industry. Consequently, the Legislature passed and Governor Brian Sandoval, on June 15, 2017, signed Senate Bill 539 (“SB 539”) into law. While SB 539 contains numerous provisions...
targeting the pharmaceutical industry, the main focus of the bill largely concerns pricing transparency of diabetes medication, becoming effective on October 1, 2017. By February 1, 2018, the NDHHS must create a list that includes all insulins and biguanides and the WAC for each. Based on this list, NDHHS will then create a list of those drugs with an increase in the WAC equal to or greater than the percentage increase in the Consumer Price Index, Medical Care Component (“CPI-M”) from the previous year or twice the CPI-M in the preceding two years. Once the list is created, by April 1, 2018, those manufacturers whose product(s) are on the list must file a report that contains information such as the cost of producing the drug, the profit the manufacturer has earned, and the costs associated with coupons. Additionally, the same manufacturers must include in the report the reason(s) justifying the increase in the WAC. It should be noted that, unlike the Vermont pricing legislation, any information that a manufacturer reports to the state is not considered a trade secret and can be disclosed to the public. Currently, the pricing transparency provisions are subject to a lawsuit from the Pharmaceutical Research Manufacturers Association of America (“PhRMA”) and the Biotechnology Innovation Organization (“BIO”). PhRMA and BIO contend that, among other things, Senate Bill 539 “interferes with the federal patent and trade-secret laws, deprives manufacturers of their property interest in their trade secrets, and improperly overrides the regulatory choices of every other state.” Unfortunately for the industry, PhRMA and BIO failed to meet the burden for granting a temporary restraining order, and the U.S. District Court for Nevada has set a preliminary injunction hearing for October 17th. 

California (Awaiting Governor’s Signature) If Senate Bill 17 (“SB 17”) becomes law, every pharmaceutical manufacturer should take note, as it contains several new reporting provisions. First, a manufacturer of a prescription drug with a WAC of forty dollars ($40) or more for a thirty (30) day supply will be required to provide written notification at least sixty (60) days prior to any price increase to state purchasers, health plans or insurers, and pharmacy benefit managers (“PBM”) where the WAC’s increase is sixteen percent (16%). The 16% increase includes the proposed increase and the cumulative increase from the previous two years. This part of the bill is due to become effective January 1, 2018. Next beginning January 1, 2019 and quarterly thereafter, manufacturers subject to price increase notification discussed above, will be required to report certain information related to the WAC, such as a description of the financial and nonfinancial factors that contributed to the increase, to the Office of Statewide Health Planning and Development (the “Office”).

City of Chicago (Proposed) The Windy City may not be through with the pharmaceutical industry. On June 28, 2017, an ordinance was introduced that would establish the Prescription Drug Price Review Board (the “Board”). Citing, among other things, Nevada’s enactment of its drug price transparency law, the ordinance would empower the Board with duties such as publishing an annual report on prescription drug pricing trends within the City of Chicago, “promulgate public advisory opinions concerning specific drugs, drug classes, or drug manufacturers that satisfy its standards for egregious pricing practices to its facilities, partners, website, and the City’s Benefits Management Division,” and a pricing hotline to encourage the public to report price increases. The ordinance further proposes that all prescription drug manufacturers to notify the Department of Public Health Commissioner of certain

54 See SB 539 § 28(3) (setting the effective date for Sections 1 to 6.5 on October 1, 2017).
55 Id. at § 3.6(1).
56 Id. at § 3.6(2).
57 Id. at § 3.8.
58 Id. at § 4.
59 See id. at § 9 (revising the definition of “trade secret” to exclude information manufacturers report under Section 3.8 and 4 of SB 539).
61 Compl. at 2, Pharm. Research & Mfrs. of Am. v. Sandoval.
62 Order at 2, Pharm. Research & Mfrs. of Am. v. Sandoval.
63 Once a bill reaches the governor’s desk, “[t]he Governor has 12 days to sign, approve without signing, or veto a bill.” Legislative Process, CAL. ST. SENATE, http://senate.ca.gov/legislativeprocess (last visited Sept. 22, 2017).
64 65B 17 at § 4, 127677.
65 Id. at § 4, 127679.
67 Id. at 1.
price increases, costly new drugs, and justification for the proposed price or increase.  

It remains unclear whether the ordinance will succeed, but even if it does not, it serves as a reminder to the pharmaceutical industry that absent a federal price transparency law expressly preempting states and cities from doing the same, the industry will face an ever-growing chorus of American states and cities looking to score an easy political victory for constituents.

A Call to Action

By the time 2017 ends, the pharmaceutical industry may have wished it was starting again. For starters, the number of state actions targeting the industry has been daunting to track accurately. For example, this author highlighted about approximately fifty (50) pricing bills targeting our industry in the May edition of Life Science Compliance Update. However, the National Council of State Legislatures’ Prescription Drug State Database shows that thirty-six (36) states have introduced a total of 176 bills.  

In addition to state legislation, companies are finding that they need to stay abreast of actions from cities, administrative agencies, state attorney generals, and even governors. To make matters worse, many compliance departments and in-house counsel are finding themselves struggling to stay up to date on the latest news while complying with current requirements.

Internally, companies should be strategic with their resources. Companies, either directly or indirectly (i.e., lobbying), also need to embrace advocacy better and begin building relationships with legislatures and administrative agencies. Trade associations should consider forming a new organization devoted strictly to pharmaceutical compliance.

On the one hand, opposing unfavorable legislation is paramount, but when it becomes clear a loss is inevitable, the industry must be willing to compromise. In certain circumstances it means proposing solutions that would be easily scoffed at and viewed unfavorably. For instance, calling for a sweeping federal law to preempt states altogether from continuing to push for passage of types of bills, laws, and ordinances discuss herein.

Globally, countries are increasing the calls for transparency and having fifty (50) American states on top of it calling for their own requirements is not sustainable. States and cities will return in 2018 with a vengeance; by the time 2018 ends, the industry may actually consider a federal preemptive move.

The Expanding Frontier - Commercial Interactions with Patients and Patient Organizations

By David Davidovic, Founder, pathForward; former Global VP, Commercial Services, Genentech and Roche

Abstract: Over the past two decades, the role that patients play in their health care has dramatically shifted. As a result, there is an increasing need and drive by life science companies to engage with patients (e.g., patient centricity). However, this approach is not without risk as this article will explore.

Over the previous two decades, we have seen a dramatic and transformative change in the role that patients play their health care. Your grandparents, and even your parents, generally were passive players in their care, content to let their “better-informed” physicians (“Doctor knows best”) make most of the treatment decisions for them. They confined their roles to making appointments submitting to diagnostic tests, getting prescriptions filled (at a retail pharmacy or via mail order), and contacting their physicians to get renewals and refills thereby ensuring they stayed on treatment. Some, but not all, of this passivity can be attributed to a health insurance scheme that had less “friction” caused by financial-burden decisions. That’s all changed.

