

## How Early Data Analysis Can Inform FCA Litigation Strategy

By Benjamin Scher, Dana McSherry and Matthew Knowles

(May 14, 2021, 5:14 PM EDT)

It is no secret that recent decades have witnessed an absolute data boom, with data now available on nearly every conceivable topic. Just recently, an analysis was put together tracking the frequency with which NBA player Kevin Durant's shoes fell off during games, by foot, year over year.

The purpose of pointing this out: If you are interested in a topic — no matter how commonplace or esoteric — data almost certainly exist that illuminate it.

Not surprisingly, the life sciences and health care arenas have not missed out on the data boom. Indeed, data are used for many purposes in these industries and are commonly analyzed in legal disputes to assist in estimating damages.

The purpose of this article is not so much to identify the various data sets that are available — we would need more pages — but rather to demonstrate how thoughtful and creative approaches to analyzing the available data can provide key insights on a variety of issues in False Claims Act cases — far earlier in an investigation or litigation than the traditional use of data in damages models.

As Steven Levitt, co-author of *Freakonomics*, once said: Data "is one of the most powerful mechanisms for telling stories."

### Data Application #1: Determining What Happened

FCA inquiries often begin with a civil investigative demand, subpoena or whistleblower complaint. Responding typically involves an information gathering exercise. What actually happened? Is there anything to be concerned about? If there is a problem, how big is it? Did it involve intentional misconduct or inadvertence or misunderstanding?

While interviews and discussions with company employees, and email and document reviews, can help discern what, if any, issues may exist, an incomplete picture may emerge. For example, information gathering can be hindered by incomplete recollections of individuals, company acquisitions, or employees having



Benjamin Scher



Dana McSherry



Matthew Knowles

moved on to different companies or positions.

Additional challenges can arise if the individuals being interviewed are themselves the subject of the allegations. Email reviews can be useful, but only if the potential issue is reflected in the users' email traffic in the first place, and you are able to identify the right custodians, collect emails for the right time period, and review them efficiently.

An early dive into the data can reveal critical information to guide the strategy for navigating discussions with the government and potentially subsequent litigation. By way of a simplified example: In cases involving alleged upcoding — or improper use of certain billing codes — it is critical to know from the outset if the alleged improper code was used 99% of the time or 1% of the time.

In other words, are the data consistent or inconsistent with the allegations or whistleblower's theory and account of the facts? The answer to that question can have substantial implications for strategy — e.g., settle or litigate — and can help to avoid surprises later on.

This is but one example. A thoughtful review of utilization, prescribing, sales or other — often publicly available — data sets can assist in informing strategy from day one.

At the start of an investigation, you often know less than the whistleblower and the government about key facts. And if you ignore the opportunity to learn from available data, you will likely fall further behind.

Notably, prosecutors are making use of data early and often in FCA cases, which some have described as decreasing their reliance on whistleblowers. This makes it even more imperative for defendants to harness data outside damages analyses — and as early as possible — to determine what the prosecutors are seeing and what defenses can be mounted.

### **Data Application #2: Interview and Deposition Support**

Data can be useful when interviewing company witnesses and, if the case evolves into active litigation, can be a vital tool when selecting and questioning deponents.

For example, suppose a medical doctor asserted in a deposition that it would never be appropriate to prescribe a particular drug in a certain way. Using claims data gathered in the matter, attorneys could be armed with data extracts showing the doctor prescribing in precisely the way he or she claimed was not appropriate, or showing that respected peers did so. Confronted with this evidence, the doctor might quickly change his or her tune. Empirical data can refresh a witness's recollection, resulting in more accurate testimony.

### **Data Application #3: Assessing Potential Corporate Scheme Liability**

Often, FCA allegations are based on a theory that a scheme or conduct imposed from the top down influenced conduct an organization. A frequent allegation is that a corporate scheme or pattern of conduct was put in place to increase profits at the expense of optimal care or medical necessity. These allegations are easy to lob and can be difficult to rebut in the early phases of an investigation.