68 Id. at § 2.
69 N. Fiorentino, Whack a Mole – Pricing Bills Keep Popping Up Everywhere, 3.5 LIFE SCIENCE COMPLIANCE UPDATE at 1 (May 2017).
The patient role has shifted to a much more participatory one. Multiple factors account for this dramatic increase in patients’ interest and participation in their own care:

- the enormous growth of easily-accessible, and arguably easier to comprehend, health information;
- the rapidly growing financial burden from co-pays and deductibles, especially for expensive treatments;
- the growing demands and expectations patients have of their treatments, especially in more difficult-to-treat and rare diseases; and
- the advent of social media, enabling greater connectivity among patients.

This increased interest and participation by patients has created an ever-increasing demand for medical answers and new treatment options. Furthermore, despite the negative stories of the myopic physician, there is plenty of research showing that most physicians welcome thoughtful requests and suggestions from their patients.71

**The Impact of the Changing Doctor-Patient Relationship**

With more patient decision-making, both aspirational and actual, comes increased purchasing power and market influence. This new dynamic and power has resulted in patients taking a larger role as stakeholders in strategies and plans in all facets of the life science industry, including pharmaceutical, biotechnology, medical device and diagnostics companies. Most current marketing plans to be credible now include some ‘patient engagement’ component; either as a major strategy or as a key element of a major strategy. These plans employ strategies and tactics that cover a wide array of options and may include:

- multi-channel patient engagement programs;
- traditional Direct-to-Consumer (“DTC”) or Direct-to-Patient (“DTP”) advertising;
- digital health and mobile applications;
- social media campaigns;
- fundraising and disease awareness events;
- advisory boards;
- patient-retention, compliance (aka renew and refill) and persistence programs; and
- third-party educational and other financial support.

More recently, these plans have added new components under banners such as “patient access and reimbursement support services”, “patient opinion leaders”, and “patient ambassadors.” These newer plans also include a greater amount of patient market research and “big data” analysis to develop insights and to map out “patient journeys” for yet better engagement with patients.

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Patient Centricity - The New Wagon Train

Many companies have embarked on a “patient centricity” bandwagon. Although there is no single, commonly-accepted definition of this term across the industry, at its heart, the concept aims to put the patient front and center of a company’s vision and mission. One natural outcome from this approach is increased funding – and creativity - for patient-related activities.

This outcome also entails increased potential legal and compliance risks as companies seek to obtain a competitive advantage and make a measurable return on their investment.

At the same time, a new, separate stakeholder has emerged. This is the “patient organization” or “patient group” or “patient advocacy group” (“PAG”). These groups or organizations are usually non-profit entities either run by patients or on behalf of patients with a focus on a particular disease. Early examples of these groups emerged in mid to late 1990’s for Lyme Disease. For example, the American Lyme Disease Foundation (“ALDF”) is a 501(c)(3) charitable organization founded in 1994, that “works to help people make wise healthcare decisions by providing key information on Lyme disease and other tick-borne infections to the public and medical community.”

Typical activities and presence of these patient entities include:

- media exposure (Print and TV), websites (disease and cause);
- email campaigns;
- social media channels (Facebook, Twitter, YouTube, Instagram, Pinterest);
- coalitions, action letters, phone calls.

They are also increasingly involved in local, regional, national and even international lobbying for healthcare-plan attention and/or legislative action.

It also is not unusual for patient groups to approach companies entirely based on their confidence that they have influence across the care continuum, based in independent credibility and patient proximity. A recent study published in the New England Journal of Medicine concluded that “among 104 of the largest U.S.-based patient-advocacy organizations, at least 83% received financial support from drug, device, and biotechnology companies, and at least 59% have a current or former industry executive on the governing board.”

Collaboration between these organizations and life sciences companies may be perfectly valid and appropriate. That collaboration can support good patient care in areas of aligned interests, which typically involve supporting or advocating research, providing disease-state education funding and resources, providing general financial support, supporting specific projects, participating on or helping conduct fundraising and awareness-raising walks and runs. However, in today’s environment, any involvement by a life science company with these organizations is likely to be viewed with skepticism on the part of the press and the regulators, and thus is not without risk.

Some of the more general risks involved with working with these groups include:

- the potential for bias, real or perceived, that comes from engaging patient organizations;
- the lack of maturity and understanding of the legal and compliance landscape by some groups, leading to bad communications and decisions;
- the need for financial accountability and independence when most funding comes from industry;
- a need to understand and abide by regulated or voluntary transparency and disclosure commitments;
- dealing with non-scientific viewpoints that may be counter to evidence or product labels; and
- dealing with participation of HCPs, i.e. customers, as leaders of some organizations.

There are, of course, the usual list of compliance risks that can occur if company – patient organization interactions are not properly handled. These include an illustrative list of issues encompassing off-label promotion, kickbacks, fraud on the FDA, inadequate adverse event report handling, practicing medicine without a license, product liability, and privacy breaches including unauthorized use of personal data.

Given the breadth of the area, as well as the various tactics employed, it is very challenging to understand the complete landscape of patient advocacy activities. Therefore, we have developed a number of vignettes each based on real-world situations and issues to illustrate both the range of tactics.

as well as the type of issues, some incidental, that occur. Rather than engage in a comprehensive analysis of each vignette, we have chosen the “issue spotting approach,” by highlighting areas of potential concern. We encourage our readers to use these scenarios as a training tool and to engage in their own analysis.

**Direct interactions with Patients by Company Employees or Their Agents**

**Vignette 1:**

A sales representative for Company X, wearing a company identification badge, is in a waiting room waiting to see a physician. A patient asks the sales representative a basic question about one of its products. The representative provides an on-label response.

**Vignette 2:**

Company X participates in a fundraising walk organized by a rare-diseases patient organization. Company participation includes some charitable funding, supporting employees to participate in the walk, and one employee from HR, one from Advocacy Relations and one from the contributions department staffing an information table. Patients participating in the walk, who also happen to be highly involved in their condition, approach the table with questions about company X’s product recently presented clinical data.

**Vignette 3:**

A company launches a program for sales representatives to present PRC-approved disease-only education and/or product education directly to groups of patients and caregivers.

**Vignette 4:**

A physician is seeing a patient for whom she’s considering Company X product. Coincidentally, the sales representative for the product is in the office. The physician asks the representative to come into the consultation room because the patient has questions about reimbursement.

Some potential risks that are embedded in all four scenarios to varying degrees:

- Privacy
- Liability
- False Claims (off-label)
- Practice of medicine without a license
- Adverse event reporting
- Ethics
- Reputation exposure

**Direct-to-Patient Advertising**

**Vignette 1:**

Company X launches a disease state direct-to-patient TV and web campaign focusing on the disease and on tips for living with the condition.

**Vignette 2:**

Company X, prompted by its advertising agency, wishes to launch a social media (Facebook, YouTube and Twitter) campaign focusing on only one key message about the product.

Some potential risks that are embedded in these scenarios to varying degrees:

- False Claims and Off-label promotion
- Adverse Event Reporting
- Advertising that is false or misleading (e.g., lacks fair balance, lacks adequate warnings and contraindications).

**Patient as Spokesperson**

**Vignette 1:**

Mary B. is a patient who participated in a Product X clinical trial. She’s invited (hired) by Company X to speak at a press conference announcing approval of the product.

**Vignette 2:**

John P. is hired as a “patient ambassador” to go into the community and speak with other patients about his experience in living with the condition and, possibly about his experience on drug Y.

**Vignette 3:**

Susan, is the parent of a child suffering a particular rare condition. Company X invites Susan to testify at an FDA hearing regarding potential approval of the product.

**Vignette 4:**

A company invites a patient and his family to an internal company sales meeting to provide their perspective on his rare disease.

Some potential risks that are embedded in these scenarios to varying degrees:

- Privacy
- Liability
• False Claims and Off-label promotion
• Fair Market Value
• Adverse event reporting
• Reputation exposure

**Patient Advocacy Organizations or Groups**

**Vignette 1:**

Patient Organization B has an “industry council” and invited Company X to join and participate. For this membership, the Patient Organization requests a contribution of $10,000 annually which will go towards general funds.

**Vignette 2:**

Company X asks the Executive Director of a PAG to participate, as a consultant, in a series of advisory boards and other company meetings. Separately, the PAG has submitted comments to the FDA regarding an upcoming product review.

**Vignette 3:**

A PAG responds to an RFP issued by a product manager in company X looking for vendors to help develop unbranded educational materials that the company will offer to patients.

Some potential risks that are embedded in these scenarios to varying degrees:

• Privacy
• False Claims and Off-label promotion
• Anti-kickback
• Adverse event reporting
• Undue influence

Looking across all the vignettes, we can see that there are some common issues and themes that continually repeat. Therefore, it is possible to frame a set of fundamental principles that should be considered in every patient centric situation. Figure 1 sets out those principles, most of which are well-known and commonsense.

**Patient Support Services Hubs & Patient Assistance Programs**

**Vignette 1:**

A medical practice asks company X sales rep for help navigating insurer to help

**Vignette 2:**

Physician complains to company sales representative that one of his patients has a challenge getting product covered and asks sales representative for his contact information so that patient can call him for help.

Some potential risks that are embedded in these scenarios to varying degrees:

• Privacy
• False Claims and Off-label promotion
• Anti-kickback
• Adverse event reporting
• Undue influence

While the patient-physician-life science company relationship is continuing to develop, we believe that it is an area that will challenge compliance professionals in the coming years as tactics and objectives far outpace legal and regulatory updates. Consequently, early and frequent communication between compliance and company marketing professionals will prove essential.

**FIGURE 1: Dealing with Patient Centric Situations**

**Fundamental Principles:**

• Ensure all communications are consistent with the product label;
• Respect the relationship between patients and their providers;
• Respect patients’ and caregivers’ rights and wishes for privacy and confidentiality;
• Look out for and report adverse events per company policy;
• Ensure all interactions and engagements are clear, transparent and are what they are purported to be;
• Ensure all engagements with patients, caregivers and patient organizations are covered with clear and thorough written agreements.
The following synopsis provides an update to the article, Ohio Drug Distribution Verification: America’s Key Battleground State Shakes Up the Pharmaceutical Supply Chain. In addition, this update provides new data, a one-page “cheat sheet” for non-controlled prescription drug sample distribution into and within the state that also includes the supporting references and an example of a sample/complimentary request form. Finally, this update is limited to a discussion on the non-controlled verification requirements for samples and complimentary supplies only.

On July 14, 2017, the Ohio State Board of Pharmacy (“BOP”) published the Verification of Licensure Prior to the Sale or Distribution of Drug Samples or Complimentary Supplies. Although it seemed straight-forward, when legal teams across the industry began reading each word carefully, things did not appear so simple.

For example, in the third paragraph of the first page, the BOP stated “[t]he [verification] process is intended for the sale of non-controlled drug samples and complimentary supplies that are being shipped to a prescriber.” Some thought that “shipped” implied the verification requirements under Ohio Rev. Code § 4729.60, Ohio Admin. Code 4729–9–12, and the modified verification process discussed within the guidance did not apply to pharmaceutical sales representatives distributing drug samples into and within the state.

The verification requirements clearly apply to sales representatives, as provided within Ohio Admin. Code 4729-9-13(B), which states “[n]o manufacturer, manufacturer’s representative, wholesale dealer or wholesaler’s representative in pharmaceuticals may sell or distribute a sample of a drug to a licensed prescriber unless requested by the prescriber and the company [i]s licensed as a wholesale distributor of dangerous drugs.” Nonetheless, the BOP issued a revised guidance on August 30, 2017. In addition to minor grammatical revisions, a frequently asked question was added: “Does this process also apply to drug sales representatives?” The BOP’s response was a simple, “Yes.”

While some companies were still trying to comply with Ohio’s previous laws and regulations on the subject, others were busy trying to find loop-holes. For instance, one of the authors of this article received a question from a client insisting the Terminal Distributor of Dangerous Drugs (“TDDD”) exemption requirements made the verification requirements for non-controlled prescription drugs inapplicable to the manufacturer. There are no exemptions or exceptions to the verification requirements, but there are exceptions/exemptions for certain prescribers (sole proprietors, sole-shareholders, and dentists) to obtain a TDDD licensure for non-controlled prescription drugs. While Ohio Rev. Code § 4729.541(A)(1) states licensed prescribers are exempt from TDDD licensure, the definition of a “prescriber” (found under “means an individual who

74 Views expressed in this article are that of the authors and do not necessarily reflect the opinions, position, or policy of G&M Health, LLC or MedPro Systems LLC. either company’s other employees, or its clients. Further, the information presented within this article is not legal advice or a legal opinion and should not be interpreted or relied upon as such.

75 See N. Fiorentino, B. Adams, et al., Ohio Drug Distribution Verification America’s Key Battleground State Shakes Up the Pharmaceutical Supply Chain, 3.9 LIFE SCIENCE COMPLIANCE UPDATE at 1 (Sept. 2017).

76 Verification of Licensure Prior to the Sale or Distribution of Drug Samples or Complimentary Supplies, ST. OHIO BOARD OF PHARMACY (July 14, 2017) [hereinafter Original Drug Sample Verification Guidance]. The Original Sample Verification Guidance is no longer available through the BOP’s website.

77 Id. (alterations added) (emphasis added).

78 OHIO ADMIN. CODE 4729-9-13(B)(1) (alterations added). Section B(2) requires the maintenance of distribution records that must be made available, upon request, by the BOP.

79 Verification of Licensure Prior to the Sale or Distribution of Drug Samples or Complimentary Supplies, ST. OHIO BOARD OF PHARMACY (Aug. 30, 2017) [hereinafter August Drug Sample Verification Guidance]. The August Sample Verification Guidance is no longer available through the BOP’s website.