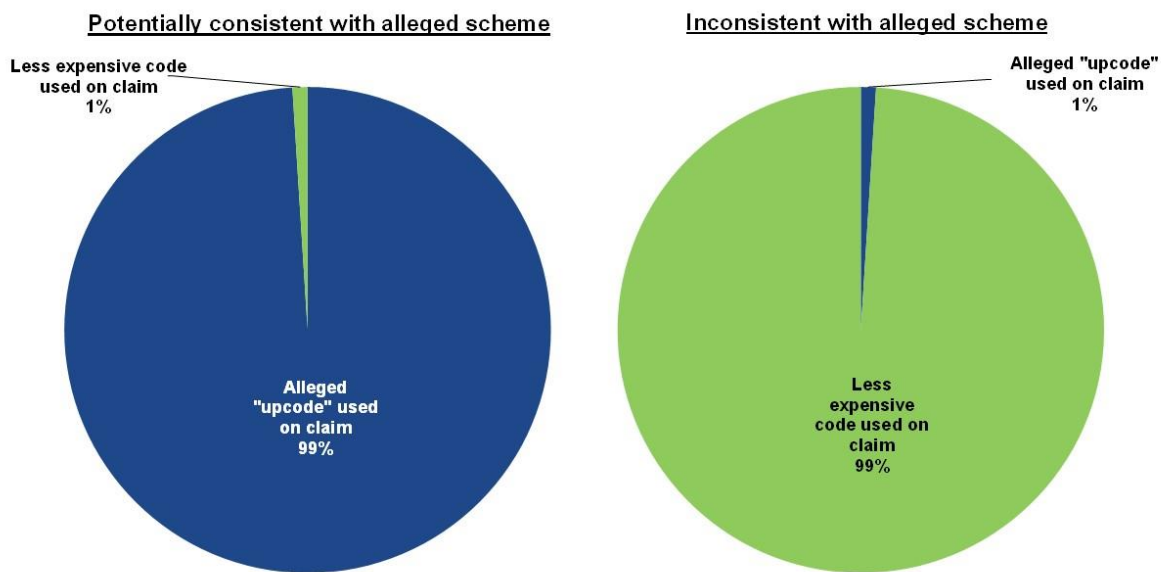
Data often hold the key to supporting or disproving such theories. Knowing how to analyze the data, what to look for and how to depict the results can be critical. For example, questions to assess with the

data include:

***How common is the conduct that has been alleged?***

Does it occur frequently — possibly consistent with an alleged scheme — or rarely — inconsistent with the alleged scheme? Some of the most basic data visuals — e.g., a pie chart — can go a long way in proving a point. For example, compare the two pie charts below. The pattern evidenced on the left could be consistent with the allegation, but the data pattern on the right certainly would not.

Of course, a pattern that is merely consistent with an allegation does not offer dispositive proof. Rather, alternative explanations would need to be evaluated and ruled out before concluding that the conduct occurred or had an impact. In any event, a pattern such as that on the right chart essentially rules out the possibility of the alleged scheme.



***Is the alleged scheme consistent with natural, largely unavoidable errors?***

In virtually all large-scale processes, people make mistakes. Statistically benchmarking the rate of allegedly improper conduct to an expected error rate can reveal that the alleged issue was simply the result of run-of-the-mill mistakes, not a scheme. Understanding the particular health care setting and what an expected error rate would be in that setting, and then explaining this all in plain terms can be critical.