80 See OHIO REV. CODE § 4729.541 (providing the TDDD licensure exemptions).

81 See OHIO REV. CODE § 4729.541(A)(1)-(3) (applying the exemption to sole proprietors under Section 4729.541(A)(1), sole shareholders under Section 4729.541(A)(2), and dentists under 4729.541(A)(3)); see also Terminal Distributor Licensing of Prescriber Practices, ST. OHIO BOARD OF PHARMACY (June 21, 2017), https://www.pharmacy.ohio.gov/prescriber/ddl [hereinafter “TDDD Prescriber Practices Guidance”]. For a description of the categories, see the BOP guidance, License Verification for Wholesale Distributors (July 14, 2017).
### Ohio’s Sample/Complimentary Supply Verification Compliance One-Pager for Manufacturers Distributing Non-Controlled Prescription Drugs

<table>
<thead>
<tr>
<th>Is your company distributing samples or complimentary supplies into or within Ohio?</th>
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| No manufacturer, manufacturer’s representative, wholesale dealer or wholesaler’s representative in pharmaceuticals may sell or distribute a sample of a drug to a licensed prescriber unless requested by the prescriber and the company is registered as a Wholesale Distributor of Dangerous Drugs (“WDDD”).

**OHIO ADMIN. CODE 4729-9-13(B)(1); see also Verification of Licensure Prior to the Sale or Distribution of Drug Samples or Complimentary Supplies, ST. OHIO BOARD OF PHARMACY (Sept. 6, 2017), [hereinafter Sample Verification Guidance].** |

**“Sample”** means a dangerous drug or pharmaceutical preparation that would be hazardous to health or safety if used without the supervision of a licensed health professional authorized to prescribe drugs or a drug of abuse, and that, at one time, had been placed in a container plainly marked as a sample by a manufacturer.

**OHIO ADMIN. CODE 4729-9-13(A)(1).**

**“Complimentary supply” also known as “starter packs,” “initial dose packs,” “starter stocks,” “replacement programs,” or any other similar supply** means a drug or pharmaceutical preparation that is distributed without charge by licensed wholesale distributors or manufacturers to pharmacies licensed as TDDDs or prescribers to assist patients in the initiation of drug therapy. A complimentary supply shall not contain the markings or labeling of a sample drug.

**OHIO ADMIN. CODE 4729-9-13(A)(2).**

### Verification Required Prior to Distribution

Before distributing prescription drugs, either by hand-carry or direct-to-practitioner, license verification is required to confirm the practice and prescriber holds or is exempt from holding a Terminal Distributor of Dangerous Drugs (“TDDD”) License. See **OHIO REV. CODE § 4729.60;** see also **OHIO ADMIN. CODE 4729-9-12;** see also Sample Verification Guidance.

### TDDD Licensure Overview

**For Non-Controlled Rx:** A prescriber must possess either a Category II or Category III TDDD license unless the prescriber meets an exemption (no exemptions for Category III). Three (3) types of prescribers are exempt from Category II licensure: (1) Sole proprietors, (2) Sole shareholders, and (3) Dentists. See **Ohio Rev. Code § 4729.541(A)(1)-(3);** see also Terminal Distributor Licensing of Prescriber Practices, ST. OHIO BOARD OF PHARMACY (Aug. 30, 2017), [hereinafter Exemptions]; see also License Verification for Wholesale Distributors (July 14, 2017), ST. OHIO BOARD OF PHARMACY [explaining the TDDD categories].

**Location Specific:** TDDD licenses are location-based so the address should match the ordering prescriber’s address. See **Sample Verification Guidance; Accord OHIO REV. CODE §4729.54(H)(2).**

### Verification Process

Per the Sample Verification Guidance, the State Ohio Board of Pharmacy (“BOP”) has authorized, by resolution, the following alternative process for non-controlled prescription drugs only: (1) Verify the prescriber’s license is in good standing; (2) If prescriber provides TDDD, then verify TDDD license; (3) Create and provide sample/complimentary supply request form; and (4) Retain all verification records for three (3) years. If a limited license, review licensee’s drug list to ensure licensee can possess the requested drug.

TDDD licenses can be verified using Ohio’s online licensing registry ([https://license.ohio.gov/lookup/default.asp?division=96](https://license.ohio.gov/lookup/default.asp?division=96)); a limited licensee’s drug list can be viewed by going to [http://www.pharmacy.ohio.gov/Licensing/PublicDocuments.aspx](http://www.pharmacy.ohio.gov/Licensing/PublicDocuments.aspx).
is authorized by law to prescribe drugs or dangerous drugs or drug therapy related devices in the course of the individual’s professional practice.”

This likely is how the BOP was able to exempt sole proprietors, sole shareholders, and dentists from requiring them to obtain a TDDD license for non-controlled prescription drugs. However, there are no exemptions for any prescriber who possesses controlled substances or compounded drugs.

For those prescribers who must hold a TDDD license and as stated in the TDDD Prescriber Practices Guidance, “if the business practice is a group practice AND there are multiple owners, shareholders, or members then the business practice (corporation, professional association, LLC, or partnership) is required to be licensed as a Terminal Distributor of Dangerous Drugs with the Board of Pharmacy.” Importantly, prior to the issuance of the Original Sample Verification Guidance, the BOP required anyone distributing drugs within and into the state of Ohio to verify TDDD licenses and if a prescriber was exempt from licensure, then had to comply with the onerous verification of exemption requirements found under Ohio Admin. Code 4729-9-12(C)(2). This required, among other things, the BOP to ask a sole shareholder for “official documentation” that he/she was indeed a sole shareholder.

Another difficulty was the fact that the BOP interpreted the statute as applying to all prescription drugs, including complimentary trade products and drug samples. The BOP also assumed that manufacturers were following the provisions. However, once the BOP’s interpretation became clear, the

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**SAMPLE / COMPLIMENTARY SUPPLY REQUEST FORM ADDENDUM**

State of Ohio Board of Pharmacy Required Notice to Ohio Prescribers

Note: Please review the information below. Pharmaceutical representatives cannot answer any questions regarding this information. If you have any questions, contact the State of Ohio Board of Pharmacy (the “Board”) for any questions by phone (614.466.4143) or by email (http://www.pharmacy.ohio.gov/contact.aspx). This Addendum is not offered, nor should it be construed, as legal advice.

**A. When a Prescriber Must Hold a Terminal Distributor of Dangerous Drugs**

- A Terminal Distributor of Dangerous Drugs license allows a business entity to purchase and possess dangerous drugs at a specific address for distribution to patients. Ohio law considers all drugs, non-controlled prescription drugs, and controlled substances, to be “dangerous drugs.”

- Under Ohio Revised Code § 4729.01(Q), a “Terminal Distributor of Dangerous Drugs” is defined as “person who is engaged in the sale of dangerous drugs at retail, or any person . . . who has possession, custody, or control of dangerous drugs for any purpose . . . and includes pharmacies, hospitals, nursing homes, and laboratories and all other persons who procure dangerous drugs for sale or other distribution by or under the supervision of a pharmacist or licensed health professional authorized to prescribe drugs.”

- Ohio Revised Code § 4729.51 states who may lawfully possess, sell, distribute, or deliver dangerous drugs. Pharmaceutical manufacturers, including their agents, cannot provide dangerous drugs to anyone other than an individual health care professional authorized by law to prescribe dangerous drugs in the course of the individual’s professional practice or a licensed Terminal Distributor of Dangerous Drugs (most prescribers’ practices/businesses).

- The Board has provided a guidance document and is currently located on the Board’s Terminal Distributor of Dangerous Drugs Licenses page under the “General Information” header. The Board has also created a short link to the document: www.pharmacy.ohio.gov/PrescriberTDDD.

**B. Exempt Prescribers (for non-controlled prescription drugs only)**

- Prescribers who are exempt must attest that they meet one of the licensing exemptions under Ohio Revised Code § 4729.541. This attestation is included on the sample request form.

- Exemptions include, but are not limited to: (1) prescribers who are sole proprietors; (2) business practices with a sole shareholder (per Ohio law, group practices with multiple shareholders are not exempt); and (3) dentists licensed by the Ohio Dental Board.

- Please see the Board’s guidance document (link provided above) for a full description of these exemptions.

**C. Prescriber Record Retention Requirements**

- The Board states that YOU must “[e]nsure that all sample/complimentary request forms are maintained for a period of three-years in accordance with the recordkeeping requirements of Chapter 4729-9 of the Ohio Administrative Code.”

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82 OHIO REV. CODE § 4729.01(I) (emphasis added).

83 See supra note 8.

84 See OHIO REV. CODE § 4729.541(D); see also Terminal Distributor Licensure Requirements for the Possession of Controlled Substances, ST. OHIO BOARD OF PHARMACY (April 4, 2017), https://www.pharmacy.ohio.gov/Licensing/TDDD.aspx (found under “General Information”) (hereinafter TDDD Controlled Substance Guidance).

85 TDDD Prescriber Practices Guidance, supra note 8 (emphasis in original).

86 OHIO ADMIN. CODE 4729-9-12(C)(2)(a).
industry pushed back leading to the “modified process” for non-controlled drugs.

Now, instead of the process outlined within Ohio Admin. Code 4729-9-12, before distributing any non-controlled sample or complimentary supply, the following is required:

1. Verify the prescriber’s license is in good standing;
2. If a TDDD license number is provided, then verify the TDDD license is in good standing; and
3. Update the sample/complimentary supply form to contain specific requirements about TDDD licensure, a way for the prescriber to attest they are exempt, and ensure the request forms are maintained for a period of three-years [collectively the “modified process”].

Some companies complied by requiring its vendors and sales force to pro-actively collect a TDDD number, while others interpreted part two of the modified process as optional. Through discussions with the BOP, the BOP decided to issue another revision to the guidance on September 9, 2017 adding the following language on page two:

**PLEASE NOTE:** It is the expectation of the Board that a wholesale distributor, manufacturer, third-party logistics provider or any similar entity licensed by the Board must do one of the following prior to sale or transfer of a non-controlled sample drug:

1. Obtain and verify a valid TDDD number of the prescriber practice; or
2. Obtain an attestation (after notification of Ohio’s licensing requirements) that the prescriber is exempt from licensure.

**Failure to obtain and verify a TDDD number or an attestation that the prescriber practice is exempt prohibits the entity from conducting the sale or transfer.**

The result is that the failure by a company to comply with Ohio’s verification requirements and distribute a sample or complimentary supply without verification is considered an “illegal sale” that can subject companies to administrative fines, as well as jeopardizing its Wholesale Distributor of Dangerous Drugs license.

**Abstract:**

With the new administration, there appears to be a renewed commitment to enforcing anti-kickback rules against healthcare providers committing fraud against the government insurance programs. In July 2017, the Department of Justice and Department of Health and Human Services announced the largest-ever fraud takedown in the health care arena. This article outlines the announcement, and what it may mean for the future of health care.

It has long been a topic of discussion among life science compliance professionals that when it comes to anti-kickback enforcement, the government favors prosecuting manufacturers and healthcare institutions over individual providers. The speculation was that those two categories were favored because of their deep pockets. However, that old rubric just may have changed.

On Thursday, July 13, 2017, United States Attorney General Jeff Sessions and Department of Health and Human Services (“HHS”) Secretary Tom Price, M.D., announced the results of largest ever health care fraud investigation. Conducted by the Medicare Fraud Strike Force, the enforcement action charged 412 defendants across forty-one federal districts for their alleged participation in a variety of health care fraud schemes that cost the U.S. Government and its taxpayers over $1.3 billion in false billings.

Of the 412 defendants, over 120 were doctors, nurses, and other licensed professionals and charged for their roles in prescribing and distributing opioids and other dangerous narcotics. HHS also initiated suspension actions against 295 providers, including doctors, nurses, and pharmacists.

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**Getting Serious About Fraud - The DOJ Charges 412**

*By Kaitlin Fallon Wildoner, Esq., Senior Staff Writer, Life Science Compliance Update*

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87 See Verification of Licensure Prior to the Sale or Distribution of Drug Samples or Complimentary Supplies, ST. OHIO BOARD OF PHARMACY (Sept. 9, 2017), https://www.pharmacy.ohio.gov/Licensing/WDDD.aspx (found under “General Information”) [hereinafter Current Drug Sample Verification Guidance].
88 See OHIO REV. CODE § 4729.25 (concerning the general authority the BOP has for enforcement); see also OHIO REV. CODE § 4729.56 (concerning the BOP’s authority to impose disciplinary actions upon a WDDD).
89 See Department of Justice, National Health Care Fraud Takedown Results in Charges Against Over 412 Individuals Responsible for $1.3 Billion in Fraud Losses (July 13, 2017), available at https://www.justice.gov/opa/pr/national-health-care-fraud-takedown-results-charges-against-over-412-individuals-responsible
Background

The cases all involved improper bills submitted to government health insurance programs (e.g., Medicare, Medicaid, and TRICARE) by allegedly unscrupulous providers. The large number of medical professionals charged is particularly significant, because essentially every health care fraud scheme requires a corrupt medical professional to be involved for Medicare or Medicaid to pay the fraudulent claims. From the government’s perspective, aggressively pursuing corrupt medical professionals not only has a deterrent effect on other medical professionals, but also ensures that their licenses can no longer be used to engage in behavior that has the potential to put government-funded health care programs at financial risk through fraud.

As noted above, the charged medical professionals participated in a wide variety of illicit schemes. For example, one set of schemes involved charging the government health insurance programs for medically unnecessary prescription drugs and compounded medications that often were never even purchased and/or distributed to beneficiaries.

Another variant involved medical professionals involved in the unlawful distribution of opioids and other prescription narcotics. A topic of particular focus for both departments and the country overall.

As part of these schemes, in many cases, patient recruiters, beneficiaries and other co-conspirators were allegedly paid cash kickbacks in return for supplying beneficiary information to providers, so that the providers could then submit fraudulent bills to Medicare for services that were medically unnecessary or never performed.