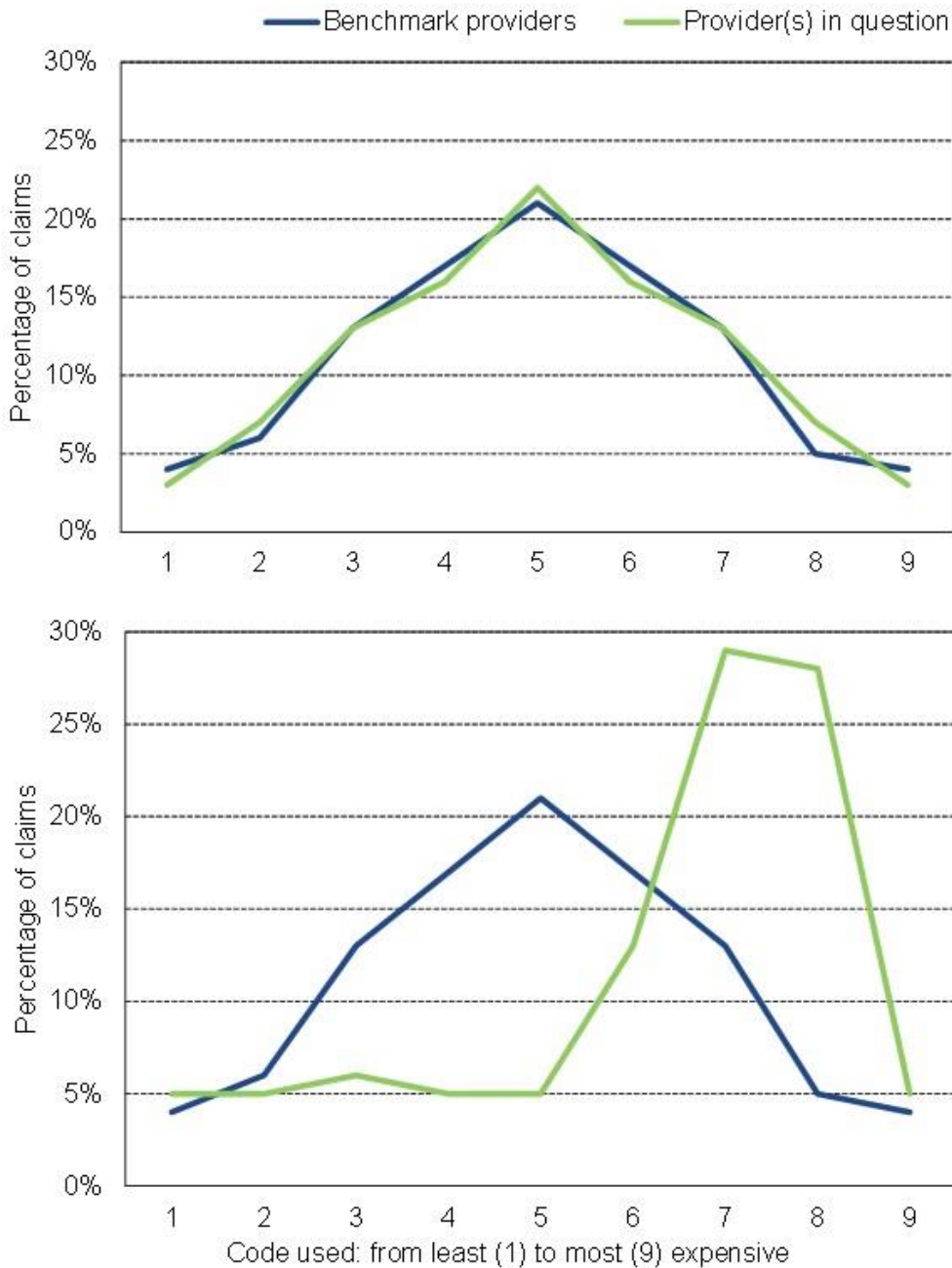
***Are the patterns consistent with benchmark providers?***

In many instances, data are available for uninvolved benchmark providers whose behavior can help evaluate the conduct among those at issue. For example, the graphs below show the percentage of time each of nine potential codes are used for providers in question — green — versus benchmark providers — blue.

In the first graph, the providers in question used codes in the same proportion as the benchmark providers — the two lines are almost completely overlapping. In the second graph, the providers in

question used more expensive codes more often than the benchmark providers.

While, of course, there could be reasonable explanations for this pattern, such as the providers in question on the bottom panel having a more complex patient base than the benchmark — which may call into question whether the benchmark is a proper comparison set — the graphs nevertheless help illustrate a baseline question of whether the patterns observed are typical.