Is There Truly a New Sheriff in Town?

Over the past several fiscal years, the number of defendants charged in national health care fraud “takedowns” has rapidly increased (see the table). In fiscal year 2013, 89 defendants were charged nationally, in ten different federal districts, while in fiscal year 2017, the number of defendants charged nationally increased more than 4.5 times to 412 in forty-one federal districts.

### National Health Care Fraud Takedown Numbers FY 2013 - FY 2017

<table>
<thead>
<tr>
<th>Year</th>
<th>Defendants Charged</th>
<th>Numbers of Federal Districts Participating</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>89</td>
<td>10</td>
</tr>
<tr>
<td>2014</td>
<td>90</td>
<td>10</td>
</tr>
<tr>
<td>2015</td>
<td>243</td>
<td>17</td>
</tr>
<tr>
<td>2016</td>
<td>301</td>
<td>36</td>
</tr>
<tr>
<td>2017</td>
<td>412</td>
<td>41</td>
</tr>
</tbody>
</table>

Individual Cases and Charges

The vast majority of the cases were filed in the Southern District of Florida followed by the Eastern District of Michigan and the Southern District of Texas. Below is a brief sampling of the individual cases.

**Eric Snyder – Delray Beach, Florida**

Dr. Eric Snyder of Delray Beach, Florida was an owner-operator of a drug-treatment center. According to prosecutors, Snyder recruited addicts to help him with his schemes, attended Alcoholics Anonymous meetings, and visited “crack motels”...
to persuade people to move to South Florida to participate in the schemes with him.\textsuperscript{91} He allegedly offered kickbacks in the form of gift cards, plane tickets, trips to casinos, trips to strip clubs, and drugs. Snyder and an associate were charged with fraudulently billing insurance companies for over $50 million for false treatment and urine tests over a period of at least five years.

Bruce Alan Zimet, a lawyer for Snyder, noted that his client had been long cooperating with investigators, “[w]e anticipate having additional communications with the government, and we’re hopeful they’ll be listening carefully and evaluating whether this is a case that should go forward or not.”

**Home Health Service Companies – Wayne County, Michigan**

Six defendants, all of whom either owned or were employed by four different home health agencies, were indicted on one count of conspiracy to commit health care fraud and wire fraud.\textsuperscript{92} Five of the six defendants (all except Hoda Sabbagh, who was the owner of two of the implicated companies) also were indicted on one count of conspiracy to pay and receive health care kickbacks. Five of the six defendants (all except Antonio Kho), also were indicted on eight counts of health care fraud.

In this case, the defendants are charged with exchanging a Medicare beneficiary’s information via text message in exchange for a cash kickback.\textsuperscript{93}

**Omar Solis and Ivar Cantu – Hidalgo County, Texas**

Omar Solis, a laboratory technician at Dr. Luis Arango’s medical clinic in Mission, Texas, and Ivar Cantu, an account representative for Quality Toxicology, LLC in San Antonio, Texas, were charged with one count of conspiracy to commit health care fraud, eight counts of health care fraud, and nine counts of aggravated identity theft.\textsuperscript{94}

Solis and Cantu worked together to cause Quality Toxicology to submit false and fraudulent Medicare claims for laboratory testing services that were not medically necessary, not authorized by a physician, and not consented to by the patient. To accomplish this criminal enterprise, Solis and Cantu forged patient signatures consenting to the submission of the toxicology testing requests to Quality Toxicology; altered patient medical records to support the fraudulent toxicology testing requests. In addition, when an employee of the Arango Clinic learned about the scheme, Solis allegedly made threats against the employee.\textsuperscript{95}

**Salim Dahdah, M.D. and Cindy Dahdah – Springfield, Ohio**

This husband-wife duo is composed of Salim, a licensed cardiologist who owns Ohio Institute of Cardiac Care (OICC)/Advanced Cardiology Associates, and Cindy, who was the incorporator of ACCU-BIL Management, Inc. (“ACCU-BIL”), a privately held billing company. Both defendant also owned a primary care practice located in the same building as the OICC practice.

The couple would, as part of the conspiracy, have non-medical staff schedule tests and procedures, including nuclear stress tests, without the knowledge or consent of the patient’s treating physicians. If employees refused to comply with the requests, Mrs. Dahdah would reprimand, humiliate, or threaten to fire them. This behavior would frequently happen at staff meetings where Mrs. Dahdah would single employees out and demean them in front of their coworkers, or when she would send pressuring emails to staff to schedule the tests, regardless of whether the test was ordered by the treating physician or medically necessary.\textsuperscript{96}

**Is the Government’s Reaction a Window into What Comes Next?**

“Too many trusted medical professionals like doctors, nurses, and pharmacists have chosen to violate their oaths and put greed ahead of their patients,” said Attorney General Sessions. He went on to say:

Amazingly, some have made their practices into multi-million dollar criminal enterprises. They seem oblivious to the disastrous consequences of their greed. Their actions not only enrich themselves often at the expense

\textsuperscript{91} See Criminal Complaint, United States of America v. Eric Snyder and Christopher Fuller, available at https://www.justice.gov/file/989346/download

\textsuperscript{92} See First Superseding Indictment, United States of America v. Hafiz Tahir, et al., available at https://www.justice.gov/opa/page/file/981336/download

\textsuperscript{93} See First Superseding Indictment, United States of America v. Hafiz Tahir, et al., available at https://www.justice.gov/opa/page/file/981641/download

\textsuperscript{94} See Sealed Indictment, United States of America v. Omar Solis and Ivar Cantu, available at https://www.justice.gov/opa/page/file/981641/download

\textsuperscript{95} See Sealed Indictment, United States of America v. Omar Solis and Ivar Cantu, available at https://www.justice.gov/opa/page/file/981386/download


of taxpayers but also feed addictions and cause addictions to start. The consequences are real: emergency rooms, jail cells, futures lost, and graveyards. While today is a historic day, the Department’s work is not finished. In fact, it is just beginning. We will continue to find, arrest, prosecute, convict, and incarcerate fraudsters and drug dealers wherever they are.

Former Secretary Price noted “[h]ealthcare fraud is not only a criminal act that costs billions of taxpayer dollars - it is an affront to all Americans who rely on our national healthcare programs for access to critical healthcare services and a violation of trust”:

The United States is home to many of the world’s best medical professionals, but their ability to provide affordable, high-quality care to their patients is jeopardized every time a criminal commits healthcare fraud. That is why this Administration is committed to bringing these criminals to justice, as President Trump demonstrated in his 2017 budget request calling for a new $70 million investment in the Health Care Fraud and Abuse Control Program. The historic results of this year’s national takedown represent significant progress toward protecting the integrity and sustainability of Medicare and Medicaid, which we will continue to build upon in the years to come.

What Do We Expect

While the policy priorities of the current Administration are not predictable, we believe that given the strong responses and pride taken by Attorney General Sessions, we believe that the government will continue to target fraud by healthcare providers. It not only fits with the overall Republican agenda of reducing government spending, but it also directly benefits the elements of Trump’s political base: the economically disenfranchised Midwesterners beset with an opioid abuse epidemic.

These cases make it clear that it is highly unlikely that this will be the end of kickbacks. There is simply too much money in healthcare not to tempt some into taking chances.

However, given the complexity of the current regulations, it also is possible to inadvertently cross the line. Therefore, for those who have the potential to trip over the requirements to remain safe under the Stark Law and anti-kickback statute, it is more important now than ever to remain educated on the topic. This series of cases should be taken as a warning that the government is serious about curbing healthcare fraud.

98 See Department of Justice, National Health Care Fraud Takedown Results in Charges Against Over 412 Individuals Responsible for $1.3 Billion in Fraud Losses (July 13, 2017), available at https://www.justice.gov/opa/pr/national-health-care-fraud-takedown-results-charges-against-over-412-individuals-responsible
99 See Department of Justice, National Health Care Fraud Takedown Results in Charges Against Over 412 Individuals Responsible for $1.3 Billion in Fraud Losses (July 13, 2017), available at https://www.justice.gov/opa/pr/national-health-care-fraud-takedown-results-charges-against-over-412-individuals-responsible

Will Your Whistle Be Heard at Home?

By: Sally Foroughi,
Staff Writer, Life Science Compliance Update

Abstract: The distinct split between the Second and Fifth Circuit Courts’ interpretation as to when whistleblower protections are allowed has now summoned the attention of the U.S. Supreme Court. Despite clarifications issued in 2015 by the SEC to shed more clarity on Dodd Frank’s anti-retaliation protection to whistleblowers who reported alleged misconduct either internally to company officials or externally to government regulatory bodies, the U.S. Supreme Court will take the case of Digital Realty Trust v. Somer in the Fall of 2017, and finally render a final verdict for when whistleblower protection becomes enforceable. During the interim, it becomes vital for Compliance Officers to have appropriate policies and procedures in place to guide employees in reporting potential misconduct and/or fraud, and to establish a tone of non-retaliation for such reporting, in order to safeguard the best interests of the public and shareholders of the company.

As a result of the financial crisis during 2007-2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (“Dodd-Frank”) was signed into federal law in July 2010 by President Obama to prevent the economic “meltdown” from happening again.

Dodd-Frank Whistleblower Rules

Ostensibly, the legislation was primarily designed to increase overall regulation of the financial industry. However, and perhaps more importantly for compliance professionals, Dodd-Frank also contained a number of enhanced provisions designed to encourage and protect whistleblowers in and outside of the financial industry. These new provisions

98 See Department of Justice, National Health Care Fraud Takedown Results in Charges Against Over 412 Individuals Responsible for $1.3 Billion in Fraud Losses (July 13, 2017), available at https://www.justice.gov/opa/pr/national-health-care-fraud-takedown-results-charges-against-over-412-individuals-responsible
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expanded upon earlier provisions contained in the Sarbanes-Oxley Act of 2002 (“SOX”).

The main whistleblower focal points included:

- Creating new whistleblower protection for employees serving the financial services industry;
- Creating new monetary incentives and protections for whistleblowers serving publicly traded companies and public capital market participants regulated by the US Securities and Exchange Commission (“SEC”); and
- Expanding the scope of coverage and protections for whistleblowers, adding new monetary incentives and protections for whistleblowers in the commodity markets regulated by the Commodity Futures Trading Commission.

Dodd Frank amended the Securities Exchange Act of 1934 (“Exchange Act”) both to establish a SEC-administered whistleblower awards program, and to prohibit retaliation against corporate whistleblowers.

At the heart of the amended statute were two new provisions on whistleblower protection:

1. Section 21F(a)(6) of the Exchange Act defines “whistleblower” as “any individual who provides ... information relating to a violation of the securities laws to the Commission, in a manner established, by rule or regulation, by the Commission.” (Emphasis added.)

2. Section 21F(h)(1)(A)(iii) of the Exchange Act prohibits retaliation against “whistleblowers” who make disclosures that are required or protected under the Sarbanes-Oxley Act, the Exchange Act and “any other law, rule or regulation subject to the jurisdiction of the SEC.” Of significance in this context, Section 806 of SOX protects employees who report internally from retaliation.

Under the Exchange Act, as amended, whistleblowers who report violations to the proper government authorities (e.g., SEC, DOJ, Commodities Futures Trading Commission) are entitled to anywhere between 10% and 30% of any government penalties in excess of $1 million, based on the significance of the information and degree of assistance provided by the whistleblower, among others.

A few other key differentiators between Dodd Frank and the Sarbanes-Oxley Act (“SOX”) are noted on the right above.

<table>
<thead>
<tr>
<th>Dodd Frank</th>
<th>SOX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whistleblower protection for employee reporting a complaint to the SEC, irrespective of the ultimate validity or reasonableness of the complaint.</td>
<td>Whistleblower protections are based on reasonable belief that a violation has occurred.</td>
</tr>
<tr>
<td>Employee alleging retaliation under Dodd Frank may take the action directly the U.S. district courts.</td>
<td>Administrative complaint must first be filed with the U.S. Department of Labor, Occupational Safety and Health Administration, before bringing suit in federal court.</td>
</tr>
<tr>
<td>Employee is eligible to make a claim within six years from the date of the violation, but can be brought within three years from the date that “facts material to the right of action are known or reasonably should have been known” by the employee-whistleblower. However, all actions (whether or not known) must be brought within 10 years of the violation.</td>
<td>The administrative complaint must be filed no later than 180 days after the employee-whistleblower becomes aware of the violation or the date of the adverse act.</td>
</tr>
</tbody>
</table>

### SEC Confirmation of Whistleblower Protections

In 2015, the SEC sought to clarify some of the provisions of Dodd-Frank by issuing an ‘interpretive rule’ stating that if anti-retaliation protection was offered to only those individuals who reported to the government, then employees would be discouraged from reporting compliance issues to internal management, thereby placing investors at risk.

According to the SEC’s interpretation of the Dodd-Frank requirements “an individual who reports internally and suffers employment retaliation will be no less protected than an individual who comes immediately to the commission.”

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Therefore, as interpreted by the Agency, individuals are covered by the anti-retaliation provisions even if they have not reported the matter directly to the SEC. It also is position that most in-house Compliance Officers apply every day.

To support their interpretation, the SEC offered three reasons not to limit Dodd Frank whistleblower protection solely to disclosures to the SEC’s Office of the Whistleblower:

1. Rule 21F-2(b)(1) clarifies that Dodd-Frank whistleblower protection extends to the broad range of disclosures identified in Section 21F(h)(1)(A), such as:
   a) disclosures made to the SEC through the whistleblower program;
   b) initiating, testifying in, or assisting in any investigation or judicial or administrative action of the SEC based upon or related to a whistleblower submission to the SEC; or
   c) making disclosures that are required or protected under “SOX” or “any other law, rule, or regulation subject to the jurisdiction of the Commission.” The whistleblower protection provision of SOX includes internal disclosures about a violation of any SEC rule or regulation.