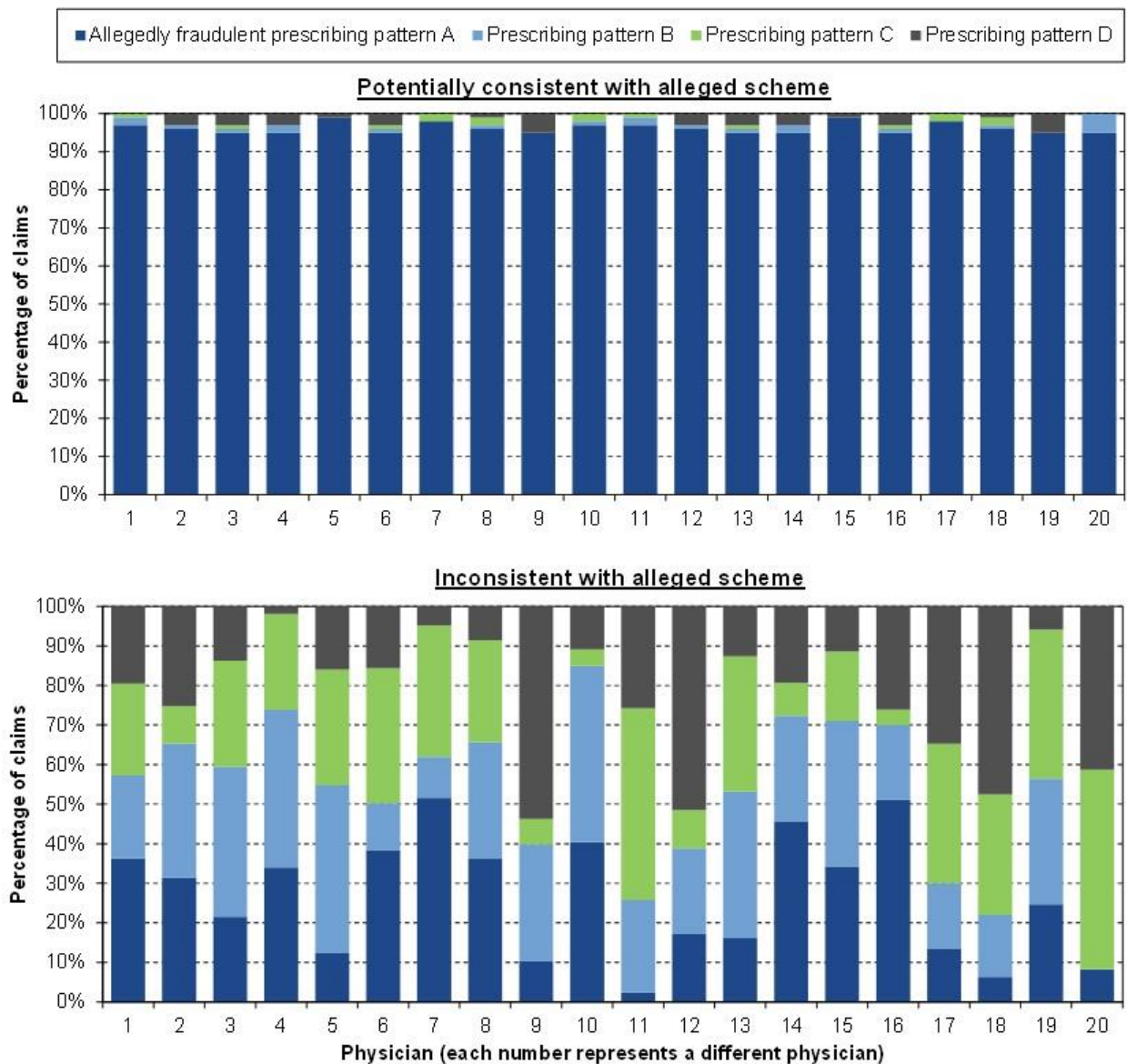
**How much variation is observed among individual actors within the organization?**

Say a large-chain health care provider or hospital with numerous physicians is alleged to have imposed a

scheme of conduct. It might be useful to assess patterns across the physicians and across time to ascertain whether the behavior is homogeneous or heterogeneous.

For example, the hypothetical graphs below juxtapose homogeneous prescribing patterns among 20 physicians — potentially consistent with an alleged scheme — compared to heterogeneous prescribing patterns — inconsistent with an alleged systematic scheme.

Notice the monotone blue in the top panel shows a common practice across physicians of engaging in the allegedly fraudulent prescribing. Compare that to the variety of colors shown in the lower panel, which illustrates a wide variety of prescribing decisions and considerable variation across the physicians in the organization.



Of course, simply because all the physicians in an organization prescribe in a certain way or use a certain code does not necessarily indicate that it was the result of the alleged conduct. For example, the patient base of the physicians, an ex ante policy decision that a certain approach is medically optimal, and a

variety of other legitimate considerations could lead to the same empirical pattern as one that would result from the alleged conduct.

That said, again, the alternative — e.g., the wide variety of prescribing practices shown in the lower panel graph — essentially rules out the possibility of a scheme that prevented the physicians from exercising their individual medical discretion.

***When the alleged conduct occurs, does it appear correlated with reasonable explanatory variables, such as patient-specific conditions?***

As mentioned above, a pattern consistent with an alleged scheme does not necessarily offer dispositive proof that the conduct caused the pattern. Indeed, it may be the case that patterns allegedly consistent with a scheme are in fact completely unrelated.

For example, data and information in medical records may provide evidence that the conduct was explained by specific patient factors completely unrelated to the allegation.

#### **Data Application #4: Questions of Materiality and Falsity**

Since the U.S. Supreme Court's landmark 2016 decision in *Universal Health Services Inc. v. Escobar*, questions of materiality have joined questions of falsity at the center of the stage in FCA proceedings. These questions often turn on whether the government or its contractors have knowingly paid claims despite being aware of the alleged regulatory violation that made the claim false.

Data can be used to show either the frequency with which the payors required prior authorization for a drug before paying for it or whether certain information in the prior authorization was material to the ultimate approval decision. This objective information can then be used to show that in many instances the alleged regulatory violation was well known to the payor, as it was spelled out directly via the prior authorization form, and the payor decided to pay the claim anyway.

Data allow for the transformation of such observations from anecdotes to quantitative summaries that provide hard evidence on the frequency with which such payor scrutiny occurred.

#### **Data Application #5: Damages**

Of course, data remains a key tool in modeling and understanding the implications of damages theories. This is not limited to the late stages of an investigation or litigation — i.e., trial or settlement. Government investigators and private whistleblowers respond to economic incentives, and understanding the scope of the potential problem — even assuming that there is one — is also vital to a thoughtful and strategic approach to an internal investigation.

If the allegations at issue do not have a meaningful damages implication, this presents a powerful argument that a compliance improvement or other internal "course correction" is the appropriate outcome, rather than years of warfare under the FCA or a similar statute.

#### **A Final Note: Creating Data From Unstructured Information**

As noted above, data are typically available on nearly every conceivable topic. This includes publicly available physician-by-physician prescribing data for public programs — Medicare Part D and B;

purchasable data from various entities with granular information on nearly any topic — e.g., weekly prescribing by doctors throughout the United States and longitudinal patient data; and, of course, sales, billing, prescribing, service, etc. data from the parties in a specific matter.

Even when data are lacking, however, they can often be created from qualitative sources. Sometimes key relevant information is only available in an unstructured form — e.g., a PDF medical record with handwritten notes — as opposed to in a database.

In those situations, automated techniques, along with appropriate human review, can transform the unstructured information into meaningful data that can be analyzed. This can, in turn, shed light on key issues like those described above that otherwise would have been subject to less rigorous and systematic analysis.

In conclusion, the exploding pool of data available in FCA matters can provide key answers and insight into fundamental questions and issues that extend well beyond traditional damages analyses.

---

*Benjamin Scher is a partner at Bates White LLC.*

*Dana McSherry and Matthew L. Knowles are partners at McDermott Will & Emery LLP.*

*The opinions expressed are those of the author(s) and do not necessarily reflect the views of the firm, its clients, or Portfolio Media Inc., or any of its or their respective affiliates. This article is for general information purposes and is not intended to be and should not be taken as legal advice.*