2. Rule 21F-2(b)(1)(iii) expressly provides that “[t]he anti-retaliation protections apply whether or not [an individual] satisf[ies] the requirements, procedures and conditions to qualify for an award.”

3. SEC’s construction of Dodd-Frank whistleblower protection is driven by the policy goals and intent of the SEC whistleblower reward program.104

The Circuit Courts of Appeals Are in Conflict

Since the promulgation of the SEC’s “interpretive rule,” there have been a number of district court decisions seeking to address that matter. As might be expected, the district courts have made rulings based on varying interpretations of the Dodd-Frank and SEC regulations. Currently, the Second and Fifth Circuits are sharply divided on the matter. Recently, the Ninth Circuit ruled on a case in which it adopted the Second Circuits position.105

Fifth Circuit- no protection for internal reporting

In July 2013, the Fifth Circuit disagreed with the breadth the SEC’s interpretation of the anti-retaliation protection provision. In the case of Khaled Asadi v. G.E. ENERGY (USA) LLC, the Court, taking a literally reading of the statute, concluded that to be protected under Dodd Frank’s anti-retaliation provision, an individual must fit the definition of a “whistleblower” -- defined by the statute as an individual who has made a report to the SEC.

Mr. Asadi reported a potential Foreign Corrupt Practices Act violation to internal management but was not afforded whistleblower anti-retaliation protection because he did not provide information on the violation of the securities laws to the SEC directly.

The basis of decision made by the Fifth Circuit, while squarely within the four corners of the statute, nevertheless directly conflicts with the SEC’s interpretation that employees who make internal reports to company management are protected under Dodd-Frank even if they did not make reports to the SEC. While it is not uncommon for courts to rule based on the four corners of the statute as a settled premise of administrative law, courts will normally grant regulatory agencies wide discretion when developing implementing regulations. Here the Fifth Circuit did not give the SEC that deference.

It also is notable that the Fifth Circuit decided the case on different grounds than the district court, which held that Dodd Frank’s anti-retaliation provision did not apply extraterritorially to Mr. Asadi, who worked in Jordan.106 The Fifth Circuit did not address that issue on appeal, resting


105 In one other case of note, the Sixth Circuit, in the case of Verble v. Morgan Stanley Smith Barney, sidestepped the notion of whistleblower retaliation if reports of misconduct are made only to the SEC. Instead, the Sixth Circuit reviewed a prior decision issued by the U.S. District Court for the Eastern District of Tennessee dismissing a former financial advisor’s Dodd-Frank retaliation claim after finding that Dodd-Frank’s anti-retaliation provision was limited to whistleblowers who reported their concerns directly to the SEC. On appeal, the Sixth Circuit opted to avoid deciding whether that ruling was correct, and upheld the dismissal on the separate ground that the plaintiff had not plausibly alleged that he engaged in protected activity even under the more expansive reading of the statute. The court ruled unanimously against the plaintiff’s claim that he was fired in 2013 for cooperating with the FBI in an investigation. See “Sixth Circuit Sidesteps Whether Whistleblowers Need to Tip Off Regulators to Receive Protections Under Dodd-Frank,” Katz, Marshall & Banks (March 20, 2017), at http://www.kmblegal.com/sec-whistleblower-blog/sixth-circuit-sidesteps-whether-whistleblowers-need-tip-regulators-receive

its decision solely on the definition of whistleblower under the statute.

**Second (and Ninth) Circuit- Anti-Retaliation Protection For Internal Reporting**

In September 2015, the *Berman v. Neo@Ogilvy LLC* case marked the emergence of a distinct split among the circuits on the issue of anti-retaliation protection for whistleblowers. The Second Circuit sided with the SEC rule in this case, which extended Dodd Frank’s anti-retaliation provision to individuals who report suspected wrongdoing internally, rather than to the SEC.

In *Berman*, the Second Circuit held that the plaintiff, a finance director, would qualify for protection under the anti-retaliation provisions of Dodd Frank even though he reported the alleged accounting fraud only to company management, and not directly to the SEC. He did not report the matter to the SEC until after the company terminated his employment, allegedly in retaliation for being a whistleblower. The court concluded that the provisions of the Dodd-Frank Act described above were sufficiently ambiguous to warrant deference to the SEC’s interpretative rule.

The court also pointed out that some categories of employees who were the most likely to learn of potential securities violations, such as auditors and attorneys, are not permitted to bring the information to the SEC without first reporting it to the company. Therefore, the Second Circuit concluded that Dodd Frank protects employees from retaliation when they report potential securities violations internally.107

As demonstrated in the 2017 ruling for *Digital Realty Trust v. Somers*, the Ninth Circuit adopted a similar position to the Second Circuit. Namely, the Ninth Circuit upheld the SEC’s position that employees are protected against retaliation from corporate officials, even if the misconduct or complaint was only made to internal company management. In essence, whistleblower protection is granted to those who report internally and those who report to the government. Judge Mary Schroeder concluded: “SEC’s interpretation of the Dodd-Frank Act correctly reflected Congress’ intent to “provide protection for those who make internal disclosures as well as to those who make disclosures to the SEC.””108

**Off to the Supreme Court We Go**

The percolating issue whether the SEC’s whistleblower regulations provide anti-retaliation protections to whistleblowers who report potential misconduct directly to the SEC, or whether the protections also applies when the whistleblower report concerns to a company’s internal management will soon be settled. The Second and Ninth Circuit Courts’ position is that internal reporting is protected under Dodd-Frank, while the Fifth Circuit concluded protections applies only when misconduct is reported to the SEC.

The U.S. Supreme Court agreed in June 26, 2017 to take up the case *Digital Realty Trust v. Somer*. The Justices were asked to review whether Dodd Frank prohibits retaliation against internal whistleblowers, or only protects those reporting directly to the SEC. Oral arguments are scheduled in the Fall of 2017, after the new term begins, with a decision expected in 2018. This would resolve a nearly two-year-old Circuit split regarding the Dodd Frank’s whistleblower protections. It is a case being closely watched by all compliance professionals.

**In the Meantime**

If the Supreme Court sides with the broader definition that the Ninth Circuit adopted, whistleblower complaints will increase with anti-retaliation measures protecting them, creating more opportunities for white collar enforcement. However, if the Supreme Court sides with the more restrictive language of protection like the Fifth Circuit’s, then the number of whistleblower complaints may drop in future SEC actions.

It’s important for Compliance Officers to remain vigilant about the outcome as it could mean potential changes to compliance programs. Compliance officers should, at a minimum, a more enhanced management training program and periodic review of internal complaint procedures and investigation protocols. The Supreme Court’s decision will help companies develop enhanced internal processes to successfully address whistleblower complaints – they will need to exercise a careful balancing act of establishing a comprehensive compliance program that encourages internal reporting of potential misconduct while at the same time not setting a silencing tone that stifles whistleblower complaints to the SEC.


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